THE UNIVERSITY *of* EDINBURGH

Group Rights in Biolaw

A Model Approach

Nadja Konstantina
Kanellopoulou

THESIS SUBMITTED TO THE UNIVERSITY OF EDINBURGH FOR
THE DEGREE OF DOCTOR OF PHILOSOPHY - MARCH 2008

To My Family

And Ben

‘the problem is, precisely, to decide if it is actually suitable to place oneself within a “we” in order to assert the principles one recognizes and the values one accepts’

Michel Foucault 1984

Contents

Table of Figures

Table of Cases

Preface

This thesis would not have happened had I not come to Edinburgh to pursue an LL.M. Master's degree at the Edinburgh Law School. I became fascinated with medical jurisprudence, and in particular genetics and law, during the inspirational teaching of Ken Mason and Graeme Laurie. My study with them has been a privilege, especially since the former established the tradition of Scottish medical law together with Sandy McCall Smith, and is dedicated to the teaching of medical law and its deep connection with moral issues. The idea for this thesis matured during that first year in Edinburgh, at Graeme Laurie's old office, under the skylight. A long time has passed since then and this work took twists and turns that I never imagined at the time. The key question in this work is whether medical law, or rather, law in the life sciences, biotechnology, and medicine (biolaw) can accommodate claims for the protection of human group participants in genetic research *as groups*.

The challenge was overwhelming, at first, in that groups vary widely, for example from families, patient groups, native tribes, ethnic or national populations, and in that the kinds of research involved vary as well (for example, medical genetics, behavorial genetics, molecular anthropology, biobanking, human genetic variation sampling, patenting). Non-legal expertise was necessary to assess both the work of scientific research and the nature of related collective claims. I received a lot of help in figuring things out by talking to many colleagues from other disciplines. My methodology consisted mainly of document analysis and one-to-one interviews with anthropologists, bioethicists, commercialisation managers, geneticists, academic lawyers, law practitioners, medics, psychologists, sociologists. These interactions helped me to develop interdisciplinary insights, confidence and expertise while reviewing the literature and keeping up with developments. These connections grew while assessing the merits of emerging protocols at international and comparative

levels with the twin aim of identifying best ways to conceptualise groups in biolaw and proposing a much-needed novel approach for their protection.

It is important for me to highlight that this work would not have been achieved had it not been for the generous and unconditional support of my *parents*. I am eternally grateful to my mother and father for their love, sacrifice and contribution, both material and emotional, beyond words can say. I dedicate this PhD thesis to them.

I am deeply grateful to my primary supervisor, Professor Graeme Laurie, for his constant encouragement, patience, professionalism and commitment. I want to express my deep respect and appreciation for his legal expertise, his sharp, critical thinking and his ability to painstakingly deal with puzzles and problems. I thank him for everything he has done for me!

I am extremely thankful to my second supervisor, Professor Ken Mason, for being a massive source of specialist expertise as well as immense positive energy during the good and the darkest hours of my postgraduate study! He has been a constant inspiration for me in many different levels! For his elegant spirit, his thorough proof-reading up to the last hours in the life of this endeavour, and for his kindness, I am forever grateful.

I want to give special mention to my colleagues in Edinburgh, especially Dr Gill Haddow for having been so helpful in my investigations into medical sociology and for her friendship; a special thanks to my fellow PhD students and colleagues at the AHRC IP Law Centre, in particular Kathryn Hunter, Wendy Marsden, Rena Gertz, Gerard Porter, Shawn Harmon for our conversations at the office and in the pub, and the much-needed occasional pat on the back! Also to Nadine, John, Lorna, and Tessa for their administrative assistance; they have been fantastic to work with. I would also like to thank my colleagues during my three-year fellowship at the ESRC Genomics Forum, especially Professors Michael Banner and Steve Yearley for their

initiative and support, and Drs Emma Frow and Steve Sturdy for our cheerful conversations. I want to express special thanks to Professors Jon Marks, Jon Merz, Dianne Nicol, Jenny Reardon and David Winickoff for their interest in my ideas and encouraging comments. I am grateful to the Hellenic Ministry of Education and Religious Affairs for generously funding the early years of my postgraduate study; to the AHRC Centre for Research in Intellectual Property and Technology Law and the Edinburgh Law School for securing conference funds to present my work to international audiences, and for fostering an excellent environment for study. The Old College, the University, and its staff have a unique place in my heart.

I thank my friends, Jess Sussmann and Marc Robertson for their help and for sharing laughs and love; Aristotle Kallis, Vaios Karavas, Manolis Melissaris, Penny Travlou, Alex Xanthaki for their love, support and motivation; Eleanor McCann and Mic Cliff for their friendship, flat sharing, good food, art and fun during my years in Edinburgh. I also want to give a special mention to my uncle, Kostas Andritsos, for being an earnest thinker, a big-hearted and supportive friend. I devote immense thanks to my sister, Eleni, for her continuous encouragement; she is a fabulous sibling and wonderful mate. Lastly, I dedicate a most precious thanks to Ben for his love, wit, determination and help. He has contributed enormously to the completion of this doctorate by giving me tremendous assistance, constant emotional support and generous love. For his involvement, loyalty and belief in me I am moved, and remain deeply, eternally thankful!

I believe the law to be accurate as at March 2008.

NKK

Edinburgh

March 30th, 2008

Declaration

I declare that:

(a) this thesis was composed by myself;

(b) the work presented here is my own, except where stated otherwise; and

(c) the work has not been submitted to any other degree or professional qualification

Konstantina Nadja Kanellopoulou

Abstract

This thesis investigates legal, ethical and social aspects of group participation in genomic research. Groups in research are diverse. They can be families, patient groups, native tribes, local communities, ethnic collectives or entire national populations united by disease heredity, common cultural or personal ties. Despite rapidly rising scientific and policy interest in research with groups, legal protections for group rights and responsibilities are scarce.

This work discusses current problems in defining what constitutes groups, together with dominant normative assumptions and ambiguities in existing research protections. It focuses on key issues of representation, accountability, resource-sharing and control in the management of scientific and commercial uses of group research. It highlights the increasing value of groups as research *partners* and examines emerging cooperative models, in the quest for appropriate legal frameworks for group protections.

The thesis recommends a new concept of *group empowerment* and considers legal models for the implementation of the empowerment principle in modern research ethics. It proposes a way forward for law to focus on the collaborative aspects of group-researcher relationships, and to identify group research gifts as *conditional, reciprocal returns* of favours. Under the principle of group empowerment, reciprocity and cooperation are central in the development of adequate mechanisms for group protections. This new approach contributes to current thinking about ways to redress inequities in the balance of power between groups and researchers, build viable mechanisms for shared governance, and facilitate group involvement in genomic endeavours.

Introduction

Group Rights in Biolaw: Thesis Overview

This work discusses current problems in the recognition of groups as participants and contributors in genetic and genomic research. Whilst legal scholarship has focused in the development of research-related rights for individuals in the last six decades since World War II, very limited attention has been given to the nature and scope of possible rights for groups. The design of meaningful protections for groups has invariably been considered to be too difficult, too complex or sometimes even plainly undesirable under the influence of models that are focussed solely on individual rights and liberties. This reluctance in traditional research ethics to understand and address group claims has fed the emergence of self-help solutions to support particular group claims. It now fuels an increased interest towards developing legal and ethical mechanisms to protect collective claims in research. This thesis aims to contribute to novel thinking in designing adequate models for group protections in research. It highlights the increasing value of groups as research *partners* and examines the merits of new cooperative models in the quest for appropriate legal frameworks to protect group interests in research.

The principal aims of this thesis are to propose novel solutions to three major problems: i) promote *interdisciplinary understanding* of group claims in research and their significance in law; ii) expose the *inadequacies of current regimes* to protect group interests so as to assess the availability and viability of rights for groups in research and iii) develop a *novel approach to group protections* in research. The solutions to these problems are essential for building coherent, effective frameworks and legal safeguards for the protection of group interests in research.

This thesis is divided in three parts. Part I (chapters one and two) discusses the collective nature of genomic research with groups, its conceptual underpinnings, complexity, detailed context and implications. Part II (chapters three and four) examines the different kinds of existing legal protections currently used in the

management of the use of human biological samples for research purposes. It assesses their advantages and limitations and offers a novel analysis of key problems for protecting groups. Part III (chapter five) presents a novel model for group research protections. It recommends a new definition of group research 'gifts' as *conditional* gifts. This new model focuses on the relational character of group-researcher interactions. It proposes a new way for *reciprocity* to be used as a tool for balancing group-researcher interests, and recommends a new principle of *group empowerment* as a clear normative basis for the development of adequate group research protections.

Chapter One introduces fundamental issues when considering groups to be important in this context. These issues include a preliminary investigation on the concept of collective research and its shared nature, an observation of the increasing interest in the role of groups in research and the absence of relevant legal protections, followed by a call for caution because of the sensitivity that is inherent in thinking about groups. This sensitivity is linked to difficulties and controversies with discriminatory practices in the history of biomedical research, especially in the last century. This part of the thesis offers a brief account of the background within which calls for the regulation and protection of groups are being forwarded in recent years.

The complexity of the concept and context of groups in this field is examined in detail in **Chapter Two**. This chapter proposes an umbrella definition of groups in research and a methodology for the classification of groups in six broad categories. This typology is proposed as a workable taxonomy for groups set within different cultural, political, historical and geographical contexts; it helps to define their footing in the research process. The proposed types are characterised by varied degrees of connection depending on intra-group dynamics, research participation rationales, individual and collective needs among other factors. These degrees are affected by the extent of risks and benefits involved in the different kinds of research undertaken with groups, respective research-related drivers, expectations and requirements from the part of researchers, their funders, and groups themselves. The novel methodology

that is proposed in this chapter allows for flexibility in assessing different aspects of 'groupness'. The extensive case-study analysis pursued in this chapter adopts a firm interdisciplinary stance, in recognition of the limits of law alone to reserve categories in such a sensitive and diverse context. At the same time, by placing the role of the law in broader social, economic and political context, this approach celebrates the critical role of the law as a valuable tool for the identification of parameters that can connect group ties with major issues of legal concern in this field.

These legal issues include concerns about groups becoming involved in research, the consequences of being involved in research, directing research, influencing the ways research outputs are used, benefiting from research outputs, and concerns against bias or stigma that sometimes is associated with research. They raise questions of group membership, consent and representation, privacy, discrimination, property, resource-sharing and control. They are problems of *agency*, *accountability* and *power* of groups in research and they are linked to a great extent. In the interests of novelty, brevity and clarity, the second part of this thesis focuses on the last of the three (*power*) and sets out to investigate problems of consent, power sharing and control in research with groups. These key issues lie at the core of protections for continuous group input, influence and oversight in research but they remain largely unaddressed in current research frameworks! Their examination is divided in two strands in the following chapters to consider i) the merits of legal mechanisms currently available in the regulation of research with human biological materials and ii) the need to propose new and viable legal solutions.

In assessing the adequacy of existing mechanisms to protect group interests, **Chapter Three** offers a critical examination of the consent model as having been traditionally the first – and last – step in protecting participants' interests in research. The chapter considers the limitations of traditional consent theory with its focus on the rights of individuals to be insufficient to address the concerns of groups. It examines the birth of *group consent* theory and subsequent sister theories about group consultation, communication and review together with their advantages and

limitations. It discusses the implications of who can speak on behalf groups, under whose authority, under what conditions, and proposes a core approach in favour of group consultation and representation. The investigation in this chapter connects these issues to enduring concerns about the relation between group and individual rights and highlights the *complementary* value that group rights can add to individual rights. This analysis seeks to bridge the gap opened by scholarly attention on the conflict between group and individual rights by contributing new thinking about the role of group rights in the research context.

In the last part of this chapter, particular emphasis is placed on the limited scope of individual consent protections to cover group concerns about continuous research oversight and control. The chapter critically assesses the extent to which current uses of consent in research nurture a discourse of *disempowerment* that is unsuitable to provide guarantees outside the initial stage of communication and consultation. In the absence of such guarantees, there are no provisions to satisfactorily address increasing claims for group involvement and continuous influence in the research process, seen as a continuum. These claims include group interests in research feedback, use of research data and samples for future unanticipated purposes, withdrawal from research including return of samples, commercialisation of research and the distribution of outcomes. By assessing the merits and pitfalls of the consent model, this work argues in favour of designing novel legal safeguards that can *empower* group participants when becoming involved in research.

Following on from the critical analysis of the consent model which finds existing models wanting in providing adequate protections for groups, **Chapter Four** assesses the adequacy of other legal mechanisms that apply in the regulation of research using human biological samples, especially in the case of groups. It examines the strengths and weaknesses of the donation model (or else, free gift model), the particularities of patient advocacy methods, the viability of property rights, the advantages and limitations of benefit sharing models. It does so in order to assess the quality of the solutions these models provide towards questions of

continuous group influence and control in research. For example, the study of the existing donation model reveals problems in considering the transfer of human biological material for research purposes to be a question of altruism. This model is linked with attempts to define the participation of groups in research in terms of a special obligation often framed as a question of 'solidarity'. A central theme in this thesis is that current appeal to unconditional, benevolent, free giving pays little service to group participants' interests. Exclusive reliance on altruism contributes to increasing unease towards supporting research in such terms, as it tips the balance one way. It is of rather limited value to groups as it maintains rhetoric based on disempowerment rather than empowerment.

In pursuit of a reasonable stance between disempowering rationales and collaborative models that support a more *balanced engagement* of groups in research, this chapter examines other current approaches. These are based on the quest for the recognition of property rights in various forms, patient advocacy agreements, proposals for sharing benefits with local communities. Existing models are based either on 'do-it-yourself' attempts to secure better research oversight and proprietary control in the outcomes of research via advocacy contracts; calls for the recognition of property rights (indigenous property debates / DNA on loan scheme); or recent humanitarian approaches towards aiding or recompensing group research participants (benefit sharing proposals). The former two are inspired by a wish to establish legal rights on the use of tissue research materials as proprietary to the research participants (patient groups and native tribes respectively) as the *sources* of these materials. They are met by an entrenched antipathy both in jurisprudential and policy terms, but in academic scholarship there is renewed interest in bodily property rights in this field. On the other hand, emerging benefit sharing models are in need of further clarification, both as regards their normative basis as well as their practical aspects. The analysis pursued in this thesis reveals that all these different types of models present limitations in that they promise either excessive or rather limited degrees of control (power) for groups. Nevertheless, their study offers extremely valuable insights when considering how to devise better legal models for the protection or group interests in research.

Chapter Five draws on core problems caused by the disparity of legal power between researchers and groups in more detail. The first part of this chapter includes an original analysis of the shortcomings of the donation model. First, it exposes the inconsistencies that beleaguer the direct endorsement of this unconditional gift relationship idiom in research. Then it critically examines enduring paradoxes and ambiguities in current research frameworks, by using the UK as a case study. This chapter proposes that group research 'gifts' should be (re)defined as *conditional* returns of favours, not as *gratuitous* transfers. This new approach is based on an understanding that what is transferred between group participants and researchers is not a static, isolated object. It bears value (biovalue) that is continuously circulated between them and is highly dependant on their *relationship*. It undergoes transformations in and out of gift and commodity forms while defined by the dynamic of their historical and personal interaction.

As the engagement between groups and researchers in genomic research is a long-lasting affair, the thesis asserts that it is important for law to consider their relationship more carefully. In group-researcher engagement, cooperation and trust are paramount. This chapter proposes that in this dynamic context, the connection between group-researcher cooperation and trust can be described in accordance with rules of *mutuality* – which requires that the parties are jointly bound as regards the benefits and risks from their interaction; and *reciprocity* – which requires in addition that a *balanced* return exists between respective parties to shelter ongoing cooperation. In the quest for devising better protections for groups, the thesis recommends that a new and better way for conceptualising group-researcher interaction should be in line with notions of *reciprocity*.

In seeking to develop ways to implement reciprocity in group research protections, the thesis puts forward a new research ethics principle. '*Group Empowerment'* is proposed as a principle that provides a clear normative basis and a set of balancing criteria about what can constitute appropriate reciprocation. The Group

Empowerment principle places emphasis on the need to recognise the value of groups as *partners* in research and to inscribe group research relationships in law as *continuous* and *reciprocal*. It respects the interface between groups and researchers as a rich site of sensitive social relations constitutive of a dynamic engagement. It focuses on the *collaborative* aspects of group-researcher relations and stipulates that there is a need for a *balanced* evaluation of the *shared* role of groups in research process. In offering ways to review and enhance group power and involvement in research, the concept of group empowerment is inspired by notions of justice and fairness. These principles commend that group value is understood both as intrinsic as well as instrumental in the realisation, facilitation and organisation of long term research. According to this novel principled approach, groups are considered to be *proactive contributors* with the ability to create and manage collective research resources, navigate through their own and researchers' expectations and facilitate the process and progress of research.

The thesis considers a number of ways in which the Group Empowerment principle can be integrated in the regulation of research with human biological materials via legal mechanisms. The last part of this final chapter offers a critical and novel discussion of three potential models, *fiduciary duty*, *contract*, and *conditional gift* respectively, as possible legal 'group empowerment mechanisms' (GEMS). Their comparison exposes serious limitations for the first two and recommends that the *conditional gift* model is the most advantageous approach for achieving empowerment, especially for groups that can no longer be considered to be vulnerable or invisible in research. The thesis proposes that the conditional gift model is well suited for protecting group interests particularly in how samples are used or what kinds of research is pursued with them. The model allows for mutual acceptance of *conditions* that give the gift effect following a collaborative assessment of group and researcher expectations. It is proposed that these conditions incorporate an evaluation of *group contribution* – to be understood broadly, in line with group history and personal connection with researchers, their invested time, effort, funding and networking, their motives and expectations, including their intended and/or undesirable uses of samples, data and any other resources that groups may provide

for research. By seeking to establish a more intuitive understanding of group-researcher engagement in law, the proposed conditional gift model is also a flexible way for awarding groups with better levels of *power* when they participate in research.

Overall, this work defends a new conceptual approach in the governance of group participation in genomic research. It proposes a new methodology, a core normative principle and a set of criteria for the evaluation of the role and influence of groups in research. It provides a new way for law to consider the nature of the gift relationship between groups and researchers, the multiplicity and the scope of increasing group claims in research in tandem with an interdisciplinary understanding of the context in which research *with* groups takes place. The development and implementation of novel protections for groups in research is crucial on a background of increasing commercialisation of research knowledge, pursued by a variety or public and private agents. The approach that is proposed in this thesis considers and recommends new legal mechanisms with the aim to provide a more comprehensive, systematic and normative understanding of this sensitive and complex field.

Part I. THE COLLECTIVE NATURE OF GENOMIC RESEARCH

Chapter 1

Group Rights in Genomic Research: Fundamental Issues

I. Groups: a disregarded concept

The biomedical and legal importance of personal autonomy and the significance of consent to any violation of a person's bodily integrity have been increasingly recognised in the half century following the Second World War.[1] Nowhere has this been more evident than in the field of human medical research and a mountain of literature has been devoted to the subject.[2] The importance of genetics and genomics in the medical and social sciences has escalated even more recently and, in parallel, so has the need for research on human groups, as opposed to research on human individuals.[3]

The regulatory ethics involved in the former have not, however, been studied to the same extent as have those in the latter – indeed, it is the view of many scholars that the rights of groups have been seriously disregarded.[4] The purpose of this study is to review the extent of this ethical and legal gap and to propose ways to address it. The thesis discusses models for the protection of group participants in research and examines the law's power to address collective interests, by assessing possible mechanisms for group protections as new models for the facilitation of group synergies with researchers and funding institutions.

Careful consideration of possible group claims is required before regulating their protection. This is not an easy task and depends on complex factors which include:

---

[1] Milestone developments in post-war years were the Nuremberg Code [Nuremberg Code 1947] and the Helsinki Declaration [World Medical Association Declaration of Helsinki 1964, revised in 2000]

[2] For key examples [Annas & Grodin 1992] [Faden & Beauchamp 1986] [Levine 1999]

[3] As scientists widen their study of human morphology, there is increasing focus on communities and, indeed, whole populations. Examples are discussed throughout this thesis, see especially chapter two.

[4] Among many others [Chalmers & Nicol 2004] [Greely 1997] [Harry & Kanehe 2006] [Knoppers 2003] [McGregor 2007] [Underkuffler 2007] [Weijer & Emanuel 2000]

a) biopharmaceutical research priorities and changes in funding strategies;[5] b) evidence of a negative impact of previous research on groups;[6] c) concerns about increased commercialisation of research on material that is donated freely;[7] d) additional difficulties due to conflicting different knowledge systems, local interests, cultures and beliefs, which give rise to diverse approaches about the desired use of large-scale research – and its value – for groups.[8]

Systematic efforts to accommodate group participants' interests are scarce. With very few recent exceptions to the contrary, current regulatory systems of group research offer the groups themselves a rather limited role in actively contributing to the design and direction of group research. Indeed, such involvement has traditionally been viewed as irrelevant or even undesirable. But, such views are now shifting and a consensus has been evolving in the last fifteen years to create systematic ethical and legal tools for group participation in research.[9]

---

[5] There exists an abundant social and economic research literature examining the emergence and operation of market forces involved in the funding and development of pharmacogenomic drugs and diagnostic therapies, for a selection, see [Brown 2003] [Eisenberg 2003] [Hedgecoe & Martin 2003] [Krimsky 1999] [Lyall & Tait 2005] [Malinowski 2002] [Malinowski & o'Rourke 1996] [Merz et al. 2004] [Nightingale & Martin 2004] [Parry 2004] [Rothstein & Griffin Epps 2001] [Thacker 2005]

[6] [Harry & Kanehe 2006] [Lock 2000] [McGregor 2007] [Mead 1996]

[7] Social research is emerging, in recent years, on the impact of increased commercialisation of biomedical innovation on public attitudes and views about the value and use of such research. This body of work examines how research priorities and market dynamics affect public willingness towards participation in science and technology research. Key aspects of these developments are discussed in later chapters, with particular focus on the emergence of national genetic databanks as research resources and their implications for public trust. These findings are based on empirical research with focus groups, public consultations, opinion polls and population surveys in the UK and abroad, e.g. Canada and Australia [Einsiedel 2003] [Eriksson et al. 2007] [Haddow et al. 2007] [Haddow et al. 2004] [Hadgood & Shickle 2001] [Levitt 2003] [Levitt & Weldon 2005] [Nicol 2004] [Tutton 2007]

[8] [Davis 2000] [Davis 2004] [Dickenson 2007] [Knoppers 2003] [Weijer et al. 1999]

[9] Examples are given in following chapters – for an introduction to the issues, see [Knoppers 2003] [Weijer 2000] [Greely 1997]

Internationally, scholars have begun to acknowledge the importance of groups as contributors to biomedical research.[10] The recent success of patient advocacy groups in promoting research on specific diseases highlights the significance of 'partnerships' between group participants and researchers.[11] In this thesis, I suggest ways in which a comprehensive effort to anticipate participants' interests can provide a valuable tool for research facilitation and further development of public confidence towards research as a whole. As a corollary to this, I maintain that failure to protect groups and their interests will encourage still further the public distrust towards group research, and could thereby undermine the entire research enterprise.

II. The 'shared' nature of research

In recent years, international documents highlight the significance of group research and its impact at the collective level. Since the late 1990s, the wording in international guidelines, declarations and advisory body reports includes group-related considerations. They point at the need to protect personal genetic information that is derived from genetic research as it affects not only *family* but also *other group members*. The UNESCO International Declaration on Human Genetic Data specifically acknowledges this dimension.[12] This attention highlights two key aspects of genetic information and its relevance to groups, *biological relevance* but also *cultural significance*.

---

[10] *Ibid*.

[11] See for example, patient advocacy activities for the Cystic Fibrosis Foundation (US) and the UK Cystic Fibrosis Trust, where the role of the CF Foundation has become significant in drug discovery and development. The role of patient and advocacy groups as emerging contributors in the creation of new therapies for rare diseases is discussed especially in chapter four of this thesis, with an analysis of controversial legal US cases [Callon & Rabeharisoa 2008] [Dresser 1999] [Epstein 1995] [Merz et al. 2002] [Rabeharisoa & Callon 2004] [Rao 2007] [Terry et al. 2007]

[12] [UNESCO International Declaration on Human Genetic Data 2003]

For a key example, according to Article 4 of the UNESCO Declaration on Human Genetic Data, human genetic data may:

> "…be predictive of genetic predispositions concerning individuals; [human genetic data] can have a significant impact on the family, including offspring, extending over generations, and in some instances on the *whole group to which the person concerned belongs*; [human genetic data] contain information the significance of which is not necessarily known at the time of the collection of the biological samples; [and they] may have *cultural significance for persons or groups*"[13] (emphasis added)

In another example, a working document issued by the Article 29 Data Protection Working Party, an independent European advisory body on data protection and privacy set up under Article 29 of Directive 95/46/EC,[14] contains guidance on the definition of a number of characteristics that genetic data have:

> "…while genetic information … distinguishes an individual from other individuals, it may also at the same time reveal information about and have implications for *that individual's blood relatives* (biological family) including those *succeeding and preceeding* generations. Furthermore, genetic data can characterize *a group of persons (e.g. ethnic communities)…"*[15] (emphasis added)

The Article 29 Data Protection Working Party concluded:

> "…a *new, legally relevant social group* is coming into existence – namely, the *biological* group, the *group of kindred* as opposed, technically speaking, to one's family. Indeed, such a group does not only include family members such as one's spouse or foster children, but it can also consist of entities *outside this family circle* – whether in law or factually…" (emphasis added)

---

[13] *Ibid.*

[14] [Directive 95/46/EC]

[15] [Article 29 Data Protection Working Party 2004]

To the extent that genetic data has a *group dimension*, it can be argued that it is *shared* information with potential consequences for the health and future life of other family or kindred group members. Human genomic research is almost always research *about groups* of people defined not only by a common tie of disease heredity but also other bonds, as is discussed in this thesis. It is fair to say that human genomic research is, *by its nature, collective* research.[16]

In an era where biological self-knowledge is forcing new ways of thinking about genes, society, responsibility and choice,[17] there is a boom of social studies on reproductive *kinship* and genetic *relatedness* across families, communities and populations.[18] Part of this research gradually becomes introduced, albeit at a slow pace, into legal scholarship. In attempting to deal with the implications of the fluid social and biological character of constructs for shaping future research relationships, legal scholars have criticised existing regulatory practices in that they miss an *ethics of participation of communities* in genetic research.[19] Some have further argued that feelings of interdependence and "belonging"[20] might lead to a rekindling of "solidarity ethics" between group members across populations.[21] This may be true to a higher or lesser degree depending on each situation but the task to define the circumstances under which such 'solidarity' is to be nurtured and protected by law requires vigorous critical analysis, joint effort and interdisciplinary expertise.[22]

---

[16] [Greely 1997, 1431] [Weijer & Emanuel 1999, 289]

[17] [Carsten 2003] [Edwards & Strathern 2000] [Featherstone et al. 2006] [Franklin 2001, 303] [Franklin & McKinnon 2001] [Strathern 1992,182] [Strathern 1982]

[18] [Finkler 2005] [Finkler, Skrzynia & Evans 2003] [Nash 2004]

[19] For example, Bartha Knoppers states that research frameworks would benefit by taking on board considerations sympathetic to claims related both to *group harms* but also to *group benefits* from genetic research [Knoppers 2000a, 38] and see also [Weijer & Emanuel 1999, 289]

[20] [Edwards & Strathern 2000]

[21] [Knoppers 2000a, 38]

[22] For a recent critical view on how to implement solidarity as governance principle in international health care research and health care policy see [Harmon 2006]. For an interesting discussion of the multiple levels of expression of collective identity in interpersonal relationships at national and transnational social levels in pursuit of shared characteristics and definitions of solidarity, see [Steans 2007]

Theories influenced by ideas of group connectedness and significance first emerged in the early 1990s, in the writings of law and ethics scholars who were involved with the controversial Human Genome Diversity Project. These scholars acknowledged that the absence of group protections in research frameworks was problematic. They stressed that genetic research on groups who are – or are perceived as being – closely connected has implications for all members of those groups, whether or not they decide, or even are asked, to take part in the research.[23] Sometimes, these implications can be positive, for example, in the case of a health intervention being achieved, but they can also be negative, in terms of stigmatisation, discrimination, or affront to a (native) group's culture – for example, by contestation of the group's historical knowledge.[24]

Ever since, some limited attempts have been made to promote group-related discourses into legal literature but, as it is explained in this thesis, these have been rather scarce. This is partly because the notion of groups, evidenced in the form of varied genetic and genomic collectives, is a differentiated and complex concept. Their study reveals a range of entities; groups in this context are families, native tribes, patient advocacy groups, ethnic communities, national or geographically defined populations, future generations, and humanity at large. Their views about their relatedness can vary significantly across communities. Group differences can also depend on the particular social, economic, historical and political contexts of the collectives in question.[25] The varying types and degrees of *connection* among their members raise considerable challenges when seeking to design a one-size-fits-all approach for the regulation of their participation in research.

---

[23] [Greely 1997, 1431] [Weijer & Emanuel 1999, 289] and see detailed discussion in chapter three and five of this thesis.

[24] In similar vein, they stressed that whatever the effects of the research, they will affect group members who did not give their informed consent after weighing foreseeable benefits and risks [Greely 2001a, 222]

[25] [Davis 2000] [Greely 1997] [Underkuffler 2006] [Weijer et al. 1999]

III. A diverse and complex context

Technological advances in genomics and bioinformatics render the study of gene variation increasingly significant in biomedical research and future clinical treatment. As the scope and depth of research expands, so do the corresponding stakes for research participants. Diverse kinds of research with groups raise various concerns, in different degrees. The analysis of differences and similarities between these groups is instrumental in understanding their nature and their goals. This thesis asserts that any attempts to develop protections for groups in this context need to consider literature that discusses not only legal but also ethical, social, cultural and economic issues of importance to groups, as these are related and affect the willingness of groups to participate in research.

I contend that a good step for the law to meet the challenge of defining group interests in this context is to develop a new methodology by drawing on interdisciplinary literature and expertise. In the next chapter, this thesis recommends a typology of groups on the basis of parameters such as research rationales, self-reporting, nature of risks and other consequences of group involvement in research, group resources invested, benefits expected, and other factors. The categories proposed in the next chapter help compose a map of different kinds of groups but also of the various kinds of concerns that groups can voice when considering to participate in research.

Before I discuss this new methodology and its merits in detail in chapter two, it is important to make some preliminary observations. This thesis does not seek to offer an exhaustive or definitive survey of groups, but rather, a comprehensive overview of the kinds of groups who participate in research, and a critical understanding of related group claims that remain unaddressed by the law. While working towards a principled way for developing criteria for group protections and addressing group

concerns in research, it was paramount to keep in mind the *sensitivity* required in categorising human populations, particularly in the context of biomedical research. Reading in preparation for this thesis is carefully informed by historical accounts of the management of collective risks and related genetic group discrimination in research.[26] There already exist various ways to categorise human groups – by genetic markers, ancestry, locality, cultural identity, lifestyle, among other criteria – some of which are deemed more useful for the purposes of biomedical research and clinical treatment than others. Concerns persist over inadvertently exacerbating attitudes, practices or beliefs that stem from sorting people in categories, and doing so may not avoid social patterns of discrimination. For example, it has been argued that the long-established epidemiological and clinical use of racial/ethnic group categories in biomedical research can inadvertently give support to exaggerated deterministic lay claims about some genetic uniqueness, and thus perpetuate attitudes that disadvantage one group and its members more than others.[27]

In this thesis, I discuss the meaning of 'group' and 'social identity' when linking human groups and biology by drawing on scientific, legal and ethical literature in support of the fact that it is problematic to account for categorisations and genetic differences between people by resorting to biological differences between races.[28] This work is aware of the grave implications of discriminatory or eugenic practices of the past. It merely seeks to measure the law's capacity to regulate collective interests in genomic research and to provide models for their protections since the human genome may have been fully sequenced in April 2003,[29] but the legal, socio-ethical and political debate about it is 'far from over'.[30]

---

[26] For a few examples see [Andrews 2001] [Duster 2006] [Duster 2003a] [Epstein 2004] [Jones 1992] [Kerr et al. 1998] [Kevles 1995] [Lemke 2002] [Malinowski 2003] [Reverby 2000]. Also see the discussion on the history of the Tuskegee study in the US, in chapter two.

[27] [Bamshad, 2005] [Ellison & Jones 2002] [Gannett 2005] [Gannett 2003] [Gannett 2001] [Goodman 2006] [Outram & Ellison 2006] [Rischn et al. 2002] [Soo-Jin Lee 2005]

[28] *Ibid.*

[29] [Major Events in the U.S. Human Genome Project and Related Projects]

[30] [Knoppers 2003]

With this understanding in mind, the methodology proposed in this thesis aims to clarify conceptual issues on the nature of group involvement in genomic endeavours, research which is designed to have future unanticipated uses and requires long-term commitment. In the following chapters, examples are used to showcase particular group contexts and interests, paired by their concerns about group membership, representation, control and influence over the outcomes of a diversity of research projects. Chapter two displays a range of research projects involving groups that vary across a wide board of applications, such as gene banking, human genomic variation sampling, genetic testing and gene patenting. These applications raise key issues of particular group concern that remain unaddressed in present day frameworks. The analysis that follows aims to contribute towards developing core criteria for the protection of groups in research, and the evaluation of their role and contribution in this process.

Chapter 2

Defining Human Groups in Genomic Research

I. Categories of groups

A. A definition and a few examples

In this thesis, the term '*group'* is used as an *umbrella* term, to portray the wide variety of associations including families, disease groups, local communities, tribes, ethnic groups, entire populations and parts thereof, who participate in particular types of research. *Groups* in this context are traditionally viewed as collections of people who share some genetic characteristic(s) or disease in common.[31] Persons included are both those actually affected and also those, such as their families, who may be perceived to be affected, by the disease.[32] The key question for the purposes of this thesis is who these 'families' are. In more recent years, some authors discuss that many groups can be loosely characterised in both biological and social ways, in that the 'bio' and the 'social' reinforce each other, thus forming 'biosocial collectives'.[33]

One type of such collectives is groups of families who suffer from a rare genetic disease. These can include families who have networked to form patient organisations or *disease advocacy* groups. Organisations like these exist for a number of genetic conditions;[34] many of them are now part of large patient coalitions geared towards coordinating advocates' activities and lobbying governmental bodies in control of health research funding.[35]

---

[31] [Greely 1997] [Rabinow 1996]

[32] See also previous discussion in chapter one with references to the *biological relevance* but also the *cultural significance* of groups when considering who genetic information affects and who may have a say in its management or control.

[33] [Hacking 2006, 81] and see also [Epstein 2004, 183]

[34] [Merz et al. 2002] [Terry et al. 2007]

[35] E.g. Genetic Alliance Biobank, EGAN (European Genetic Alliances Network), IGA (International Glaucoma Association), and GIG (Genetic Interest Group) [Kent 2006]

Groups can also be *indigenous (or aboriginal or native) peoples* who become targets in human genetic variation research[36]. Key examples discussed in detail in this thesis are the targeted populations in the (defunct) Human Genome Diversity Project, proposed to study their origins and migrations;[37] other controversial cases of attempts to patent human 'indigenous cell-lines in the South Pacific;[38] a currently pending law suit of the Havasupai, a North American Indian tribe, in Arizona. They agreed to participate in genetic research on diabetes but subsequently sued the University of Arizona upon discovery that the researchers misused the blood taken from tribe members for the purposes of research into native migration and schizophrenia.[39] These cases have created a set of novel legal concerns about the protection of groups, in the form of group consent, intellectual property rights and tangible property rights respectively.

A more recent example of groups is the range of populations selected to participate in the HapMap project, an international effort to create a research resource to determine the common patterns of DNA sequence variation in the human genome.[40] The definition of the HapMap populations raises concerns, as the project is sampling populations with ancestry from Africa, Asia and Europe, while keeping open the

---

[36] The term varies mainly on the basis of the different geographical location where such groups live, across different continents. For example, native tribes in Canada are referred to as 'First Nations' or 'aboriginal communities'; American Indian and Alaskan natives are usually referred to as 'native American communities' or 'aboriginal communities' as well; populations in the South Pacific or in Panama are referred to as 'indigenous'. In the terminology of international human rights law, the most widely established term for all these groupings is "indigenous peoples". I discuss the meaning of this term later in this chapter.

[37] [Cavalli-Sforza et al. 1991] [Greely 2001a, 222]

[38] [Friedlaender 1996] [Liloqula 1996] [Scientists attacked for "patenting" pacific tribe 1995]

[39] ['Havasupai suits involving blood research moved' 2005] ['Lawsuit over Havasupai blood moved to state court' 2005]

[40] [IHMC 2003]

possibility of adding populations with ancestry from other parts of the world later.[41] The project has been criticised for its ambiguous stance towards clarifying what the participant populations are considered to be representative of.[42]

Ethnic groups have traditionally been targeted as research participants. Classic examples are cases of the Amish families contributing to research on mental disorders,[43] Ashkenazi Jewish participants in genetic screening for Tay Sachs disease or African Americans in sickle cell anaemia screening.[44] The potential for misuse of genetic information and other related knowledge that becomes available through such research, at the potential expense of participants as members of an ethnic group, has not gone unnoticed by legal and ethics scholars. There is increasing interest on the extent to which understandings of the *familial* and *shared* nature of genetic information may undermine traditional legal conceptions of individual autonomy, in this context.[45] The predictive potential of information *vis-à-vis* members of one's group challenges current ethical and legal paradigms, and creates new dilemmas for consent and representation within these groups.

Another example of groups where debates on consent have been more prominent is populations who participate in genetic database projects. In the last decade, a number of large-scale research biobanking projects have been developing internationally, alternatively called human genetic databases. These raise a range of questions about the nature and interests of the populations involved, including consent, privacy, control and intellectual property issues. Key examples are the Icelandic Health

[41] [IHMC 2004, 470]

[42] [Foster 2005, 1] [Reardon 2007] [Sleebom-Faulkner 2006]

[43] [Mabrey June 2005]

[44] [Hecht & Cadien 2000, 84] [Mitchell & Happe 2001] [Richards 1996, 307]

[45] But also the extent to which the shared nature of genetic information highlights the social bonds and dynamics developed between members who live together as part of a wider community [Dolgin 2001] [Lillehammer 2001, 595]

Sector Database, set up in 1998 with the aim to create a centralised computerised database of national medical records that would allow private company to also access clinical records and a genealogical database for the study the causes of genetic disease;[46] or the UK Biobank, set up to collect blood samples and data from 500,000 volunteers, with the aim to study the complex environmental and genetic factors of common serious disorders, such as heart disease, stroke, cancer and diabetes.[47] Similar initiatives, each with its own institutional design, research aims, management strategy and geographic, socio-political, economic environment have been developing in the last decade, in several other countries.[48] In later sections, I will discuss the merits of a few of these projects as they have attracted a lot of attention and they raise critical issues for the future of the regulation of large-scale research. These issues are especially relevant to this thesis, especially in as much as they focus on how targeted populations are viewed by relevant scientific and policy agents interested in high levels of participation.[49]

B. The need for a classification

The range of projects mentioned above often represents a variety of policy approaches. They involve different kinds of collaborations between public and private agents, who are committed to biomedical research innovation and raise novel questions for the protection of group participants that they target.[50] Whether it is family, disease organisation, national population, native tribe or ethnic group, I argue that groups are essential to research progress. They are crucially affected by research practices and outcomes, in their diverse roles – either as collectives approached directly, or as intermediates between individuals, communities, research institutions,

[46][Potts 2002, 8] [Pálsson & Rabinow 2001]

[47] The project started collecting samples in 2007 [UK Biobank website]

[48] Such as Estonia, Canada (Quebec), Sweden or Singapore, as per discussion further below.

[49] [Greenhough 2007] [Pálsson 2007]

[50] [Austin et al. 2003a, 37]

and governments. The extent to which these groups become *special* when linked to particular projects raises the stakes in the pursuit of protections that can offer better research oversight, control of outcomes and guarantees against group harms.

In order to determine what makes groups special or rather, how the concept of groups can be understood better in this context, I propose a new way to broadly categorise groups who become participants in research, in the following sections. So far, very limited comprehensive attempts have been made to classify groups in the biomedical context, some by sociologists, anthropologists, and philosophers, but also by epidemiologists and geneticists; in the latter two cases, the relevant expertise relies on scientific protocols and sampling strategies necessary for a particular study, and not the socio-cultural, historical or political circumstances as defined by groups themselves.[51] Scholars have described groups in research as "study populations" or "communities" or refer to ethnic groups, aboriginal or indigenous groups and other "large-scale" populations as "representative" targets for research.[52]

A novel classification is proposed instead here, as part of an effort to systematically understand the claims and diverse types of group participants in research, seen in a broader social and cultural context. The following table divides them into six broad categories, taking into account both social and biological connections acknowledged by group members themselves, expectations that they may have expressed in becoming involved with research, as well as research strategy rationales. The case studies discussed in this thesis refer to examples within these categories, explained in detail, in the section that follows the table below.

[51] [Greely 1997] [[Harry & Kanehe 2006] [Juengst 1998] [Weijer 1999]

[52] [Greely 1997] [Juengst 2000, 52] [Reardon 2007] [Sleebom-Faulkner 2006] [Weijer et al. 1999]

Table 1. 'Group as…'

Group as…	**Connection**	**Examples**
National/ Political/ Geographical population	*An entire national population, or part thereof, becomes target for the purposes of large-scale research, at national or regional level*	Icelandic Health Sector Database Estonian gene bank database UK BioBank Tongan gene database (defunct)
Disease/ Patient advocacy group	*Disease links both those personally affected by disease and those who may be perceived to be affected, and their families*	PXE International Canavan Foundation Cystic Fibrosis Foundation Alpha-1 Foundation
Aboriginal/ Native/ Indigenous tribe (often geographically isolated)	*Long-standing historical, geographical, cultural, spiritual factors or common traditions strongly define group membership and tribal affiliation*	Indigenous tribes (e.g. Havasupai, Hagahai, Guaymi, Solomon Islands) Human Genome Diversity Project (defunct)
Ethnic/ Racial/ Cultural group	*Existence of particular ethnic/racial identity as socially constructed, defined by religion or political status*	Amish communities African-Americans Ashkenazi Jews
Family Blood relatives/ Extended family/ Spouses/ Future children	*Social and biological notions of kinship* *Family ties* *State intervention*	Amish communities Generation Scotland Scottish Family Health Study (SFHS) Cyprus Thalassaemia Prevention Screening
Humanity (at large)	*Humanistic notions of 'global community' or 'human family'*	Common genetic heritage of mankind (CHM) Responsibility to future generations

II. Geographical, political or national groups

A. Human genetic databases for research

1. Definitions

A variety of governmental and commercial agents is involved in supporting research on human genomic variation and associated disease. Interest in mapping the inheritance of genetic disease patterns among humans and in examining the impact of clinical and environmental factors in their occurrence dates back only to a few decades of population genetics history. The quest for the development of pharmacogenomic drugs and therapies is flourishing now – not without major controversies – although circumstances and public acceptance can vary significantly between different projects.[53] In recent years large-scale research becomes increasingly desirable as research gene banks initiatives are being set up internationally, in the quest for a better understanding of the disease pathways of common complex diseases, such as heart disease, diabetes, asthma or schizophrenia. Many of these projects research the patterns of inheritance of genetic disease and the interaction of genes, lifestyle and environment in genetic disease.[54] The corresponding commercial interest in establishing these resources is driven by the development of association genetics and the search for genes and genetic markers correlated with specific diseases or particular responses to drug therapy.

For the purposes of this thesis, a human gene database or bank can be defined as "a stored collection of genetic data and samples, in the form of human blood or tissue

[53] [Rothstein & Griffin Epps 2001]

[54] For a good comparative overview see [Salter & Jones 2005]

that can be linked with medical, genealogical and lifestyle information from a specific population".[55] These databases are tools for exploring the genetic roots of common diseases, created by the integration of genotype data and personal medical and health information.

Increasing scientific appeal exists in research on isolated and relatively homogeneous populations for the study of the genetic basis of complex diseases, and for the purposes of pharmacogenomic research aiming to develop genomically-tailored drugs.[56] As randomised clinical trials on the effects of pharmacogenomic drugs cost less if conducted on populations who possess a higher degree of genetic similarity, the appeal to target isolated populations is obvious; *homogeneous* populations have a high frequency of certain genomic variants as they descend from a small group of founders and may have been genetically isolated by geography or culture. A limited number of founder populations exist and many are included in gene banking projects.[57] There are disadvantages in using founder populations, in that research results may not be generalisable to other groups outside that study,[58] so national genomic projects are also set up to research the causes of common complex diseases and/or their interaction with environment and lifestyles, in various countries with *heterogeneous* populations.[59] A number of projects have been initiated in different countries such as Iceland, UK, Estonia, Sweden, Latvia, Canada, Australia, Tonga, Singapore, Japan, China and many others, including recent proposals for a national study in the US.[60]

---

[55] See [Austin et al. 2005, 116]

[56] [Rothstein & Griffin Epps 2001]

[57] [Hsieh 2004] [Lewis 2000]

[58] [Pálsson 2007]

[59] For example, Singapore or UK [Greely 2000] [Hsieh 2004]

[60] [Collins 2004, 475]

These projects, national or regional, are being established each with a different remit, organisational structure and funding protocol; consequently, their scope, design, recruitment strategies and collection management can vary considerably. They can be divided in three categories on the basis of how they are funded and organised, as: i) projects funded by national governments and based within academic and medical departments, anticipating co-operation with a commercial enterprise (e.g. Estonia, Sweden, UK); ii) governmentally funded institutes created for genetic research with no expectation of commercial involvement (e.g. Norway, Quebec); iii) commercial sector companies backed by the pharmaceutical industry and licensed by government (e.g. Iceland, Tonga) for drug discovery and development.

These projects emerge within different organisation, social, economic and cultural settings but they all aim to collect data and samples from groups chosen for the purposes of national or regional research.[61] They rely on the collection and storage of various data and DNA samples, with protocols that allow linkage of genetic data and samples with medical records and personal information, from interviews, genealogies and family histories on whole populations.[62] Existing possibilities of accessing large family or health records and using linkage analysis based on medical family-history research in order to build health research databases as research resources raises complex questions of security, control and trust for the groups involved. Much controversy surrounds the assembly of large-scale population genetic databases but attention is also given to similar initiatives at smaller-scale. The design and rationales of these projects can differ greatly since the incentives, strategies and expectations that affect the governance of each project vary substantially but they all pose fundamentally similar questions for ethical governance. In the following sections, I contend that overall key dilemmas raised by such projects can be divided in four strands of concerns about:

---

[61] [Barr 2006] [Cambon-Thomsen 2004] [Tansey & Burgess 2005]

[62] [Cambon-Thomsen 2004] [Gibbons 2007]

- appropriate consent requirements
- control over scientific and commercial uses of collected samples and data
- confidentiality and other security measures against unauthorised uses of personal data
- provisions for feedback and future communication with participants

I argue that research protections aimed at addressing relevant concerns tend to focus partially on the first, third and the fourth of these areas, leaving the second largely wanting. Furthermore, current protections are not being developed with group claims or interests in mind; instead current frameworks remain focused on a traditional individual-oriented model of consent, and thus fail to provide adequate guidance for the protection of collective interests. A consideration of a few examples is useful in highlighting current problems for the regulation of group interests in this area.

2. Icelandic Health Sector Database

The first large-scale population genetic database to be established in the world was the Icelandic Health Sector Database in December 1998,[63] when the Icelandic parliament (Alþingi) passed a bill authorising the creation of a centralised database of non-personally-identifiable health data with the aim of improving health and health services.[64] The database was to be set up, maintained and serviced by a licensee, deCode Genetics, to be granted an exclusive licence on its commercial exploitation. The company was licensed to build a database of Iceland's medical

[63] It was followed by the Uman Genomics proposal in Sweden, the Estonian Genome Project, the Latvian Genome Project and the UK Biobank, among others – [Austin 2005] [Austin et al. 2003a] [Austin et al. 2003b, 451] [Tutton & Corrigan 2004] to name a few authors from a fast-growing literature that charts the rise of large-scale genetic databases.

[64] [Act on a Health Sector Database 1998-1999]

records including diagnoses and test results, treatments and side effects, and combine and analyse these together with genetic and genealogical data. [65]

Controversy ensued not only because of the absence of appropriate informed consent protections,[66] but also concerns about privacy, scientific freedom, the nature of the benefits to Icelanders and the implications of the commercial monopoly assigned to decode, as the endeavour attracted criticisms for its heavy association with commercial private interests.[67] Public acceptance of the project was recorded by the media drawing on public fascination with themes of Icelandic history, identity and heredity,[68] as attraction to genealogical trees and family histories is evidently extreme in Icelandic society, characterised by long-held practices of keeping and tracing genealogy-record information in everyday relationships on a routine basis.[69]

In an era of increased bio-power, the tracing of family histories combined with the use of genealogical data on most of the Icelandic population by a large private enterprise seeking to establish presumed genetic causes of common diseases on a commercial basis, provoked debates and competing expert and lay assumptions about Icelanders' identities and their relatedness to each other as a whole.[70]

---

[65] *Ibid*.

[66] Aspects of this debate are discussed later in this chapter and in the next chapter.

[67] [Pálsson & Rabinow 1999] [Pálsson & Rabinow 2001]

[68] [Chadwick 1999] [Greely 2000] [Pálsson & Hardadóttir 2003, 271] [Potts 2002] – The homogeneity of the Icelandic population has been challenged [Arnason etal. 2000] *cf.* [Pálsson & Helgason 2003] on media examples and implications of historical research using genetic data from studies with Inuit groups in Greenland and Victoria, Canada.

[69] Such as the use of the Book of Icelanders, see [Pálsson 2002]

[70] [Pálsson 2002] – The author is a famous anthropologist from Iceland who has argued that genealogical records "are never innocent phenomena"; they have a *social life of their own*, a biography informed by the contours of the cultural landscapes to which they belong, *ibid* at 338. For a critique of this position, see [Simpson 2000]

This controversy affects thinking about groups in at least three ways; the problematic use of presumed consent as a means of 'normalising' Icelanders' participation in the project on an opt-out basis, the deployment of strong narratives of scientific and national progress as a way to enhance participation in the project, and also considerations of who is entitled to benefit from such research and what grounds.[71]

3. Tongan Gene Database

This is another case which attracted criticism for the association of the project with private commercial interests, and which was heavily opposed for failing to anticipate group values. In November 2000, an Australian biotechnology company, Autogen Ltd., announced plans to map the genome of the people of the Kingdom of Tonga in agreement with the Tongan Ministry.[72] Their plans to collect human DNA and tissue samples for the purposes of gene research in diabetes were met by fierce public opposition from church and pro-democratic human rights groups for transparency in Tongan governance.[73]

The Tongans are a fairly homogeneous isolated indigenous population in the South Pacific, where diabetes is widely prevalent. They were an appealing pool for the Australian company interested in developing drug research on the genetic basis of diabetes, and aiming to expand their activities across other countries in the Pacific.[74] Autogen offered a bundle of future benefits to the people of the Kingdom of Tonga, including free provision of drugs from the potential discoveries, research funding for the Tongan Ministry of Health, possible royalties from any commercially successful

---

[71] See also [Greenhough 2007] [Pálsson 2007] [Pálsson & Rabinow 1999] [Winickoff 2006]. Similar issues about the use of narratives on national progress and entitlement to benefits were raised in the case of the Estonian gene bank, see further below.

[72] [Burton 2002a] [Dickenson 2007, 170] [Pálsson 2007, 102]

[73] [Burton 2002b, 443] [Austin et al. 2003a, 42] [Pálsson 2007, 102] [Rouse 2001]

[74] [Nowak 2000]

discoveries to the Tongan government yet public opposition ultimately prevented Autogen's plans.[75]

The failure to establish the database can be attributed to a number of key factors, in that the proposal *did not consider extended family networks and values* characteristic to Tongan society; also because it was not acceptable that the proposed 'agreement' could be justified without public consultation that would evaluate the potential benefits, which did not take place.[76] This case illustrates how significant shared local customs, values and beliefs were in shaping willingness for research participation. In the Tongan case, these values had crippling consequences for Autogen's project which required wide and long-term cooperation. The merits of this case are discussed in chapter four, as it raised significant issues on how the Tongans viewed the plausibility of proprietary rights on their genome.

4. Estonian Gene Bank Database

In early 1999, Estonia followed Iceland's example with a proposal for a national bank of phenotype and genotype data of the entire Estonian population.[77] The national gene bank database was proposed by researchers at the University of Tartu, with two goals in mind. Firstly, to identify common disease genes – particularly those involved in multifactorial diseases such as asthma and heart disease – by comparing genotypes within a group of patients with a given disease. Secondly, to

[75] According to [Austin et al. 2003a], Autogen claimed at the time that the main problem was scarcity of funds.

[76] [Burton 2002a] [2002b] [Senituli 2002] Dickenson hypothesises that if Autogen had displayed a more sensitive understanding of Tongan traditions and values, constructive discussions between Autogen and the Tongan people may have been possible [Dickenson 2005, 47] and also, especially [Dickenson 2007, 170]

[77] [Estonian Genome Project website] [Hsieh 2004] [Maheshwari 2000] [Sutrop & Simm 2004]

set up a healthcare database as a resource that "would give Estonians access to their own data" and help Estonians benefit from personalised medicine in the future.[78]

The legal framework to support the plan was organised in December 2000, when the Estonian Parliament (Riigikogu) passed the Human Genes Research Act, to facilitate the creation and maintenance of the gene bank.[79] The Act established the non-profit Estonian Genome Project Foundation (EGPF) with the aim to coordinate the project.[80] The Estonian government created a public private partnership between EGPF and EGeen, a commercial private company, based in California, to finance the EGP through EGeen International, apart from the costs related to the project's Ethics Committee, which were to be covered from public funds. In exchange, EGeen was granted an exclusive licence for commercial access to the data emerging from the EGP. Their collaboration ended in December 2004, when the contracts between the EGPF and EGeen were terminated by mutual agreement.[81]

By that time, data collectors of the project – general practitioners – had collected and deposited data and tissue samples of about 10,000 gene donors, including genetic profiles as well as information on individual health status and lifestyle, in accordance with he commissioned pilot study. Following financial problems that the project suffered in 2004, the Estonian Government injected €8m into the project over four years, enough to raise the number of participants to 100 000.[82] Having declared biomedicine as one of the key foundations of a knowledge-based Estonia, the government considered this project as a resource which, based on the entire Estonian population of 1.4m, would offer a rival genetic resource to Iceland's halted project.

---

[78] [Estonian Genome Project Foundation]

[79] [Estonian Human Genes Research Act 2000]

[80] [Pálsson 2007, 105] comments that, in Estonian, the name for the project, *Geenivaramu*, literally means "gene collection" or "heritage".

[81] ['Genome Project Ends Cooperation with Current Financier' 2004]

[82] [Burgermeister 2004] [Twyman 2007]

Their interest in attracting private funding, commercialising and marketing the project to international pharmaceutical investors stemmed from the need to meet the costs of the project, which was covered mostly by venture capital from abroad.[83] Interestingly, whereas advocates of the IHSD (in Iceland) used international media to stress the "*homogeneity*" of the Icelandic gene pool, essentially built on Iceland's comparative isolation from the rest of the world and earlier policies restricting immigration throughout much of the 20th century, Estonia, by contrast, stressed the significance of the *heterogeneity* of the Estonian gene pool and the ability to generalise from Estonian genomic studies of the link between genes and disease for other genetically 'European' populations, located around the world. [84]

Critics challenged the corporate interest in the EGP, by comparing the project to the contested experience of the Icelandic database. They argued that the Estonian government was selling out the nation's genetic pool while at the same time siphoning funds off the Estonian health care system. They claimed that the public health infrastructure was already under-funded and that this large, expensive project might provide little benefit to the population.[85] In rebuttal, the project's supporters said that the project would bring in much-needed revenues to the state. Government officials argued that the gene bank would become a medical resource for Estonian patients and doctors and would help to improve the quality of medical care.[86]

---

[83] 98.6% of the funds invested in the project were private capital, covered mostly by venture capital from abroad [Koik 2003]

[84] [Fletcher 2004, 9]

[85] For example, critics contented that in a country where alcohol-related heart diseases and lung cancer are among the major causes of death, spending government money to create a state-of-the-art gene bank may seem extravagant [Koik 2003]

[86] [Koik 2003] [Maheshwari 2000] and [Pálsson 2007, 106] who refers to comparisons with success of the neighboring Finnish with Nokia as an example of dynamic innovation of "new" economies; he comments that public discussion of the project emphasised the need for an "Estonian Nokia"; and that for many, biotechnology and the gene database project were a potential avenue to a similar success. For more discussion see [Korts 2007] [Pärl 2003] [Rainer & Rivo 2004] [Tammpuu 2007] [Tammpuu 2004]

In view of debates on public acceptance of such projects examined in following chapters, it is useful to consider briefly what the Estonian population had to say in these debates. In academic journals and web communications, project officials claimed that the majority of Estonians supported the project, quoting public opinion polls that only 5% of the population was against the project and that that those with dissenting views were few. In contrast, some critics repeatedly expressed concerns over the degree of public awareness concerning the details of the project, on the grounds that it would be difficult to guarantee informed consent and to ensure that non-directive counselling of participants was carried out properly.[87] A critic argued further that there was urgent need for public education about the implications that genetic information may have "for the individual as well as family members and unborn children".[88] Critical questions to note regarding the protection of groups were issues of consent, accountability, commercial uses of research and distribution of benefits on the realisation of this project. These include concerns about the role of public opinion in national biobanking for research and its commercialisation.

5. CARTaGENE

Another project in progress is the CARTaGENE project in Quebec; it involves the systematic collection of socio-demographic and health assessment data, biological material and DNA samples from Quebecois people, with the aim of mapping human genetic variation in a large reference population. The original aim was for blood samples and anonymised health information to be collected from 50,000 - 60,000

[87] [Tasmuth 2003], stating that this would be particularly difficult in "paternalistic post-communist Baltic States".

[88] [Frank 1999, 1263]

individuals aged 25-74, over a period of four years, via a random selection process, with a longitudinal follow-up of fifty years.[89]

The project will seek to determine the mutation of frequencies in the different regions of Quebec, with the hope to improve understanding of the role of genetic health determinants and environmental factors in health outcomes. The short-term goal is to enable medical genetic services programmes to become tailored to the needs of regional sub-populations. The long-term goal is to create an international project for integrated population genomics, to provide case-controlled sub-cohorts for finding genes predisposing to common, complex diseases and to expand the development of predictive and diagnostic technologies. The project is managed by a non-profit institute; the CARTaGENE database is considered to be public property, with no explicit commercial involvement.[90]

As opposed to the one-way "communication approach" that the Iceland Health Sector Database and the Estonian Genome Project adopted against public outcry, the CARTaGENE project chose a hybrid "partnership approach" in order to involve the public into decision-making processes by focussing on meeting local needs for public participation.[91] This is a careful attempt to address issues of public participation and legitimacy of research which aims to anticipate a number of challenges in large-scale population research. At the same time, it draws attention on the difficulties involved in such projects. For example, even when there is regulatory willingness to address reported concerns about confidentiality and to respect donors' interests in their genetic material – as is the case of the Canadian initiative – there is still a significant risk that the public will mistrust researchers and may not participate in sufficient

[89] [Godard et al. 2007, 147] – In June 2007, the Canadian Government and the Government of the province of Quebec announced funding of $28.5 million over three years for the project to start recruiting 20,000 Quebec citizens aged 40-60 [Stewart 2007]

[90] [CARTaGENE website]

[91] [Godard et al. 2004]

numbers.[92] Bearing these challenges in mind CARTaGENE researchers are looking to develop participatory methods and appropriate consultation strategies to help with recruitment and project development.[93] In comparison, it is noteworthy to consider the approach that has been adopted in the UK where similar concerns about representation, consultation, accountability and legitimacy have been raised.

6. UK Biobank

The UK Biobank was proposed as a research resource to help study the separate and combined effects of genetic and environmental risk factors of common multi-factorial diseases affecting adults in the UK. It is publicly funded jointly by the Medical Research Council (MRC), the Wellcome Trust, the UK Department of Health, the Scottish Executive and the Northwest Regional Development Agency. It is supported by some of the UK's major medical research charities, including the British Heart Foundation and Cancer Research UK, and it is also supported by the National Health Service.[94] The research team aims to collect biological samples from 500,000 still healthy volunteers aged between 40 and 69. The collected samples will include height, weight and blood pressure measurements, together with details of medical history and lifestyle information. The team will monitor follow-ups on medical and other health-related records.[95] The project began contacting volunteers through its first pilot centre in March 2006,[96] at which time it was considered to be the world's biggest resource for the study of the role of nature and nurture in health and disease.[97]

---

[92] [Knoppers et al. 1999]
[93] [Godard et al. 2007] [Godard et al. 2004]
[94] [UK Biobank website]
[95] [UK Biobank website]
[96] [Brice 2006] [Ghosh 2006]
[97] [UK Biobank website]

There is no single specific statute that regulates the project. The organisation of the governance and ethics framework for the UK Biobank has for the most part been the responsibility of the funding partners themselves. The current overseeing body is set up as the Ethics and Governance Council (EGC) to "act as an independent guardian of the Ethics and Governance Framework [EGF][98] … and to advise the Board and report publicly on the conformance of UK Biobank's activities … with the interests of participants and the general public".[99]

The proposal for the UK Biobank was the subject of criticism by the House of Commons Select Committee on Science and Technology, in 2001. The Committee's report drew attention to the project's consultation process, peer review and funding processes.[100] The project attracted various kinds of criticism, ranging from concerns that it may over-emphasise the significance of genetic factors rather than environmental factors, to questions as to why so much public money is awarded to it, worry over future unanticipated uses of samples – either for research purposes, or private company access to the biobank or law enforcement access, this last seen in the light of legal precedent which allows the override of presumed confidentiality over samples for the purposes of law enforcement.[101] Opinion surveys, polls and working papers were commissioned between 2000-2003, in an effort to encourage

---

[98] The EGF is public and it was developed in order to set standards for the project; for the latest version at the time of writing, see [Ethics and Governance Framework Version 3.0, 2007] available at the project's website.

[99] When dealing with a breach of that framework, the EGC has powers under a four tier procedure that ranges from informal communication to a formal resignation and public denouncement. Arguably, this could be considered as a powerful tool, allowing acknowledgement of socio-political pressures from a number of stakeholder groups, including media, public interest groups, and, at the same time, accounting for public perceptions and response. However, in terms of specific enforcement of governance principles, it has been argued that the EGC may be weak, since any recourse to legal enforcement of governance will be limited purely to circumstances where the breach of governance principles is also a breach of existing laws [Cutter et al. 2004, 191]

[100] [House of Lords Select Committee on Science and Technology, *Human Genetic Databases* 2001]

[101] [BBC News 'Concern over DNA database access' 2007] [GeneWatch Memorandum 2002] [Ghosh 2006] [Ghosh 2003]

public support for the project with emphasis on the future public health benefits, ethics and competent management of the project, whilst making extensive use of a language of 'genetic citizenship', 'genetic solidarity' and 'altruism'.[102]

These promises of future health and wealth were set against a background of crises in public trust in both the medical (e.g. Alder Hey) and scientific and governmental spheres (BSE, GM food), which were widely reported by the media.[103] Early on, law and ethics scholars pointed out the need to take account of the 'crisis in confidence' and lack of public trust in science and medicine as applied to genetic research in the UK.[104] Experts called for the need to maintain a genuine and consistent dialogue between science and society in order to avoid repeating mistakes of the past.[105] Social sciences experts cautioned against the uncritical importation of notions of altruism and donation from other areas of research when regulating public participation in human genetic databases.[106] Empirical evidence on these debates reveals concerns about consent, access, feedback and withdrawal, together with further concerns over commercial and third-party access to data. Yet, according to the same findings, patients and relatives of patients seem overall more positive about medical research than the public at large.[107]

---

[102] [UK Biobank public consultations]: these notions are examined closely in following chapters.

[103] [McGrath 2002]

[104] [Laurie 2002, 309] [O'Neill 2002, 11]

[105] [Levitt & Weldon 2005, 311] [O'Neill 2002, 11] [Petersen 2005, 303]

[106] [Tutton 2004, 19-38] [Busby 2004, 39-56] [Waldby & Mitchell 2006]

[107] Some have argued that in project documents there is an extensive use of language of persuasion placing emphasis on researchers' abilities so as to encourage acceptance but these views have been heavily criticised [Cragg, Ross, Dawson 2000, 1-134] [People Science and Policy 2002, 1-46] [People Science and Policy 2003, 1-35]. I discuss these issues in later chapters, while assessing the inadequacy of existing donation models for research purposes.

7. Calls for regulation

The variety of personal information collected by gene database projects and the legal, social, ethical issues raised by their use has caused heated debates in many countries, in the last decade. Literature and media research shows that many professional organisations, academics and the press receive the development of national and regional human genetic databases with caution.[108] Expectations and concerns are raised by various groups about the adequacy of a wide array of protections, such as consent, recruitment, feedback and withdrawal of participating populations, rights of access, security, privacy, control, benefit sharing, ownership, patenting, commercialisation, ethical oversight and management of these databases.[109]

Some of the countries with gene-banking projects have responded by establishing regulation to meet public needs for increased scrutiny and standards for population genetic studies, as in the cases of Iceland or Estonia, or independent ethics governance bodies, as in the UK. According to the Human Genetics Commission in the UK, protections of personal genetic information are considered with four underlying principles in mind; *consent*, as "genetic information about a person should generally not be obtained, held or communicated without that person's free and informed consent", *privacy*, as "a person should not be obliged to disclose information about his or her genetic characteristics", *confidentiality*, as "genetic information should generally be treated as being of a confidential nature" and *non-*

[108] For an early example see the Mannvernd association for the promotion of ethical standards in medical research, scientific research and in the biotechnology industry, which was set up by a sector of Iceland's research community, including the Icelandic Medical Association, just after the bill for the Icelandic Health Sector Databases was first made public [Mannvernd website]. Also, see [Wellcome Trust, Report on the Workshop on Human Biological Sample Collections 1999, especially pp.3-4], an early UK report on the impact of the industrial development of human genetic databases.

[109] For a good analysis see [Godard et al. 2002]

discrimination, as "no person shall be unfairly discriminated against on the basis of his or her genetic characteristics".[110]

In the following chapters, I discuss some of the existing mechanisms that the law provides in this context and explain how novel concerns relating to groups challenge these legal mechanisms. These include issues of presumed consent, group consent, privacy, group-based discrimination, management of benefit sharing initiatives, collective property, and return of research materials, among others. The laws that apply in this area are often complex and contradictory. The majority of the issues that affect groups are not being addressed in a coherent manner across jurisdictions, a fact which does not help to sustain a uniform legal structure for population genetic databases research across Europe.[111] I argue that new regulatory models need to be based on a critical understanding of current practices and their limitations, an analysis of the law and consistent normative principles for the sustainable governance of genetic research databases. A clear articulation of the role and impact of groups in research is long overdue. This thesis examines the extent to which existing regulations fall short of protecting group interests in this context, before proposing new solutions.

---

[110] [HGC 2002] [HGC 2000] These raise a number of ethical and social issues e.g. on types of consent to the use of data, and to the secondary unanticipated use of previously collected data, security and anonymisation, access to data and genetic discrimination risks, control of ownership and sharing of benefits from the development of new products. Different interested parties have called for legal safeguards and concerns about the optimal balance between public and commercial interests [POST, The UK Biobank 2002]. A detailed discussion on specific protections is made in later chapters.

[111] [Kaye et al. 2004, 15-33] [Kaye 2001] [Gibbons 2007]

III. Disease and patient advocacy groups

I noted earlier that groups in this context can be groups of people who share a particular genetic characteristic or disease, including personally affected persons but also persons perceived to be affected by disease and their families. These are families with members suffering from rare genetic diseases who may also have organised themselves into a patient organisation or a disease advocacy group. There exist many advocacy groups organised around specific diseases who co-ordinate their activities and form coalitions with patient organisations.[112]

These alliances promote research on particular diseases of their interest, often by attempting to pair basic genetic science with epidemiological and clinical studies while actively encouraging participation of affected individuals and their families, networking with other volunteer groups, fund-raising, and lobbying for legislation. Their strength lies in their ability to organise large cohorts of patients willing to participate in research and, where feasible, build data registers or tissue banks as research resources. They aim to accelerate research and help develop genetic tests and therapies that could translate research into products to services. They often engage in close collaborative relationships with researchers and they facilitate research by motivating potential patient families to participate in research, and by providing access to, and assisting, affected families, by increasing trust in participation and credibility to researchers, and by reducing the costs of research recruitment. An additional policy advantage of advocacy mobilisation is their commitment to promoting public confidence towards the capacity of research to map

[112] For example, PXE International, the Canavan Foundation, the Tay-Sachs and Allied Diseases Association, the Cystic Fibrosis (CF) Foundation and many others. For an elaborate update on patient organisations in genetic diseases see [Terry et al 2007]; for further comparative insights, see [Mayrhofer 2008]

disease and help develop therapies. The variety of their strategies is discussed in detail in chapter four.

A. On the road to true research partnerships?

Problems arise in advocates' collaborations with the research establishment, especially in respect of commercialisation of developed research. As the drive to map the genetic basis of disease has undeniable commercial aspects, problems occur particularly when research institutions or researchers seek patents on genetic sequences or on the diagnostic tests they develop from joint work. One then wonders, what is the exact nature of the relationships between these groups and researchers and how could the dynamics between participants and researchers get redefined today to address these concerns?

Different experts call the relationship between advocates and researchers a 'partnership' but, as far as the law goes, the question remains open as to whether it is a true partnership or not. For example, in a notable controversy in the mid-1990s,[113] the Canavan patient families sued a researcher – with whom they had an arrangement and they had assisted in various ways – and the Miami University Hospital over the patenting of a genetic test developed for the rare Canavan disease. They felt that even though they had assisted substantially in the discovery of the gene, the researcher and the University intended to profit commercially from the test without taking their contribution into account. They also thought it inappropriate that they would have to pay for testing since the research was developed with their assistance.[114] I discuss the merits of this case in detail in chapter four, together with other advocacy agreements. As the courts have denied acknowledging property interests to the sources of tissue

[113] [*Greenberg v. Miami Children Hospital* 2003]
[114] [Gorner 2000]

material, either individuals or groups, a key issue which stems from these cases is the extent to which groups *can* have a say in the use of potential future commercial applications of research to which they have contributed materially.[115] The analysis reserved for chapter four, details the strategies which group advocates employ to develop resources and advance research that would not have been possible otherwise – not within the realms of university research, because of the costs involved, and neither in the realm of venture capitalists, as the market is not big enough to making up for the investment risk taken.[116]

These groups arguably play a *gatekeeping* role in making decisions about which researchers can gain access to affected families, working with other volunteer groups, fund-raising and seeking to influence legislation. Their role is crucial in promoting research on rare diseases and in fostering alliances. Despite the fact that these organisations have developed new and influential strategies in the last few decades, there is still a long way to go. Their study offers a genuine opportunity to understand the complexity of interests involved, especially with regard to issues of power and control – for example, what resources a group can have or who can directly benefit from research and its products.

IV. Indigenous / Cultural groups

A. Projects studying human diversity

In the history of modern research, there have been at least two key instances where major initiatives sought to establish large-scale projects to sample human genomic diversity. These projects target 'representative' populations in several parts of the

[115] [Anderlik & Rothstein 2004] [Oberdorfer 2004] [Rao 2007]

globe to study patterns of genetic variation that can be used in research[117]. The Human Genome Diversity Project faced fierce opposition and institutional hurdles in the early 1990s. The more recent International HapMap Project has been recruiting populations since 2004, with the view to create a vast research resource for researchers worldwide. These projects raise a number of key and controversial questions for the development of group protections in research.

1. Human Genome Diversity Project (HGDP)

In 1991, geneticists and evolutionary biologists in the US proposed a project to map human genetic diversity worldwide. Their aim was to collect samples from populations considered to be "broadly representative of the human species" and provide new and larger sets of DNA markers for further research in "human origins, evolution [and] prehistory".[118] The proposal met opposition by many experts and activists and on many merits. Several concerns were expressed to question the kind of information that the project was proposing to collect, preserve and store.[119]

These reactions were topped by ethical concerns about the future use of samples for unknown purposes and most importantly, novel questions as to whose consent would have to be secured. Should – and could – project populations have consent rights as groups, apart from as individual research participants?[120] In addition, worry was palpable that the project could be misinterpreted as supportive of genetic differences between groups.[121] This worry was heightened by concerns that the project was a

---

[116] [Merz et al. 2002]
[117] [Cavalli-Sforza et al. 1991] [IHMC 2004, 470]
[118] [Greely 2001a, 222] [Cavalli-Sforza et al. 1991]
[119] [Reardon 2005]
[120] [Greely 2001a, 222]
[121] [Greely 2001a, 222]

naïve, if not racist, undertaking,[122] but experts have argued since that it would be historically inaccurate, and morally insensitive, to understand the Diversity Project as an extension of older racist practices by labelling it the product of 'white scientists wielding the power of science to objectify and exploit marginalised groups'.[123]

Furthermore, representatives of indigenous populations and various activists reacted to the project as a new form of biopiracy. Their response was triggered by concerns that 'western' pharmaceutical and biotechnology companies would exploit project information for commercial profit.[124] They worried that collected samples would be used as information to the benefit of others, not the populations themselves. They interpreted the researchers' project proposal as if to them, indigenous existence did not seem to have any particular value.[125] This opposition was fuelled further by the unfortunate use of language used in the HGDP proposal referring to indigenous groups as "rapidly disappearing populations". This vocabulary was perceived to be marginalising and disrespectful to native sacred values;[126] it further denoted lack of interest on the part of researchers and funding bodies to assist these populations in their isolated and poor living conditions, treating them instead as science or museum specimens.

Importantly, in the eyes of HGDP critics, there was little indication that the diseases to be studied or the treatments likely to be developed from the project would *benefit* indigenous groups from who samples would be taken. Indigenous supporters saw the

---

[122] [Guerrero 2003, 173] [Lock 1999, 83] and [Reardon 2001, 357] who states that the project leaders included some of biology's most respected, socially conscious scientists, who had devoted significant energy over many decades to fighting racism and promoting human rights.

[123] As [Reardon 2005, 2-4] comments in her PhD monograph on the project; for a critical view on scientific practices surrounding the HGDP, see [Marks 2005, 38-39]

[124] [Cunningham 1998] [Declaration of Indigenous Peoples of Western Hemisphere 1996] [Mataatua Declaration 1993] [Reardon 2001]

[125] [Lock 1997b] [Mead 1996]

[126] [Foster 1999, 343]

proposal as an attempt to access native human genetic resources, without dedicating infrastructure, material support or other efforts to help native groups deal with the social, economic and health disparities that burdened and disadvantaged them.[127] In the midst of mixed media coverage and press reaction, the project failed to attract substantial funding from the US National Institutes of Health and the US Department of Energy who had been the two main funding support sources of the Human Genome Project in the past decade.[128]

This brief account of the project serves as an introduction to at least two kinds of debates in the context of group research; i) the possibility of group representation and group consent in research, and ii) the question of entitlement to benefits. The HGDP is used as a case study in two following chapters that deal with consent and property claims because it raised multiple issues, and still affects indigenous attitudes towards research participation today.

2. International Haplotype Mapping Project (HapMap)

The controversies about the Human Genome Diversity Project raised sensitivity on the ethics and legal ramifications of large-scale projects among scholars, who subsequently sought to take these into consideration in the International Haplotype Mapping Project.[129] HapMap researchers seek to determine common patterns of

---

[127] [Amani & Coombe 2005] [Liloqula 1996] [Mead 1996] – For further discussion on the politics and ethics surrounding the HGDP see chapter four.

[128] The Human Genome Project (HGP) must *not* be confused with Human Genetic Diversity Project (HGDP). The HGP was a $3 billion effort jointly funded in the US by the National Institutes of Health and the Department of Energy; its goal was to map and sequence the entire human genome. The major rationale for this project was to provide information to assist the decoding and better understanding of genetic disorders, and eventually, to produce gene-targeted therapeutic interventions for them [HGP website] [NHGRI website]. HGDP, as just discussed, was merely concerned with tracing human populations and their evolutionary history, with the primary aim to understand human evolution [Cavalli-Sforza et al, 1991]

[129] [Clayton 2005, 125] [IHMC 2004, 467] [Rotimi et al. 2007]

DNA sequence variation in the human genome and facilitate future studies on human genetic variation, health and disease. The project involves the sampling of large populations with imprecise boundaries,[130] selected to create a resource that can be "used in populations throughout the world […] not to 'define' particular populations or to study population relatedness".[131]

Scholars have raised questions about the adequacy of HapMap sampling and selection strategies, as these relate to issues of group representation, participation and consent, but also possible discrimination, as well as distribution of benefits that might accrue for the populations involved.[132] The project announced that a process of community engagement and public consultation would give the opportunity for scholarly and public input on how the populations from which the samples were collected would be named.[133] Critics discuss that project efforts to become more 'inclusive' left many of those who were asked to take up these participatory roles disgruntled.[134] A great difficulty for critics is the definition of who are "the people" sampled, in what ways they can be engaged in the project, whether they have clear wishes, who speaks for them, whether they can exist as "organised" publics.[135]

---

[130] The project working groups recommended that the HapMap be developed, at least initially, with samples from populations with African, Asian and European ancestry. HapMap is currently studying 270 DNA samples from four populations: 30 trios (two parents and an adult child) from the Yoruba people of Ibadan, Nigeria; 45 unrelated Japanese in the Tokyo area; 45 unrelated Han Chinese in Beijing; and 30 trios from Utah population residents (United States) with ancestry from northern and western Europe. Japanese and Han Chinese samples are both being included because of the interest of funding agencies in Japan and China to use samples from their own majority populations [IHMC 2004, 470]

[131] [IHMC 2004, 470]

[132] [Clayton 2006] [Ossorio 2006] [Reardon 2007] [Reardon 2006] [Sleebom-Faulkner 2006]

[133] [IHMC, 2003, 792]

[134] [Reardon 2007, 240] states that a few of the bioethicists and social scientists whom she interviewed even went so far as to state a desire to dissociate themselves from the project.

[135] [Reardon 2007, 240] – Additional issues have also been raised on questions of access to research tools and control of project patents and licenses, as they may affect the costs of future products from genomic variation research [Ballantyne & Nelkin 2007] [Gitter 2007] [Hope 2006]

Ethnographic research on the workings of HapMap is currently under way. It will hopefully provide more empirical evidence on how these questions are being addressed with the sampled communities themselves. At the time of writing, it is not clear how the last sampling phase of the project will proceed. This case raises distinct issues on group definition and representation, which are fundamental in considering the organisation and representation of group participants in research. I discuss the methods of community consultation used by the project in chapter three of this thesis.

B. Patent claims on indigenous cell lines

The opposition debates surrounding HGDP were influenced by controversial practices which caused major opposition from indigenous populations between the late 1980s and early 1990s. During that period, there were at least three occasions, where private US companies sought patent rights on indigenous blood cell lines. Their researchers developed these lines from blood samples that they collected from members of several indigenous tribes in the South Pacific.

US companies filed patent claims in the cases of the Hagahai tribe,[136] the Guaymi woman,[137] and the Solomon Islands population,[138] out of which some were withdrawn and some abandoned. In indigenous supporters' minds, these incidents confirmed that major research institutions and drug companies were interested in the extraction and exploitation of native genes extracted from isolated, rare, homogeneous populations. What is noteworthy in this context for the purposes of this thesis is that the debates on patenting of indigenous cell lines affect significantly the

[136] ['Scientists attacked for "patenting" pacific tribe' 1995] ['US drops patent claim to Hagahai cell line' 1996, 500]
[137] [Friedlaender 1996]
[138] [Liloqula 1996]

ways in which indigenous groups consider issues of consent, commercialisation and distribution of research benefits to this day. I discuss particular aspects of these debates in detail in chapter four of this thesis, in order to assess their extent and impact on current biopolitics of genomic research with groups.

C. Participatory research with American Indian and Alaskan Native (AIAN) tribes

In similar vein, current interest in developing novel communication and consultation protocols for research with groups is dependent on the history and circumstances of native communities who become involved in research. American Indian and Alaskan Native (AIAN) communities are being targeted for research purposes for a number of decades; many of them have become less trustful when considering participation in research than in the past.[139] A brief introduction on their particular economic and cultural histories illuminates their particular context in more detail. This is important because their circumstances affect greatly their ability and willingness to become involved in research. These circumstances include their prior history of perceived exploitation due to bad research practices which continue until today.

1. American Indian and Alaskan Native tribes: a brief overview

Tribal communities are distinctive groups with significant variations in culture, language, and beliefs.[140] Over 1,000 tribal communities exist in North America, each with a unique culture and system of beliefs. Expert authors in the field of Native American studies recognise that there is no single American Indian culture and that it is not appropriate to consider them as a single or homogeneous population.[141] In this thesis, I refer to American Indian and Alaskan Native communities (AIAN)

[139] [Bowekaty 2002] [Sharp & Foster 2002] [Warne 2005]

[140] [Harry & Kanehe 2006] [Riley 2005] [Tallbear 2001] [Tsosie 2007]

altogether as a well-established umbrella term but I keep in mind their distinctiveness and cultural variation.[142]

A number of biological but also socio-economic and cultural factors affect AIAN involvement in research. These include their particular attitudes about treatment, recovery and healing as they affect future health-care interventions and the dissemination of future research findings.[143] For example, some of the southwest American Indian tribes currently suffer some of the highest rates of diabetes in the world. It appears that a strong genetic component regarding predisposition to diabetes and alcoholism may be responsible. However, the genetic basis for these diseases is but one component of a much larger picture of Indian health, which includes socioeconomics, poverty-related lifestyles, access to health-care services, and cultural factors. North American Indian tribes often live under difficult socio-economic conditions, having the lowest per capita income and the lowest educational attainment in the country.[144] Experts argue that it is important to understand the significant influences on diabetes predisposition among American Indians but that this understanding of the genetic components of diseases affecting AIAN communities should be examined in a larger context of socio-economic patterns, such as access to healthy food, adaptation to changes in physical environment, access

---

[141] [Tallbear 2001]

[142] *Ibid*.

[143] [Harry & Kanehe 2006] [McGregor 2007] [Schanche Hodge 2000]

[144] The Indian Health Service, the primary agency responsible for providing health-care services to AIAN communities, is severely under-funded. HIS was established in 1955 under legislation that created a responsibility of the federal government to provide health care and other social services to native peoples in exchange for land and natural resources. Approximately 65% of NAI (North American Indian) population has a high school education as compared with 75% of the non-Indian population. Approximately 32% of NAI population lives at or below the federal poverty level as compared with 13% of the non-Indian population; see also [Warne 2005, 191] for an outline of their income and educational disparities.

to effective health-care interventions; this view helps to build a comprehensive strategic plan to reduce health disparities among them.[145]

On the background of such disparities, the possibility of participation of AIAN communities in health-related, genetic and genomic research faces a significant barrier: a *trust* deficit. While working with AIAN communities, cultural anthropologists report that "a large proportion of researchers have been dishonest and unscrupulous when working among American Indian and Alaskan Native communities".[146] A key illustration of an alleged misuse is the case of the lawsuit that the Havasupai tribe filed in Arizona, in 2004.

2. Research (with) the Havasupai: a pending legal case

In this case, a native tribe has sued researchers for the unauthorised use of blood samples that researchers collected from the tribe for diabetes research. The Havasupai tribe and 52 individual tribe members filed two lawsuits in Arizona, in 2004. They alleged lack of consent, fraud, breach of fiduciary duty and negligence among others.[147] They claimed that researchers of Arizona State University and the

---

[145] [Bowekaty 2002, 145] [Warne 2005, 191] – For example, in Arizona, prior to the 1930s, local tribes lived on a healthy diet dependant on farming, hunting and gathering that required regular physical activity. With the completion of river dams in the area in the 1930s, many native communities became dependant on federal government commodity food programmes instead, consisting of foods high in refined sugar, white bread, lard, canned meat, peanut butter and cheese among others, paired by lower physical activity levels. As a result, by the 1970s, some of these tribes had among the highest incidence and prevalence of diabetes in the world, whereas prior to 1930, there was only one documented case of diabetes.

[146] [Bowekaty 2002, 145] [Sharp & Foster 2002, 165] [Warne 2005, 191]

[147] [*Havasupai Tribe et al. v. Arizona State University* 2005] and [*Tilousi v. Arizona State University* 2005] respectively – They listed six causes of action: breach of fiduciary duty and lack of informed consent (including not having appropriate procedures for vulnerable subjects such as children, people with mental illness, and people whose main language was the tribal language); fraud and misrepresentation - fraudulent concealment; intentional or negligent infliction of emotional distress;

University of Arizona collected blood samples from them to research diabetes, but that they undertook additional unauthorised research on those samples for the purposes of research on schizophrenia, inbreeding, and population migration.[148]

The Havasupai are a tribe of about 650 members, 450 of whom live in an isolated village near the Grand Canyon.[149] For the purposes of scientific research, the tribe is seen as an isolated restricted gene pool in which certain genetic diseases are at higher incidence than in a general urban population. The Havasupai have one of the highest incidences of type 2 diabetes in the world.[150] They agreed to participate in research on diabetes but they would have not agreed to take part in research on schizophrenia, migration or inbreeding that the researchers pursued unbeknownst to them; they would deem these inappropriate, potentially stigmatising and disrespectful, as they attack their core beliefs.[151]

In the lawsuits, the Havasupai asked for damages of $50 million and $10 million respectively but their claims were rejected by the Maricopa County Superior Court for lack of specificity on how they were harmed and what justified the damages.[152] The court did not find any breach of consent, fraud, or fiduciary duty and did not address further the issue of the return of samples to the tribe, which they alleged.[153] The tribe filed an appeal for the purposes of which the two lawsuits were consolidated; in 2008, the Arizona Court of Appeals reversed the judgment of the

---

conversion; violation of civil rights; and negligence, gross negligence and negligence per se. For a brief commentary on the legal issues involved see [Andrews 2004, 10-11]

[148] [Dalton 2004]

[149] [Sorenson 2007]

[150] ['Havasupai suits involving blood research moved' 2005] ['Lawsuit over Havasupai blood moved to state court' 2005]

[151] [Collom 2007] and see also [Hart & Sobraske 2003]

[152] [Collom 2007] [Sorenson 2007]

[153] ['Tribal suit over blood samples dismissed' 2007]

lower court and instructed it to go on with the proceedings.[154] At the time of writing, it is not known what the outcome of the new judgment will be.

The pending Havasupai legal case may offer a unique opportunity to place under scrutiny regulatory frameworks and scientific practices in order to clarify the duties of researchers, the scope of consent and the need for groups to spell out limitations on the use of biological material for research before collection. As science and technology expand the possible uses for tissue samples related data, the need for ways to guarantee such limitations becomes paramount, as evidenced in this pending case.

Furthermore, this case raises unique issues of personal privacy of tribe members, and the cultural and religious privacy of the tribe, in as much as their samples were used for research which conflicts with their own religious beliefs about their history, ancestry or origin.[155] These issues alone are worth considering in a separate thesis altogether. It is also important to note that The Havasupai case is not the only one where tribe members sought to have samples returned to them (this was another of their claims) but they are the only one to have gone to court. In the history of US and Canadian scientific practice, there are many instances where indigenous tribes have been trying to reclaim blood samples in vain or with decades of delay; such were the case of Nuu-Chah-Nulth in British Columbia, and the case of the Yanomami in South America, who are still waiting. [156]

---

[154] [*Havasupai Tribe v. Arizona Board of Regents* 2007] The Court of Appeals did not agree that "a notice of claim alleging general damages fails… if it does not describe physical manifestations of emotional distress suffered by the [tribe members]"; see also [Rubin 2008] and [Kiefer 2008]

[155] [Rubin 2008]

[156] [Dickenson 2007] [Harry & Kanehe 2006] [Fischer 2004] [Miller 2005] [Schmidt 2001] – I thank Prof. Jon Marks for introducing me to some of these cases and for his insightful remarks on the issues raised.

V. Ethnic / Racial groups

Groups are also involved in research for the study of the prevalence of genetic disease among them, often defined on the basis of common ancestry or ethnicity. Even though there is epidemiological evidence that particular diseases are strongly associated with social factors, such as poverty, lack of education and health disparities, persistent attempts exist to pursue scientific studies of particular diseases through links to genetics of ethnicity or race.

Examples of these can be found in research with Ashkenazi Jewish populations, who have participated in research for the study of different types of cancer or Tay-Sachs disease; and African American populations where hypertension, prostate cancer, and sickle-cell anaemia are highly prevalent. When scientifically accurate, this research is aimed to help with the prevention, diagnosis and treatment of group members (e.g. breast cancer in Ashkenazi women). At the same time, such research has been criticised as leading to a problematic fit between social and biological characteristics with adverse implications for group members, for example, in the form of discrimination or other bias. This is an issue that is difficult to quantify as the connection between group members is often an ethnic identity that is socially constructed and defined by religious, cultural or political status.[157] It is worth considering a few examples below.

A. Ashkenazi Jews

A lot of clinical information is known about mutations that are highly prevalent among Ashkenazi Jewish populations. For example, in the US, Ashkenazi Jews have

[157] [Brunger 2003] [Dolgin 2001]

long been involved with genetic studies and researchers still find them relatively convenient to study. Main reasons for their availability have been that Ashkenazi Jews are identifiable as a genetically linked group and they tend to keep good genealogical records. These make it is much easier to track the presence of a particular mutation, its frequency and links to the development of disease than in undocumented populations.[158]

Another factor may be that genetic screening for Tay Sachs in Ashkenazi communities is often accompanied by the benefits that corresponding genetic testing can bring.[159] It would be fair to speculate that Ashkenazi populations are involved in research both out of awareness of potential medical benefits to themselves as well as commitment to the public good – for their communities and beyond. Their case is interesting in considering the multiplicity of motivations of collectives who engage in research.

There are also possible downsides to such willing participation that has resulted in a growing list of disease mutations linked to Ashkenazi, including Tay Sachs, Gaucher's disease and mutations associated with colon, ovarian and breast cancer.[160] It has been argued that the accumulation of research findings on a particular ethnic population could cause perceptions that these populations are unusually susceptible to disease and encourage practices that could lead to discrimination and stigmatisation. As social stigmatisation is a profound issue for Jewish communities

---

[158] [Duster 2003b, 267-269] The author discusses genetic testing and genetic screening for members of social groups with strong endogamous traditions, such as ethnic/racial groups who generally are at higher risk of pairing recessive genes and passing on genetic diseases through generations.

[159] [Lehrman 1997, 322]

[160] For a few examples [Edelson 1997] [Press et al. 1998] [Richards et al. 1998] [Zhang et al. 2004] and [Laken et al. 1997] where geneticists reported a genetic mutation in one of about 17 Ashkenazi Jews – those of Eastern European descent – that seemed to double the risk of colon cancer. The research team quoted the mutation as the most common cancer gene found so far within a particular population.

in particular, experts have cautioned scientists to be aware of social and ethical aspects of research participation and the ways in which anti-semitic notions of the past may reappear in the interpretation of genetic research results today.[161]

For example, concerns about the potential misuse of research results surfaced in the US in 1997 among several Jewish religious leaders. They were alarmed by the number of research project aimed to identify high patterns of specific genetic mutations in Ashkenazi Jewish populations. They expressed official concerns that this level of research attention could nurture perceptions that Ashkenazi Jewish people are unusually susceptible to disease, and could lead to stigmatisation both *outside* and *within* the Jewish community.[162] They called for the US National Human Genome Research Institute to develop guidelines for genetic research on Ashkenazi Jews.[163] They stated that they would prefer genetic research on the Ashkenazi population "to be abandoned altogether",[164] which shows that they were prepared to mobilise their members to prevent participation in further research. They were further concerned that these particular populations may become targeted as a new market for genetic tests for colon, ovarian or breast cancer – as was the case of genetic tests developed for BRCA 1 and BRCA2 alleles.[165]

---

[161] [Lehrman 1997, 322] quotes a Jewish religious leader concerned that "…anyone with a Jewish sounding last name could face discrimination in insurance…" and see also [Birenbaum Carmeli 204]

[162] [Ashkenazi signals are timely 1997, 315]

[163] [Lehrman 1997, 322]

[164] *Ibid.*

[165] It is useful to offer some background on this issue: in June 2005, the European Patent Office (EPO) narrowed the scope of the US-based Myriad Genetics patent (EP 785216) on the *BRCA2* gene following opposition proceedings against it. The patent now covers the use of a particular nucleic acid carrying a mutation of the BRCA 2-gene associated with a predisposition to breast cancer in Ashkenazi Jewish women, as opposed to covering all possible research and diagnostic tools involving the gene [EPO press release 2005]. According to [Abbott 2005] and [Marshall 2005], European patients would be asked whether they are Ashkenazi; if so, they would have to pay the same high royalties for *BRCA2* testing as US patients (the US Patent Office has granted broad patents for *BRCA1* and *BRCA2*). Ashkenazi women with the mutation frequently develop breast cancer and a simple routine genetic test identifies those at risk. Israeli, French and Belgian geneticists expressed fears that

A number of questions then arise in that calls for specific legislation have been voiced to address issues of group discrimination. An issue for the law is to consider whether such protections can be developed for groups, what would their scope be and how they could be implemented alongside individual protections. In discussing models for the protection of personal information, experts call for the design of new protections to reform provisions on consent and ethical research oversight but also on privacy and anti-discrimination issues as raised by groups.[166] In later parts of this chapter, I explain that this thesis will focus on core protections for consent, continuous research oversight and negotiation of risks and benefits, which to some extent will anticipate issues of discrimination. I further suggest that issues of privacy and discrimination for groups will have to be examined as part of separate, subsequent work.

B. BiDil: a drug for African Americans only?

A closely related issue on how considerations of ethnicity, combined with reliance on biological accounts of ethnicity as race can get involved in attempts to construct a population as a group is the case of the drug BiDil, in the US. In June 2005, the FDA approved BiDil as the first drug approved to target congestive heart failure for African Americans as a specific ethnic group.[167] NitroMed, the medium-sized

---

women of Ashkenazi Jewish descent might not be able to get tested in countries that would not pay for the licenses required for testing. They described this as an unacceptable situation tantamount to discrimination, in that "there is something fundamentally wrong if one ethnic group can be singled out by patenting [ESHG press release 2005] [Marschall 2005] ['Slimmed down breast cancer gene patent upheld' 2005] ['Discrimination fears over breast cancer test' 2005]l see also [Dalpé et al. 2003] and [Kahn 2005]; for more recent discussions see [Gibbon 2007] [Parthasarathy 2007] [Taussig 2007]

[166] For example, experts argue that current individually-based paradigms become problematic when "some genetic diseases appear only or primarily in certain ethnic groups, such as Ashkenazi Jews, raising questions not only of an individual's privacy but also of the *group's privacy*" [Regan 2000]

[167] [Wadman 2005]

pharmaceutical company that helped bring the drug to the market had previously secured a patent for the use of BiDil as a drug to treat congestive heart failure in African Americans only, in October 2002. The approval of BiDil by FDA was greeted with enthusiasm by both the Association of Black Cardiologists and the drugs industry,[168] but caused great controversy among US law, ethics, social sciences and science experts.

These experts cautioned that the decision to approve the drug as an 'ethnic' drug was based on flawed scientific interpretation of trial results which claimed differential drug response by race. This interpretation seemed oblivious to the significance of considerable literature on the causes of racial disparities in health and health care.[169] They were highly critical that the use of 'race' to gain commercial advantage was not an appropriate way towards eliminating racial and ethnic disparities in health care.[170]

The controversy surrounding the approval of BiDil focused on the peculiar way in which references to 'race' were used to bring the drug to the market, and the implications of developing ethnic/race-specific drugs for tailored drug markets.[171] The debate about BiDil offers a new way to reflect on the consequences of endorsing erroneous biological models for categorising populations (on the basis of race); such endorsement elevates biological differences in medication response to an important cause of health disparities, without evidence. The drug's approval for specific groups

---

[168] *Ibid.*

[169] [Bibbins-Domingo & Fernandez 2007]

[170] [Kahn & Sankar 2005] [McCain2005]

[171] Further concerns were expressed that the FDA approval of BiDil only for African Americans "would give the federal government's stamp of approval to using race, in effect, as a genetic category". Critics stressed that race is not genetic and that, once we sanction such talk, "we are only a short step far from new forms of discrimination and talk about different races as inferior and superior, [an] issue which should not be taken lightly, given the troubled histories and echoes of racial oppression both in US and Europe in the last century" [Kahn 2004, 5]

implied a differential drug response that had not been rigorously tested.[172] Furthermore, by approving the drug for a specific ethnic/racial group, the US Food and Drug Administration created incentives for pursuing trials in less diverse patient populations, which could lead to a diversion of resources away from studies for better therapeutics.[173]

In the pursuit of segmented markets for commercial pharmacogenomic drugs, ethnic populations may become a new category of research targets for future therapies. This case is of interest in that it exemplifies how market priorities can affect not only the interests of ethnic groups in general,[174] but also the contestation of their classification as populations with distinct roles in research.

C. The Tuskegee study

The opposition to the marketing of BiDil as an exclusive drug for African Americans also partly on vast sociological and economic research dedicated to the history of health disparities in the US. In this history, the impact of an infamous study conducted in the 1970s, in the US, has been paramount. For this reason, I consider it important to make a brief reference to the Tuskegee study; it is frequently referenced by literature concerned with the balance between the public interest in research and the rights of participants in research as well as with sociological accounts on the willingness – or lack thereof – of particular populations, such as African Americans or Native American Indians, to participate in research.

---

[172] For further discussion please see key articles by [Bibbins-Domingo & Fernandez 2007] [Kahn 2004] [Kahn & Sankar 2005] and also see a comprehensive review by [Daar & Singer 2005]

[173] [Bibbins-Domingo & Fernandez 2007]

[174] NitroMed subsequently shut down its effort to market and sell BiDil [Armstrong 2008]

Tuskegee was the site of infamous syphilis experiments on black males when the US Public Health Service studied the racial effects on how the disease damages black people, in contrast to whites.[175] The study was halted in 1972 as following national press attention on the grim fact that between 1932 and 1972, approximately 600 African American men in Alabama had unwittingly served as research subjects in that study.[176] The project caused a scandal that shook US public and experts; generations of poor African American men without resources and with few alternatives were betrayed in believing that they had found hope, by being offered free medical care by the United States Public Health Service that co-ordinated the study. In 1997, the US President Clinton issued a public apology for the study, "remember[ing] the hundreds of men used in research without their knowledge and consent" and ensured that such a project can never be allowed to happen again. [177] He called for strengthening researchers' bioethics training and broadening understanding of research-related ethical issues to help assure people that their rights and dignity is respected as new drugs, treatments and therapies are tested and used.

This attempt aimed to encourage involvement of ethnic and minority communities in research and health care but the legacy of the Tuskegee syphilis experiments continues in the US today, as, nearly 30 years after the scandal, biomedical research studies get very low levels of participation by African Americans.[178] The impact of the study has done very little to promote research on common diseases which are highly prevalent among African Americans or to help narrow disparities between blacks and whites.[179] It has contributed to historical and political narratives of

[175] [Jones 1992] [Duster 2003a]

[176] [Jones & Reverby 2000]

[177] ['Apology for Study Done in Tuskegee' 1997]

[178] See [Erickson 2003, 983] [White 2000] who also discuss that numbers of African American organ donors remain low.

[179] [Duster 2003a, 39-59] discusses conditions for genetic screening of target populations

research racialisation that may take the US very long time to overcome, if ever. They remain highly pertinent today as they continue to influence current involvement of particular groups in research.

VI. Family

As mentioned already, genetic research targets populations with high frequencies of certain genetic disorders such as sickle cell disorders in Afro-Caribbean communities, or Tay-Sachs disease, in Jewish communities. Such research can also extend to populations in which a particular disease is unusually common or rare. Some of these populations share particular close cultural ties and patterns; they have their own approaches, knowledge, beliefs and practices, outside mainstream culture, as is the case of the Amish communities.[180] The study of these populations offers valuable insights on how risk is perceived and also how it is managed at collective level. In this context, 'family' can be defined in several ways. It can be understood as the traditional, core consanguineal relationship between parent and child or siblings; biological families necessarily share genetic variations as each child receives half their genome from her mother and half from their father. But family is also the relationship with one's blood relatives and extended family, and includes spouses and future offspring. So, the notion of 'family' as it is discussed in this chapter can include closely-knit communities, and large extended families. One of these is the case of the Amish communities.

[180] [Richards 1997]

A. Amish communities

The Amish are a classic example of ethnic and cultural group who consistently contributes to genetic studies.[181] They have large, extended families. Information on their ancestry is well known and available.[182] Genealogical records can trace their ancestry back to about thirty European progenitors. In addition to information on ancestry, medical and hospital records with demographic details are also available.[183]

The Amish are located within a small geographic location. Individuals who leave the community tend to remain in the immediate area. They are considered to be both genetically and culturally homogeneous, thereby reducing the variables that can complicate genetic studies.[184] In addition, cultural taboos essentially eliminate alcohol or drug abuse, a fact which is important for the study of affective disorders, since the symptoms of these disorders can be masked by alcohol or drug use.

Individuals within this community have very well-defined roles; close interactions between members mean that behavior which falls outside the norm is easily detectable. Because they are very concerned about health, in particular about mental illness such as bipolar disorder, the Amish have been very cooperative with researchers who seek to understand the basis for these disorders.[185] Their involvement in such research is particularly important also because other groups often hesitate or refuse to participate in research linked to the study of mental illnesses, out of fear of stigmatisation.[186]

---

[181] [McKusick 2000]
[182] [Krull 2004]
[183] *Ibid.*
[184] *Ibid.*
[185] [Krull 2004]
[186] As in the case of Native American Indians or African Americans [Greely 1997] [Warne 2005, 191]

The ways in which these communities organise themselves are interesting for the purposes of this thesis as they have been rather successful in managing themselves and in participating in research continuously, with beneficial results for the progress of research and themselves. They provide examples of successful community-building and coordination that can be used in the discussion of group consultation processes. Another example of successful management of community health needs, preparedness and expectations that lends useful insights in community organisation strategies is the case of haemoglobinopathies screening in Cyprus, mentioned directly below.

B. Genetic screening programmes for haemoglobinopathies

Even though this example is not drawn from the context of research but rather from the field of genetic disease prevention management, I consider its discussion important in showing that even though this model goes against individually-based ethically norms, it yields great results through careful coordination and collective management. These genetic screening programmes are preventative measures for public health purposes with tremendous impact on reproductive decision-making and family life choices.

1. Thalassaemia prevention in Cyprus

In Cyprus, populations are highly predisposed to a major haemoglobinopathy called beta-thalassaemia. Sickle cell disease and thalassaemia are autosomal recessive diseases that cause significant ill-health in areas where relatively large populations of African, Afro-Caribbean, Mediterranean, Indian or Pakistani origin live. For example, health technology assessment reports on strategies for the management and prevention of sickle cell disease and thalassaemia in the UK highlight the need for

implementation of antenatal and neonatal screening and the encouragement of preconception carrier testing for these major haemoglobinopathies.

Current steps to implement comprehensive national policies for their prevention need resources that create multiple barriers to the implementation of national screening programmes for sickle cell disease and thalassaemia.[187] The Cyprus Thalassaemia Screening Programme (TSP) represents an interesting example of genetic disease prevention. TSP has dealt successfully with the prevention of thalassaemias, a type of chronic inherited anaemias with significant morbidity and mortality in Cyprus.[188] This case is of interest as a particularly successful example of *managing genetic risk at a collective level* that can provide valuable insights for group self-management, in various ways. As I will not make extensive reference to later parts of thesis, I believe that it is important to present the merits of this model in this section.

High morbidity and mortality thalassaemia rates in Cyprus in the 1960's led to the use of a system of blood transfusions so as to mobilise the Cypriot population to donate blood. Arguably, these attempts enabled an atmosphere of "national solidarity".[189] Parallel to these developments, the significant financial costs of a drug that was introduced to help with treatment led to severe resource allocation problems for treating other diseases.

---

[187] For example, [Streetly 2000] discusses strategies and resources for cost-effective management of sickle cell disease and thalassaemia screening; see also [Davis 2000] and [Zeuner 1999] according to whom, the public health importance of the issue is "now unquestioned"' in the UK, with the establishment of the NHS Sickle Cell & Thalassaemia Screening Programme [NHS Executive 1999] in the late 1990s. The programme aims to determine in which populations screening using haematological tests should be selective or universal, and establish a linked newborn screening programme for sickle cell disorders and an antenatal screening programme for sickle cell and thalassaemia in UK. See also [Chadwick et al. 1998]

[188] The morbidity and mortality rates amount to the highest density of inheritable genetic diseases world-wide [Modell & Petrou 1989, 114]

[189] [Prainsack 2006]

By the 1970s, the excessive financial and social burden for thalassaemia patient families played a major role in the implementation of a genetic screening and testing programme for the general population in Cyprus. The World Health Organisation (WHO) helped introduce a comprehensive programme including opportunities for public education, premarital carrier population screening, genetic counselling for carrier couples and prenatal genetic testing. As a result, an increasing number of Cypriots resorted to preventive genetic testing. In (Greek) Southern Cyprus, premarital carrier testing in governmental laboratories is now practically mandatory through the requirement of a premarital certificate by the Cypriot Church, as part of an attempt to enhance awareness among people opting for a religious wedding. Citizens of (Turkish) Northern Cyprus are legally required to present a screening certificate for haemoglobinopathy before marriage. Initially financed through donations, the costs of the screening programme were covered by public funds. The church helped support the programme since premarital genetic testing would help reduce the previously high abortion rates. [190]

The programme has been a success. The number of annual prenatal genetic diagnosis cases remains relatively constant and the number of abortions for thalassaemia is low. The implementation of the programme faced no significance resistance from within Cypriot society; on the contrary, acceptance of the programme within the populations is very high.[191] As a result, the annual rate of newborns with thalassaemia is virtually zero and the number of living patients has been stable over the past three decades.[192] Yet criticisms of this programme are voiced from scholars abroad against the quasi-coercive nature of the programme or its implicit acceptance of abortion.[193] Yet, as a strategy for the collective management of genetic risk across

[190] [Hoedemaekers & ten Have 1998]

[191] [Angastiniotis et al. 1986] [Hadjiminas 1994]

[192] [Cao et al. 2002]

[193] [Chadwick et al. 1998] [Hoedemaekers & ten Have 1998]

an entire population, this model has built useful insights among experts in dealing with collective risks. Arguably, it could provide a basis for developing novel models in the management of group research risks and harms.[194]

C. Genetic database research and family recruitment

A recent area of research is the development of genetic database projects which recruit families. Family member recruitment is central in their collection strategy and overall success. Concerns about establishing appropriate conditions for recruitment and for understanding family members' motivations to participate are pervasive in this context. I will discuss two types of recent cases in this area, one in Scotland, UK, and one in Iceland – the latter being linked to debates about the ISHD, discussed earlier in this chapter.

1. Family-recruiting databases: Generation Scotland

An example of a UK-based research project targeting families for the purposes of research in common complex diseases affecting Scottish people is the Generation Scotland: the Scottish Family Health Study.[195] Family-targeted databases are not entirely new and there has been a number of smaller-scale projects such as the Avon Longitudinal Study of Parents and Children (ALSPAC) or Oxagen, operating small disease-based biobanks in the UK since the early nineties.[196]

Generation Scotland is a national partnership between the Scottish University Medical Schools, Biomedical Research Institutes, the NHS in Scotland and the people of Scotland to help evaluate the healthcare and economic implications of the

[194] [Weijer et al 1999] [McGregor 2007]
[195] [Generation Scotland website]
[196] [Tutton & Corrigan 2004]

use of genetics in healthcare. The project focuses on understanding diseases that burden the Scottish population, such as cancer, heart disease, stroke and mental health. The first phase of the project aimed to recruit individuals from different regions of Scotland. It is doing so in order to build control cohorts that are representative of Scotland's populations and to help create a knowledge-base that will be valuable to current and future studies. The principal aim of the main component of the project, the Scottish Family Health Study, is to recruit 50,000 family members over 5 years, aged between 35 and 55, to help build a large, family-based, cohort study.

Particular issues are involved in the management of such a study, as specific issues of consultation, representation and consent of family member and their families. Different ways are being devised on how to successfully recruit family members – an example being to make arrangements with a family member to contact others, or to agree with a person separate from the family to contact the others, so that the family members do not know who has a particular condition or who has given their name as contact. Further concerns are raised about potential social stigmatisation outcomes, in the case that a person – or one's relatives – who take part in the study is already affected by a genetic condition.

Additional concerns exist about the legitimacy of purpose and uses of collected samples – also in the context of the wider debate on the legitimacy of large-scale databases for research with future unanticipated purposes, as mentioned earlier. Further challenges arise in mapping the motivations and expectations of family members, relevant patient groups as well as the general public towards such endeavours. To top these, particular concerns exist among scholars on how to avoid coercion as people's motivation to participate might be affected by factors such as whether disease exists within the family – in such cases, family members might feel more likely to participate in the research as they would feel they have more to gain from future benefits from the research. These raise novel ethical questions about the

extent to which family members may be vulnerable in potentially overvaluing anticipated benefits. Hence new practices, careful management and monitoring are required and need to be developed.

Concerns also arise about security and privacy safeguards against third-party access – such as insurance or pharmaceutical companies – to protect families as a whole. Moreover, the fact that many illnesses run in families but some also run in particular ethnic groups – as people from the same ethnic group may share genes and often follow similar lifestyles for cultural reasons – has been noted by SFHS researchers. They have repeatedly stressed that the participation of members from ethnic minority groups and the mix of genetic factors with lifestyles in the Scottish Family Health Study is encouraged and welcomed as potentially valuable to the project.[197]

2. Data protection of family members: Icelandic Health Sector Database

A relatively recent case that helps exemplify further possible challenges within a family *milieu* in research with human genetic databases is the case of Ragnhildur Guðmundsdóttir [RG ever since], in Iceland. In 2003, the Icelandic Supreme Court set a precedent for any Icelander wishing to prevent the medical records of their deceased parents to be entered into the Health Sector Database – as it stood then; [198] arguably, since the judgement declared the database as unconstitutional in its form at the time, the same precedent extends to any such database where the opt-out system applies. The Icelandic Supreme Court gave legal standing to RG by ruling that information about her could be inferred from the medical records of her father. In doing so, the Icelandic Supreme Court interpreted 'personal data' as defined in part

[197] [Haddow et al. 2005] [Laurie & Gibson 2003]

[198] [*Ragnhildur Guðmundsdótiir v. The State of Iceland* 2003]

by reference to one's blood relationship with another person; this fact has implications for the privacy rights of RG and her blood relatives.[199]

The wider interpretation of the Court of the meaning of 'personal data' under Directive 95/46/EC matches emerging interest among scholars towards broadening the scope of data privacy protection so as to include family members as secondary subjects. [200] This interpretation takes account of the impact of personal data on the rest of the family, but it is beset with problems. As Gertz squarely argues,[201] a possible consequence of the ruling in connection with access rights to one's personal data could be that blood relatives would be in a position to demand access to each other's medical records, or, rather, relevant parts of those records, as their own. If, according to the ruling, genetic data of blood relatives are supposed to be also one's own, this creates a paradox as to how this could be compatible with data protection law – which prohibits revealing somebody else's sensitive data.[202] Data protection legislation prohibits the disclosure of sensitive data that could reveal the identity of another person. This presents further complications for relationships between children and living parents, because, if parental data are supposed to also be the children's own data, then data protection provisions – as they apply to those data – would provide the children with rights; these could include challenging their parents for not opting out of the database and vice versa, and they raise important novel issues in the regulation of family participation in human genetic databases research.

Furthermore, this case is not helpful in providing guidance as to *where to draw the line* between degrees of relatedness among family members, nor on how close the

---

[199] For an extensive legal commentary of this ruling and its implications [Gertz 2004b, 231] [Gertz 2004a]

[200] [Taylor 2005]

[201] [Gertz 2004a]

[202] *Ibid.*

family connection has to be to grant legal standing.[203] These issues highlight the increasing importance of scholarly realisation that genetic information is *shared*, as discussed in the introductory part of this thesis. This acknowledgment gives rise to new concerns also in combination of the recommendations of the Article 29 Data Protection Working Party as discussed in chapter one.[204]

In seeking to explain the diversity of drivers, motivations, opportunities and difficulties involved in understanding the concept of groups, so far, I have displayed an array of group examples and categories, involved in research for different reasons, in differing ways and degrees. It is not possible to consider all these categories in detail in the confines of this thesis, but it is important to stress their diversity and multiplicity before attempting to draw on possible commonalities and parallels. These can then lead to a more detailed discussion of core issues for group protections. Before doing so, one broad category remains to be considered. This is the reference to 'humanity', drawing on the concept of 'common heritage of mankind' as a notion which encapsulates a common interest in research for all humans.

---

[203] Gertz argues that by focussing on the relation between father and daughter, the Court placed 'personal data' into the domain of kinship or relatedness, and that this removes the ruling from a purely legal setting and places it in the much wider context of both law and anthropology, in [Gertz 2004a]. I would add that, for meaningful and workable ways established for the protection of family members, the limitations of law alone in understanding fully the implications of placing personal data to the domain of kinship should be assessed together with the study of the multilayered cultural meanings of biomedical conceptualisations on genetic inheritance, see [Finkler 2005]

[204] [Article 29 Data Protection Working Party 2004]

VII. Humanity

A. Notion of common heritage and responsibility to future generations

The concept of common heritage favors the conservation and sustainable use of those of the world's resources that are of collective and vital interest to all mankind.[205] It has been argued on this basis that the human genome is of collective and vital interest to mankind, and that, by analogy to other global resources, it should be protected in the interest of future generations.[206] These statements aim to protect the human genome as a "common heritage" for all humanity.

Interest in declaring the human genome as the common heritage of mankind places emphasis on notions of global human rights in the human genome, as rights for all human persons. The concept of the common heritage of mankind is founded in post-Second World War notions of management of resources, developed in international law treaties.[207] As a principle, it is included in the 1997 UNESCO Universal Declaration on the Human Genome and Human Rights, under Article 1:

> "The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the *heritage* of humanity."[208]

---

[205] [Baslar 1997] [Sheremeta & Knoppers 2007, 160]

[206] *Ibid.*

[207] [Lt. Harry 1992, 207-08] and [Tenenbaum 1990, 112] who states that the common heritage of mankind essentially provides that no private interest or country can appropriate designated property and that all states must share in its management and benefits. Tenenbaum also states that the common heritage of mankind is the legal embodiment of the rejection by developing nations of developed countries' attempts to assert property rights over land which should not belong to any country – and that the concept is also an effort of less developed countries to obtain a greater role in the international arena through international law.

[208] Art. 1 [UNESCO Universal Declaration on the Human Genome and Human Rights 1997]

In its preamble, the Declaration proclaims that:

> "…peace must be founded upon the intellectual and moral *solidarity* of mankind…"[209]

International declarations are not binding by law, although they help to encapsulate and reinforce principles that states have difficulties in implementing. By declaring humanistic and universal claims, states acknowledge that these principles, held as true today, are of common concern to all. Arguably, by referring to "solidarity" and "international co-operation" the Declaration aims to add emphasis against controversial appropriation when awarding rights in the human genome. Transplanted in the context of human gene research, the concept lends support to theories of public property and implies that no private property interest should be established on the human genome – also that any of its use should be for some social utility, and that it should be proportionate and limited.[210]

By focusing on 'humanity', the concept further implies that past and future generations are also included in 'the group', that the human genome is an integral part of every person. Scholars have called for the application of common heritage principles in the governance of human research, to establish mechanisms for sharing of global resources, also as instruments for intergenerational justice. For example, notions of benefit sharing discussed in chapter four of this thesis, are based on such calls, namely that, "in the interests of human solidarity, we owe each other a share in

---

[209] [UNESCO Universal Declaration on the Human Genome and Human Rights 1997]

[210] For a comprehensive critique of the principles embodied in CHM, see [Ossorio 2007, 425] – In international law, the common heritage doctrine includes four characteristics: no country can appropriate for itself the territory in question, all states share responsibility for managing the territory, all states share in the benefits from exploitation of the territory or its resources and all countries must use the territory for exclusively peaceful purposes [Sturges 1997, 246]

common goods, such as health".[211] In these proposals, the human genome is considered to be common, equitably and peacefully available to all humanity, and worthy of protection in order to serve the interests of future generations.

Interest in developing conceptual models and legal mechanisms to protect the human genome as a common heritage of mankind has emerged in recent years.[212] The concept is difficult to implement because of the multiplicity of interests, legal and philosophical traditions and social contexts involved in establishing a common justification for sharing.[213] Yet, increasing attempts to develop the conceptual core of this approach have gained the attention of policy makers and have helped momentum for the inclusion of benefit sharing mechanisms in large-scale biobanking projects, and regional initiatives.[214] At the moment, such mechanisms are being considered as additional mechanisms to help alleviate concerns about research commercialisation and distribution of research-related benefits to participants.[215] I discuss aspects of these initiatives in chapter four to assess their merits, also in comparison with mechanisms for 'self-help' benefit sharing as introduced by patient advocacy groups in the US in the last decade.

---

[211] [Knoppers 2000b, 49] discusses fair and equitable ways for distributing benefits from human genome research, also as defined in statements by the [HUGO Ethics Committee 2000]. HUGO comprises a voluntary association of about 57 countries, scientists, social scientists, pure scientists, bench scientists, and clinicians who wish to collaborate internationally in the free exchange of data.

[212] [Kuppuswamy 2008] [Simm 2005]

[213] [Simm 2005a]

[214] [Laurie & Hunter 2004] [Pullman & Latus 2002]

[215] [Simm 2005a] [Simm 2005b] [Sumner 2007] [Winickoff 2008]

VIII. Discussion on group categories

A. What defines a group

It becomes apparent that there exists great diversity and overlaps of interests across groups. This raises significant challenges in their regulation and protection. Scholars in support of the protection of group interests in research highlight that genetics research is, above all else, a "family affair".[216] The definition of what is a family, or rather what is a group has been difficult to quantify. For example, some scholars characterise ethnic groups as "genetically interesting" because of relatedness but describe genetic disease organisations as composed by people who share genetic variations in their families. In contrast, some native groups, in particular, federally recognised tribes are defined as legally sovereign, whereas other native groups are not. The intra-group dynamics of traditional family members are deemed different than those of ethnic groups, disease organisations or native tribes.[217] The discussion of examples in the previous section shows that groups in their diversity can be rather fluid, not only legally but also culturally. Significant questions thus arise as to whether groups can have not only *culturally based* but also *legally recognised* rights to influence and control decisions affecting the entire group. This thesis proposes a new methodology.

In this thesis, proposed group categories are considered on the basis of the following key parameters:

---

[216] [Greely 1997] [Weijer & Emanuel 1999]

[217] Questions as to whether family members could have special legal rights concerning the participation of other family members in research are the focus of a growing international discussion regarding privacy and confidentiality protections, as mentioned earlier.

- the reasons why a particular type of group becomes the *scientific target* of a particular kind of research
- the reasons why members of a particular groups *report themselves* as belonging to a particular group, by drawing on the nature of cultural, historical or political *ties* among them; *self-reported* shared connections among members can have significant impact on intra-group narratives and self-definition, which may not necessarily be of interest to genetic researchers, but become pertinent from the point of view of groups
- the nature of the *risk* that may be become associated with, a particular type of group, as a result of being involved in research
- the extent of the *benefit* that becomes associated or is expected by the participation of a specific type of group in a particular type of research project
- the kind of *resource* that a particular type of group may have invested for realisation of a particular research project[218]

These parameters reflect three further levels of complexity which create additional difficulties in mapping out group research participants in law. These levels are dependant on:

- the nature of *human genomic variation* research in common complex diseases, which requires the confluence of many genes to cause a disease but which may also require interactions between genes and the environment; these facts affect researchers' sampling strategies in designing genomic

[218] An example being a creation of a patient data register or a tissue bank set up by the group, as in the case of disease and advocacy models, discussed in chapter 4.

variation studies to map patterns of disease inheritance in human populations[219]

- the fact that a *variety* of types of research are *commissioned* by different *agents* – either national governments or private commercial corporations but also disease organisations; the different aims of each type of project directly shape the direction of research, management, and strategies of recruitment and distribution of benefits[220]

- the dependence of a successful research project on recruiting particular types of groups, an example being projects where *family recruitment* is paramount,[221] or when the targeted group must be sufficiently homogeneous or genetically rare. This complexity is due to the fact that groups can be either homogeneous,[222] isolated, rare, disappearing, heterogeneous, national, regional, native, ethnic or cultural[223]

- the above complexities create additional challenges for law in defining parameters for protection since the diversity of goals, aims, scope, research design and control immediately affect the *moment in time* when protections are sought

---

[219] [Hinds 2005] presents an analysis of common human genomic variation structure, allele correlation and distribution and the extent to which current advances enable detailed analyses of the structure of human genetic variation on a whole-genome scale.

[220] [Austin et al. 2005, 115]

[221] The implications of identifying who will speak for the group as an 'index' person or as an intermediary are discussed in chapter 3 on consent.

[222] A sufficiently homogeneous group includes any group considered sufficiently homogeneous to provide tissue or blood samples from which information is leading to the eventual identification of a disease-related gene or genes.

[223] [Greely 1997]

- furthermore, the *potential for bias* that can accrue from assigning certain disease-related risks to particular groups, imposes an additional layer of complexity dependant on the cultural, political and historical context of each relevant setting within which research is undertaken and warrants attention[224]

B. Introducing group concerns

Complex issues arise in group research because of a multitude of claims raised about respect for group values, interests and expectations in research. The question arises as to how these can be developed into legitimate concerns and the extent to which legal reform is necessary to guarantee specific protections for groups. I contend that overall, human groups who become involved in research have the following types of concerns about the research process:

- how group members are *recruited* in research (e.g. consent, exploitation, benefit);
- the *consequences* to the group of being involved in research (e.g. privacy, security);
- control over the *direction* of research (e.g. consent v. gift, oversight);
- influencing the ways research *outputs* are used (e.g. intellectual property/ property rights);
- *benefiting* from research outputs by sharing health and/or wealth benefits (e.g. contract, benefit sharing, conditional models);
- the consequences to the group *as a whole* of some members being involved in research (e.g. discrimination, stigmatisation)

[224] [Nelkin 1992]

These concerns can be mapped under a timeline of issues, as these emerge in current scholarly literature as well as legal cases and other types of evidence in the part for groups who become targeted in large-scale research. These concerns are grouped as follows:

Table 2. Group concerns

Concerns	*Protections*
1.Concerns about becoming involved in research	*Consultation / Consent*
	Authority / Representation
	Value of research
2.Concerns about the consequences of being involved in research	*Security*
	Confidentiality
3.Concerns about directing the research in which they are involved	*Consent / Donation*
	Involvement in research
	Feedback
4.Concerns about influencing the ways research outputs are used	*Consent / Potential for commercialisation*
	Ownership or other property
5.Concerns about benefiting from research outputs	*Expectation of return v. Donation*
	Benefit-sharing or other mechanisms
6.Concerns about bias or stigma	*Discrimination to the group as a whole*

This thesis will focus on current claims evidenced in the case of several of the groups examined earlier in this chapter towards *having a say* on the kinds of research they get involved in. In following chapters, case study examples illustrate the particular circumstances within which relevant concerns arise and the ways in which they are dealt with – or not – in current frameworks, and by group themselves. This process

helps to identify the advantages and limitations of current models with the view assess reference points for the development of new models.

Upon clarification of the scope and utility of existing models, the thesis then proposes novel options for legal mechanisms that can help *strengthen* the role of groups in research and establish a better balance in their interaction with researchers. The thesis focuses on key issues of group influence and power in research, under the first, third, fourth and fifth category of concerns featuring in table 2. These are issues of consent, control and resource sharing deemed central in this thesis because: a) they are most contested but least protected as issues affecting groups, and b) it is argued that their critical examination can help develop a new conceptual core upon which further protections can be shaped.

For example, it is now increasingly debated whether the traditional norm of informed consent is sufficient to meet group research needs. The next chapter assesses the limitations and advantages of consent protections for groups, starting with group consent and alternative consultation mechanisms for research recruitment. This work examines persistent practices that allow for groups to be used as a mere recruitment device in research. The chapter on consent clarifies issues of group representation and authority, including issues such as who can speak for the group or how to raise awareness about group needs during the recruitment process.

This thesis thus focuses on issues of empowerment, equity and resource sharing. With these key themes in mind, that the suitability of current altruistic paradigms to regulate the "surrender" of rights over tissue samples for research, as free donations, are critically examined as a core topic of concern.[225] These paradigms ignore

[225] [MRC 2001]

potential interests of participants in what happens to samples given to research or in how participants could exercise some control over what happens to donates samples.

They are also profoundly linked with public perceptions of the changing value of biomedical research, and they have implications for group future cooperation.[226] All the above considerations present major challenges for the recognition of rights to groups. They further tie with concerns over sharing research outcomes and fears of exploitation from increasing commercialisation of research. They include calls for adequate feedback, and increased involvement of groups in controlling the direction and ethical conduct of research.[227]

These are not the only types of claims currently forwarded by groups, as showcased in the previous section. Other areas of concern relate to issues of security, confidentiality and access to data, and fears for adverse discrimination against groups in research. Related interest in group protections has been voiced while seeking to establish ways to respect cultural group identity as part of political, social, and economic self-determination initiatives. These take account of socio-cultural attitudes that shape group members' perceptions about their own membership but also others' perceptions of *groupness*.[228] In the interests of thoroughness and clarity, it is worthwhile to create a comprehensive set of questions as these arise from current literature on group claims and concerns, in the next section.

[226] [Waldby & Mitchell 2006]
[227] [Andrews 2004] [Weijer 1999] [Winickoff 2003]
[228] [Dolgin 2001]

C. Key issues for group protections: a roadmap

Examples of the questions that this thesis examines in detail include issues of group definition, the role of group input and its value for the proposed research, group representation, authority including appropriate ways to establish who can speak for the group, the extent of overall group involvement in the design and direction of research, the distribution of research benefits and outcomes, mechanisms for controlling the use of research outputs and ways to secure an overall *better balance* in group-researcher relationships. The following roadmap provides an overview of emerging issues when considering gaps in the regulation of group-related concerns.

1. Definitions of groups and group membership

(Groups are seen not only as a biological research target but also as a social and cultural collective, or else, as a *biosocial* entity)[229]

- Is the group defined? How? To what end?
- How does one become a member? What does it mean to be a member and what are the consequences of being in the group?
- What is the significance of self-reporting as a group?
- What are the limits and impact of group models comparing groups that are self-defined compared to more disconnected forms of groups shaped by the design protocol of a particular research study itself?

[229] [Hacking 2006]

2. Respect for group identity and culture in diverse socio-cultural contexts

- How may group diversity affect the uniformity of protections, in the light of diverse local, cultural and social perceptions about the value of research, consequences of research participation?
- How can local cultural and social perceptions be incorporated in a legal framework and what are the limitations of law in doing so?

3. The role and limits of consent

- What are the prevailing models of using groups as a research recruitment device and where do they fail to take account of group interests?
- What conditions can secure timely and appropriate group consultation and continuous influence in research design, direction and conduct?

4. Group consent and presumed consent

- Are there legal and ethical measures in place to provide meaningful informed consent, including consultation process with the group prior to research, where necessary?
- Will the research team use samples only for purposes approved by the group?
- Will research samples be destroyed appropriately after a given amount of time, if so required?
- Are there appropriate safeguards for withdrawal of the group from research, at any point of the project?
- What is the desired content of consent, when required? Can this include the potential for commercialisation of the proposed research and outcomes?

5. Group representation and authority structures

- Do different characteristics of groups e.g. culture, locality or representation have an impact on ways of collective participation in research and if so, how?

- More specifically, is the existence of group representatives or authority central to the efficiency of legal protection?
- What are the difficulties in securing representative structures and what are the limitations of viewing groups as having rights in the same way as individual rights in this context?
- What representation is required for meaningful group management and what is the impact of non-conforming members on effective group mobilisation? Can the low degree of group participation in research have an adverse effect on whether a group agrees to participate in a research project?

6. Group involvement in research design, direction, conduct and feedback

- How strong is group involvement at different stages of the research process?
- Is there a requirement to provide feedback to the group about the conduct and results of the research?

7. Protection of privacy and access to information[230]

- Are there sufficient safeguards in place to protect privacy, security and confidentiality of personal information about the group?
- Can group members be recipients of privacy protection as part of the group, if so, how, to what extent and with what implications?

8. Anti-discrimination protections[231]

- Does discrimination against groups in genetic research exist?
- How can group members be protected against discrimination towards the group? What mechanisms can be in place to protect them?

---

[230] These questions will not be considered in detail in this thesis but they form part of questions that relate to the need for group protections in contexts discussed in detail in this work.
[231] *Idem.*

9. Donation and control over samples

- Why would a group participate in research? Do perceptions over the value of the research to the group influence incentives to participate or not?
- How does trust in science and/or scientists affect group members' willingness to participate in research? How do group members' attitudes about the value of research, also seen in diverse socio-cultural settings affect their willingness to participate in research?
- Does altruism work in genomic research? How does the lack of control that the donation model entails affect attitudes about participation in research with future unanticipated uses, where the benefits are not certain?
- Is there a group interest retained in samples that are given to research?
- Does the law protect continuous group interests in samples that are given to research? If not, are there any mechanisms that could grant protection for it?
- What are the limits of law in encouraging group involvement in research design? Can the law make use of empirical evidence, in collaboration with disciplines e.g. social sciences experts?

10. Definition, negotiation and distribution of benefits

(For example, through advocacy, benefit sharing, contracts or model agreements)

- What are the expected benefits to be derived from the research process?
- Will the research result in benefit(s) to the group? Does the group believe that its members will benefit by participating in a research project?
- Should group perceptions over research benefit(s) be taken into account in the research design?
- How does the definition and perception of 'benefit(s)' affect incentives to research participation? If there is a perception that the group will not benefit, this might limit participation in research.

- How can benefit(s) be negotiated and distributed? Are there measures in place to secure the availability and affordability of benefit(s), in light of repeated concerns against the impact of increased commercialisation?
- What is the impact of limited group participation in the distribution of benefits?

11. Other mechanisms for group control and monitoring of research

- Can the group trust that the research team will conduct research in an appropriate manner with respect to issues like ownership of data and samples?
- Who owns the research in which groups participate?
- Can the group own part of the research? Can the group have strong bargaining power if it contributes a research resource e.g. a tissue bank or register to the research?
- Is there an interest in protecting groups from possible exploitation?
- What other guarantees may help the group to remain powerful in negotiating a good bargaining position throughout the research process and its products?
- Can the group be involved in authorship and publication of research results?
- Can the group have joint intellectual property rights with the researchers as to the research results and products?

D. The need for group-researcher partnerships

The above questions do not form an exhaustive list but serve as an extensive roadmap on discuss issues that affect groups. Some of these issues relate to protections that individual research protections address. Nevertheless, there are calls to frame protections for groups differently than individual protections as the only way to devise adequate protections at collective level. This work defends the need to view groups as *partners* in the research process and outcomes; in this, this thesis

argues that the law needs to recognise the *collaborative nature* of the relationships forged between researchers and groups. This recognition is central for research cooperation and long-term participation and for the development of equitable models of protection for groups in research.[232]

In following chapters, I discuss selected case-studies in order to exemplify particular kinds of group concerns about group power and control and I identify the limitations and advantages of current approaches in addressing them. I examine the emergence of successful initiatives and collaborative research practices in particular cases, while looking to assess whether core collaborative features such as representation, financial or social bonds or a networked research resources can help design better models of protection for groups. I discuss a new conceptual model based on *group empowerment* with the view to developing possible parameters on what makes a group strong, and towards achieving a *less unequal* dynamic in the legal protection of group-researcher engagements.

This work outlines how traditional norms are being challenged by existing rules and practices in the research context. The work proposes ways in which the current system can be brought in line with emerging needs and proposes models of reform for better research governance. Consent, privacy, and discrimination have always been the focus of much attention until now. These conventional protections adopt predominantly *passive* views as to the role of research participants in the research process.[233] I contend that adequate protections for groups should allow them to be *partners* in the research process, so as to maximise the effectiveness and value of research and its outcomes. Groups could have an increased role in research agenda

[232] Some scholars argue that groups should be treated as co-researchers, which may be possible in some cases, see discussion in [Winickoff 2003, 187] and compare with advocacy models.

[233] As an example, see [Rao 2000, 433]: "privacy… conceives of the body as a *passive* entity to be protected from physical interference and alteration but not mined, manipulated, or exploited for profit".

setting, research design and benefits, via adoption of mechanisms to ensure adequate communication with researchers, secure provisions for representation of group interests and honest negotiation (in the broadest sense) of benefits and concerns. I argue that p*artnership* models are needed to allow groups to have a *voice* in influencing research so as to define their research-related needs and help them benefit from the outcomes of research.[234] Moreover, a partnership approach will encourage greater understanding amongst researchers about the social, cultural, economic circumstances of particular groups, foster positive perceptions on the value of research, nurture trust, and ultimately promote research engagement in the pursuit of developing drugs and therapies.

In the following parts of this thesis, I defend the view that new models are needed to introduce and maintain *proactive, cooperative* approaches in regulating research participation; these would help shape and stabilise collaborations between group participants, researchers and funding agents. Such models would be in line with emerging paradigms and recent 'self-help' initiatives to protect particular group needs. At the same time these new models need to provide a more systematic way to address group needs in various settings. With these priorities in mind, I propose ways to implement a new principle of 'group empowerment' in the form of conditional research gifts for groups in the final chapter of this thesis.

[234] [Nichols-Hill 2002, 259]

Part II. PROTECTIONS FOR GROUPS IN RESEARCH

Chapter 3

Consent for Groups in Genomic Research

I. Introducing the challenges

As discussed in the previous chapter, the current regulation of biomedical research in genomics presents serious challenges for the legal protection of groups – families, communities, populations – who participate in research. These challenges include:

- concerns on the adequacy of group *representation and consultation*
- appropriate *communication* of research risks and benefits between researchers and group members
- recognition of group claims in *controlling* the design, direction and conduct of research
- *feedback* mechanisms
- *acknowledgement* of group contribution and facilitation
- structures for *distribution* of research-derived benefits to groups

These raise serious legal, ethical and social problems in the regulation of the management and use of human tissue for research purposes.[235] They depend on diverse group affiliations and expectations in varied social, economic, cultural and ethical contexts; they are on the rise because of a lack of regulatory drive to acknowledge group interests and assign group rights during the process. I contend that ongoing ambiguities in the regulation of current research protections inhibit the creation of successful mechanisms to protect group rights, responsibilities and risks.

[235] Genetic information is available not only as information per se in the form of collected data but also in the form of collected human tissue and of bodily substances such as blood, skin, bone, hair and nail samples, that can be stored intact for decades. The capacity for storage and retention of samples and information for long periods of time has been a concern for scholars considering the impact of new genetic technologies on individual choice and control. For examples of early concerns [Deech 1998] [Kinderlerer & Longley 1998] [O'Neill 1998] [Pottage 1998]

Even so, attempts to introduce group-related rights were first made in the mid-1990s when, for example, the Human Genome Diversity Project organisers proposed the idea of group consent. More recent projects – such as the International HapMap – have evolved against a background of continuing debates about the optimal regulation of large-scale research biobanking initiatives[236] and population variation sampling.[237] These large-scale projects allow data linkage analysis of family records and lifestyle for research purposes[238] and can affect individual and collective perceptions of family, ancestry, identity and loyalty.[239] Many have caused

[236] Human gene research banks are evolving rapidly and several projects to link genetic and other personal data are well under way – the list is very long to insert here but for few examples see Iceland, Estonia, Sweden, UK, as introduced in the previous chapter. As a brief reminder, the first database of this kind was created in Iceland in 1998, where deCode Genetics, a private company, created a gene bank of genetic samples collected from Icelanders. The project combined genetic data for individuals with information about their health and lifestyle habits over time to link these data with information from the Icelandic Health Sector Database and from public genealogical records [Greely, 2000, 153]. In the UK, the UK Biobank aims to collect genetic samples from 500,000 volunteers aged 40-69 and link the genetic data to medical information, in order to investigate the effects of genetic and environmental factors in common diseases [UK Biobank website]

[237] As mentioned in the previous chapter, the International HapMap Project started in 2002 with the aim to develop a key resource for researchers to investigate the role of genes and environmental factors in affecting health, disease and response to drugs [Deloukas & Bentley 2004, 88] [International HapMap Project website]

[238] In UK, research with data from health records has been done for years, with little controversy, mainly with disease registers; computerised disease registers, such as cancer registers, designed primarily for the management, detection and prevention of genetic diseases, to improve health welfare services for public health purposes. A few national systems have public health infrastructure that could allow them to conduct research in a much greater scale than before. In a smaller scale, there are thousands of collections of human samples in hospitals and laboratories, which are stored indefinitely and could, in theory, be converted into research databases and linked with other sources of information. If data linkage from genetic databases research becomes a priority for public health research purposes, ethical and legal issues about the acquisition, storage and analysis of such data will become more controversial [Emery & Miller 1976] [Lowrance 2002] [McHale 2004] [Newton & Garner 2002]

[239] In such research, consent is sought for the use of genetic data, tissue samples and the use of genetic information derived from them. The potential risks that this information entails for one's family members and wider circle of relatives confer varying degrees of high sensitivity and call for increased security and scrutiny [Dolgin 2000]

international debates owing to their consent and privacy safeguards being considered insufficient in protecting the interests and rights of research participants.[240]

These international and regional developments raise a number of controversial issues, some of which are generic in both individual and group participation in research, and some of which are *unique* to research involving groups.[241] Existing regulatory attempts to address current concerns tend to focus excessively on *reviewing consent* mechanisms without taking into account other relevant considerations that cannot be covered by consent as a process on its own. In particular, they continue to ignore the significance and complexity that research with groups entails, and do not incorporate group interests in their frameworks. In this chapter, I argue that there exists an important strategic advantage in re-assessing the role, content, purpose and function of the *consent* process that cannot be relied upon in isolation from a comparative and interdisciplinary understanding of group consultation and communication methods and group representation structures. I contend that such a review must include careful study of appropriate means to ensure continuous group influence and better group engagement in the management and use of research.

This chapter discusses early attempts to legalise group consent and its subsequent sister theories on community approval in order to assess the advantages and limitations of these approaches. The research question in this case is whether such protections can indeed achieve their objectives. The following analysis suggests options for reform of the consent process as an attempt to develop mechanisms for the protection of rights and interests of groups in research while, at the same time, respecting those of the researchers, funding bodies and companies involved.

---

[240] [Chadwick & Berg 2001, 318] [Kaye 2001, 528] [Kaye & Martin 2000, 1146] [Lowrance 2001, 1009]

[241] [Committee on Human Genome Diversity 1997] [Greely 2001c]

II. Ubiquitous consent

A. A brief history of consent in genetic research

Traditionally, biomedical research frameworks rely on consent mechanisms to provide protections of the participants. Yet this structure is not without its difficulties. This chapter examines concerns and debates about the adequacy and limitations of consent as the main protection for group participation in research.

Consent is revered as the cornerstone of regulatory protections for ethical participation in biomedical research.[242] In 1947, consent was incorporated as a fundamental principle in international declarations on biomedical research and has been regarded as the core mechanism for ethical recruitment of subjects ever since.[243] Historically, consent safeguards developed in the post-second war world era, primarily as a concerted response against unlawful physical experimentation and to protect individual autonomy against abuse and personal harm.[244]

Under the influence of Beauchamp and Childress, the four fundamental principles of *autonomy*, *beneficence*, *non-maleficence* and *justice* are now often seen as shaping the core of research ethics.[245] These principles govern the interpretation of rights and obligations of individual participants in research[246] by asserting that participants have

[242] [Levine 1999, 143] [Faden & Beauchamp 1986]

[243] For a thorough overview, with analysis of the history of the regulation of medical research in the UK, see [Aziz 1997]

[244] For further reading, see [Annas & Grodin 1992, 121] [Reiser 1994, 499]

[245] [Beauchamp & Childress 2001]

[246] [Baker 1998, 322] [Levine 1986, 125-126]

a right to be treated respectfully and beneficently as self-determining individuals.[247] In the way that they are implemented in current frameworks, consent protections celebrate the *integrity* and *inviolability* of personal autonomy, respect for which is a requirement for ethical research participation.[248]

B. Informational consent

According to the terminology adopted in post-war years, consent provides research "subjects" with a right to be informed of possible adverse effects and to decide and act autonomously upon this knowledge. With consent as the threshold requirement for the use of sensitive personal health information and tissue, individual rights become strong guarantees against unauthorised use and disclosure of data in research. [249]

Current frameworks follow internationally agreed standards to determine requirements for consent. These safeguards embody our culture's reliance on human rights principles established in international documents.[250] In line with these

---

[247] [Beauchamp & Childress 2001]

[248] Onora O'Neill describes the essence of consent in that "… respect for agents and persons requires that nothing be done to them without their consent" [O'Neill 2001, 691]

[249] For a thorough treatise on the foundations of consent on moral and legal theory see [Faden & Beauchamp 1986]; the authors consider autonomous action as a concept based on three conditions: *intentionality*, *understanding* and *non-control*, and call for standards of *competence*, *substantial understanding* and *disclosure* before communicating information to research participants. This last condition of non-control is at the core of concerns raised by groups.

[250] [UN *Universal Declaration on Human Rights* 1948] [*European Convention on Human Rights* 1950] [*Convention on the Elimination of All Forms of Racial Discrimination* 1965] [*International Covenant on Economic, Social and Cultural Rights*, 1966, Art.15] [Council of Europe *Recommendation on Regulations for Automated Medical Databanks* 1981, No. R (81) 1] [Council of Europe *Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data* 1981] [CIOMS, *International Guidelines for Ethical Review of Epidemiological Studies* 1991] [CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* 1993]

principles, consent provisions seek to ensure that potential research subjects understand what they are being asked to volunteer for, the inherent risks, benefits and alternatives.[251] Researchers have an obligation to disclose these as well as the purpose of a study *before* enrolling subjects in research.

The internationally agreed standard for informed consent in biomedical research is defined by the World's Medical Association's Declaration of Helsinki. According to paragraph 22 of which:

> "… in any research on human beings, each potential subject must be *adequately informed* of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's *freely-given informed consent*, preferably in writing. If the consent cannot be obtained in writing, the non written consent must be formally documented and witnessed…"[252] [emphasis added]

[WHO *Declaration on the Promotion of Patients' Rights* 1994] [*EC Directive on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data* (95/46/EC)] [UNESCO *Universal Declaration on the Human Genome and Human Rights* 1997] [Council of Europe *Recommendation on the Protection of Medical Data* (1997, No. R (97) 5)] [WHO *International Guidelines on Ethical Issues in Medical Genetics and Genetic Services* 1997] [Council of Europe *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine* 1997] [World Medical Association *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 1964, revised in 2000]

[251] Consent protections are required both in experimental and therapeutic research although a larger degree of uncertainty applies to experimental research than in therapeutic research where the doctor or researcher aims to benefit the patient or research participant directly. In experimental research, the doctor or researcher is primarily seeking to validate new knowledge from the research, which may or may not benefit the participant directly [Delgado & Leskovac 1986, 67] [Holm 2002, 82] [Orlando 2001, 437]

[252] [World Medical Association, *Declaration of Helsinki*, para 22] – The European Convention on Human Rights and Biomedicine re-affirmed and adopted these standards in 1997, see discussion on

In the UK, key legal and policy documents prescribe requirements for consent before the retrieval and handling of human genetic information and biological material.[253] To use the case of genetic databases research as an example, it is recommended that information should be provided to participants about the nature and purpose of the research, the risks and benefits to participants, what happens with the results, whether feedback would be given, who controls the information and how this information is imparted to the participant.[254]

Furthermore, sufficient information has to be provided and communicated to prospective research participants in so far that is effective and personalised – that participants comprehend the nature of the research project they volunteer for, have the chance to ask questions and get answers so that they can make informed and free choices over it.[255] It is recommended that researchers anticipate and assess future consequences for the participants, provide security, options for withdrawal at any point without adverse consequences, together with opportunities for feedback or absence of it, whichever was the participant's choice.[256]

---

the legal status of the declaration as a statement of professional principles and instrument of self-regulation among members of the medical profession in [Plomer 2007, 3]

[253] [BMA 1999] [GMC 2000] [GMC 2002] [MRC 2001] [MRC 2000a] [UK Information Commissioner 2002] [HGC 2002] [UK *Data Protection Act* 1998] [UK *Human Rights Act* 1998]

[254] [HGC 2002 paras 2.27-2.31] [UK Biobank EGF 2007] [UK House of Lords Select Committee 2001, especially chapters 1 and 7] [WHO European Partnership 2000]; for key comprehensive articles, see [Martin & Kaye 1999] [McHale 2004]

[255] *Ibid.*

[256] *Ibid.*

III. Group affiliation and consent

A. Individual consent and difficulties for groups

Four main difficulties arise for consent at the level of group research:

- limitations of the *traditional individualistic* consent model in so far that it does not include groups as objects of protection;
- the complexity of *group identities and affiliations* that give rise to claims about participation or co-operation in diverse social, cultural, ethical contexts;[257]
- legal, social and ethical dilemmas in *continuous group involvement* in research, problems arising from *future unanticipated uses* of data or samples in research;[258]
- and, more generally, ongoing conceptual and practical problems in the prevailing use of consent as a *disempowering* device, because it prevents participants from maintaining a desired degree of *control* in research[259]

I discuss these four kinds of difficulties in the following parts of this chapter; I assess the limitations of traditional, individualistic consent paradigm for group protections first. Current consent regulations essentially rely on frameworks which were created to protect individual involvement in research. When fundamental principles for medical research ethics were articulated in the late 1940s, there was no anticipation of the consequences that the use of genetic technologies now entails for groups. As

[257] For early legal researchers' calls on the complexities of group-based claims see for example [Greely 2001c, 785] [Weijer et al. 1999, 275] – A detailed analysis of these concerns was made in the previous chapter.

[258] [Kaye 2004] [Kaye 2000]

[259] [Bovenberg 2004] [Haddow et al. 2007] [Laurie 2002] [Winickoff 2007]

interest in recruiting human groups for the purposes of population-based research increases, experts often declare doubts about the adequacy of the individually-focused model of consent as the appropriate mechanism for group protection.[260] International literature now increasingly contends that problems linked to research with groups cannot be resolved simply by relying on this model alone.[261]

Group-targeted research can have mixed social effects; these bring new urgency to the question of how groups are defined. Although often people view themselves as belonging to a single group, most are members of several affiliations, some based on shared heritage, others on race, others on religion and others on gender or other identities.[262] *Social factors and attributes* are involved in defining populations, even within groups that share genetic relatedness. For example, the Old Order Amish, a frequently cited example of mutually beneficial group participation in research for research participants and researchers alike, are not identified solely by the genes they have in common but rather by their shared beliefs and cultural practices.[263]

As discussed in chapter two, research-derived benefits and risks affect the lives of one's blood relatives and other group members both at individual and collective level. Group interests for safeguards against collective *risks* are claims for protection from risks that affect participants *as a whole*; similarly, group interests to ensure collective *benefits* are claims for access to benefits defined broadly, in terms of

---

[260] [Foster & Sharp 2000] [Greely 2001b]

[261] [Clayton 2002] [Greely 2001b] [Greely 1997] [Juengst 2000]

[262] According to Clayton, all groups are defined at least in part by social factors, their history, their activities, their shared beliefs. For research purposes, it may matter a great deal whether a person is of a particular background, even though that person may define herself differently. Which ones of these group identities are most important to the individual may vary over time and the attributions that are most important to the person may not be the most important in the eyes of third parties [Clayton 2002]

[263] The Amish share more alleles than usual as a direct result of their practice of marrying within their own community. As a consequence, they have an unusually high incidence of a number of metabolic disorders. This has made them the target of several genetic research projects [Andreasen 1983, 75]

health, wealth or even profit including health and medical care, contributions to local infrastructure, education and other benefits, to the participants *as a group*. These interests are inherently linked with the needs, values, reservations and expectations of group members.[264] Nevertheless, it is doubtful whether these are currently recognised and adequately regulated through consent mechanisms.

Arguably, the inclusion and recognition of group interests by law can help establish claims in a way that traditional, individual-self consent narratives cannot do. Such recognition would encourage a *holistic view* of persons within groups.[265] It is true that, in several cases, participation in genetic research affects us as individuals but there is an error in not recognising, acknowledging and addressing the collective research risks and benefits which affect us as members of social, ethnic, biological, or geographical groups. In arguing for the development of collective rights, it is important to clarify that these rights should be conceived as *constitutive* at group level. They are rights that protect the interests of persons not merely as individuals as

[264] Clayton [as above] discusses further that the identification of social and cultural factors and shared attributes is not only a tool to *categorise* individuals but also *a means to make generalisations* about these individuals within those categories. See also [Pierik 2004, 528] who discusses problems of essentialism and reductionism in the conceptualisation of cultural groups, the cognitive and social processes of their categorisation, and self-categorisation. Clayton stresses the point that being an identifiable group does not necessarily equate to being disfavored or stigmatized and therefore think that taking part in research is harmful, in spite of historical efforts to "reduce groups to their genes" often used for the purpose of justifying discrimination against them; for a historical analysis of past eugenic practices see also [Kevles 1985]. The concern about reductionism and discrimination is crucial when seeking to acknowledge factors that contribute to group identity formation. Clayton discusses that these issues surfaced again in recent years, when problems arose with the identification of mutations in cancer-predisposing genes, particularly prevalent among Ashkenazi Jews, who share a high number of alleles as a result of founder effects and centuries of living into segregated areas, see also [Struewing et al. 1997, 1401]. The mention of particular BRCA1 and BRCA2 alleles as "Jewish genes" in the media raised concerns among the Jewish community that they would be stigmatised as being especially unhealthy [Stolberg 1998]. Ironically, these particular alleles were discovered *because* members of this group had been willing to participate in research, possibly whilst hoping that new knowledge would lead to better healthcare interventions or perhaps in believing that promoting research was a 'good thing to do'.

such, but *as members of* groups. [266] In being so, they help enhance understandings of *collective autonomy*. For an example characteristically cited from the literature, it is the group's *collective autonomy* that is challenged if researchers can probe for information about the whole group with the informed consent of only a few individuals in the group.[267]

Emerging trends in bioethics and, more recently in law, support these considerations but so far they have led only to limited initiatives.[268] However, closer examination can provide useful ideas and guidance in developing provisions that meet group interests effectively. Overall, existing legal provisions do not match these trends. As an example, current provisions do not offer ways to address how diverse group characteristics such as culture, locality or particular beliefs affect group willingness to participate in research, who can speak for the group, or what structures will help communication with groups.[269] Current legal provisions do not discuss difficulties in identifying group representative and authority figures, nor the representation level required for meaningful group research recruitment and management.[270]

B. Limitations of consent in group research recruitment

There exists ongoing debate as to whether the consent process should be improved, complemented, or replaced by other types of protection so as to accommodate the

---

[265] [Tallbear 2001]

[266] For groups rights as constitutive see [Haksar 1998] [Mitnick 2000, 193] and also, more recently, [Wall 2007] who proposes a theory on collective rights as being necessary for 'collective self-rule', and 'collective self-rule' as being necessary in furthering the autonomy of group members.

[267] [Greely 1997, 1412]

[268] To name but few [Addis 1992] [Brunger 2003] [Davis 2000] [Sharp & Foster 2000] [Underkuffler 2006] [Underkuffler 2007] [Weijer etal 1999]

[269] [Bowekaty 2002, 145] [Schrag 2006]

[270] *Ibid.*

complexity of identities, affiliations, norms and expectations raised in group contexts, as introduced in the previous chapter.[271] This is because there is need to include new parameters in consent processes; for example, there is a need to integratre interdisciplinary expertise on sociological, economic and anthropological issues when seeking to address problems of group recruitment and research involvement, need which has been recognised by experts in many recent projects.[272] The next sections of this chapter focus on particular difficulties in consulting and engaging with populations for the purposes of genomic research; these center on the following requirements for viable research participation: a) group representation; b) group authority; c) group consultation; d) mechanisms for communication with the group and e) feedback to the group.

C. Group consent

Historically, the concept of group consent can be understood as the first elaborate attempt to seek consent from "culturally appropriate authorities" that could speak for groups who were considering getting involved in research. [273] It was first developed in the context of debates surrounding the Human Genome Diversity Project, introduced briefly earlier in chapter two.

1. Consent in the Human Genome Diversity Project

During the development of proposals for the HGDP, law and ethics scholars called for a notion of "group consent" to be established upon realisation that at least some

[271] [Bowekaty 2002] [Clayton 2002] [Foster & Sharp 2000] [Greely 1997] [Weijer 1999]

[272] For example, the integration of an ELSI team in the design of the Generation Scotland project started at very early stages of the project and continues to this day [Haddow et al. 2004] [Laurie & Gibson 2003] – Other examples include the multiple experts employed in the ethico-legal and social teams for HapMap, who collaborated in the publication of reports on ethical and legal aspects of community representation [IHMC 2004, 467-75]

research risks can affect the entire group, not just those members who participate in research.[274] This notion was envisaged as an addition to obtaining consent from individuals. The primary basis of the HGDP group consent proposals was that, by involving members of research populations in the research review process, researchers would be able to identify and minimise collective risks which might otherwise go unnoticed. This idea also gave support to the recognition that participant groups – in this case, Native American and Alaskan tribes – should have the authority to approve or veto research involving their members.[275]

Despite the *prima facie* worth of the approach, the HGDP group consent proposals sparked a debate with many opponents, both on the merits of difficulties in implementing group consent requirements but also on the basis of restricting individual choice to participate in research. The proposals were considered to foster serious negative consequences and undesirable implications, especially if interpreted as falsely defining cultural groups as genetic.[276] Some experts saw these proposals as paternalistic, demeaning and extreme.[277] Due to these complexities, it is worth considering these proposals and the context in which they emerged, more closely.

As it was introduced in chapter two, HGDP was proposed in the US, in 1991, as a worldwide survey of human genetic diversity among the world's peoples. It aimed to collect samples from populations considered to be 'broadly representative' of the human species.[278] Critical questions were raised about the legitimacy of its process

---

[273] [Greely 1997]

[274] [Committee on Human Genetic Diversity 1997] [Greely 1997]

[275] Difficulties about the ways in which appropriate authorities would be identified did not go unnoticed, especially if applying the concept to ethnic groups; in such case, it was proposed that the concept of 'group consent' would be "downgraded to a broad discussion in the local community" [Greely 2001c, 785] but this has been contested since [Davis 2000]

[276] [Juengst 2000] but also critical rebuttal in [Underkuffler 2006]

[277] [Juengst 1998] [Lock 1999, 83] [Reardon 2001]

[278] [Cavalli-Sforza et al. 1991, 490-491] [HGDP Workshop 1992, 1]

early on in the life of the project proposals both in terms of its scientific and practical merits – for example, whether researchers would extract DNA samples and preserve immortal cell lines of populations, the types of information they would collect, use, store and how to what purposes these would be used, which linked these concerns with doubts about its moral and ethical underpinnings. Some critics saw the project as a dangerously immature or even biased initiative that would marginalise and exploit indigenous groups. [279] These series of concerns were also paired by new questions as to *whose consent* it was important to secure, which opened a discussion as to whether participant groups could have rights *as groups*, apart from as individual research participants.[280]

In response to these concerns, the North American Regional Committee of the Diversity Project developed a "Proposed Model Ethical Protocol for Collecting DNA Samples" (henceforth Model Protocol). In the Model Protocol, the Committee emphasised that the real subject of diversity research was ***not*** the individual but ***the group*** and that it was the *entire group which faced potential risks and benefits* as a result of collective research.[281] Following on that stipulation, the Model Protocol promoted the concept of group consent as a requirement that could make the project more widely acceptable, yet empirical evidence to substantiate that claim on the part of groups remains an open question given the lack of native representatives' voices in the debate. [282]

The Committee sought to incorporate further guidance on the ethical values that the project would safeguardand promote, in which they included *respect* for the

---

[279] [Lock 1999, 83] [Reardon 2001, 357]

[280] (US) National Research Council, Committee on Human Genome Diversity, *Evaluating Human Genetic Diversity*, as before.

[281] [NARC Model Protocol 1997, 1443-44] on the rationale of the consent of the group and the notion of collective autonomy, see also [Davis 2000] [Greely 1997]

[282] [Reardon 2005]

participating population's *culture* and adherence to the standards of international human rights.[283]

The HGDP project failed to attract substantial governmental funding support and subsequently floundered – one can't but wonder whether vociferous activist indigenous opposition and mixed media coverage contributed to its demise in any meaningful way – but the concept of group consent was adopted by later projects in various forms supporting the need for communication and consultation between researchers and groups prior to and during research. A contemporary example of a possible successor of the HGSP project is the International HapMap.

2. Community engagement in the HapMap

The importance of considering that research on group groups *affects the entire group* and that some mechanisms for group consultation should be in place was inherited by the International HapMap Project (HapMap), in spite of its difficulties. HapMap was set up in 2002 to create a genomic map to identify haplotypes across the genome.[284]

Haplotypes (haploid genotypes) are sets of single nucleotide polymorhisms (SNPs) associated in ways that help the identification of DNA alleles and other polymorphisms, by determining the genotypes of sequence variants, their frequencies and patterns. They can provide information considered by researchers as valuable in the investigation of genetic causes of common diseases.[285]

---

[283] [NARC Model Protocol 1997]

[284] [IHMC 2003, 789] [IHMC Consortium 2005, 1299] [International HapMap Project website] [NIH HapMap page]

[285] *Ibid.*

The HapMap is led by the US National Institutes of Health (NIH). It involves a collaboration of academic researchers, non-profit research groups and private companies in Canada (Utah), China (Han Chinese, Beijing), Japan (Tokyo), Nigeria (Yoruba, Ibadan), UK and US. Its first stage was to create haplotype maps of genomes of populations of northern and western European ancestry, Japanese and Chinese populations, and Yoruban populations participating in the study; [286] in the second phase, scientists are testing whether the haplotypes they find in those very large populations appear in about ten other populations.[287]

The project team have published the outcomes of their interdisciplinary efforts to show how they planned to anticipate ethical, legal and social issues in science journals.[288] But the complex issues that arise in HapMap about representation and participation remain open according to current critics.[289] These issues include questions as to a) what constitutes appropriate consent, b) who speaks for participant populations and, more importantly, c) who these populations are representative of.[290]

For the purposes of population-sampling strategies in HapMap, a "*population"* has been defined as "a group of people with a common geographical ancestry and therefore a shared history and pattern of geographical migration", whereas a "*community"* has been defined as "a group with a multitude of local units of social organization within a population".[291] Arguably, on the basis of these definitions, many individuals may claim membership of more than one group while some of those who claim a particular group identity do not share the same biological ancestry. This situation makes research with identified "populations" both scientifically and

---

[286] [Couzin 2002, 1391]
[287] *Ibid.*
[288] [IHMC 2004]
[289] [Reardon 2007]
[290] *Ibid.*
[291] [IHMC 2004, 469-471]

ethically complex and raises important questions about the legitimacy of strategies for group representation. [292]

The HapMap team argues that they have integrated ethics in the project, and that their sampling strategy places considerable emphasis on initial community engagement and information transfer.[293] But there are no guarantees that the project is not vulnerable to pitfalls of representation and potential discrimination for the groups involved. For example, there exist no mechanisms to prevent the use of information derived from the project – or from future studies using project findings – so as to exaggerate or downplay differences between groups or other kind of bias.[294]

Interesting efforts have been developed to organise community engagement processes before obtaining consent in HapMap.[295] They aim to give members of local communities in each area where people are being approached to participate, the opportunity to air their views and give input on how samples are collected.[296] A system of community advisory groups (CAGs) has been devised as a point of contact

---

[292] [Reardon 2005]

[293] [IHMC 2004, 470] [Rotimi 2007] and see further below.

[294] Critics also envisage problems with future distribution of benefits that might accrue, as well as control of subsequent patents and their effect on the cost of products to be developed from this research (the research data derived from sampling are put in the public domain) [Ossorio 2006] [Reardon 2005] [Reardon 2007] – The issue of benefits is related to whether appropriate organisational structures exist for the distribution of future benefits to groups: in comparison with HGDP, the Model Protocol discussed questions about "to whom the project would be of benefit" and that *benefits* that might arise from the project "should be *shared*" as "additional" issues. In spite of this nevertheless vague acknowledgement, there remained a *lack of will* to define what those benefits would be for the participating populations and how they might be distributed; this raises additional issues about fairness and control [Amani & Coombe 2005]. In HapMap, information on the consent form states that participants "will not benefit directly from giving a sample" because of the long time nature of the research, and that "research will eventually benefit the health of the people around the world" [International HapMap Project website]

[295] [Hsieh 2004, 402]

[296] [International HapMap Project website]

for community members to receive information on how researchers are using the project or the samples collected from that particular community, for example, by publication of quarterly reports.[297] This system is considered to be promoting long-term 'dialogue' between communities and researchers.[298] The legal status of CAGs, at the time of writing, is unclear. It is suggested that CAGs are set up for each community-participant in the project; that they should include people from each community to make sure that future studies using that community's samples fall within the scope of the study the samples were collected for, or to give suggestions about what kind of research uses that community might consider harmful.[299]

Efforts have also been established to ensure ongoing communication via free periodic newsletters translated into the languages of participating communities and containing general information on the project. Despite these organised attempts to give information on the project, arguably, these efforts fall short of being a genuine "engagement" – in that engagement should be defined as mutual communication, exchange of opinion, cooperative action, and ongoing feedback as part of a collaborative relationship, not as a one-way of supplying information to participant communities.[300] In this light, current communicative HapMap practices arguably fit better the title of unidirectional communication rather than that of meaningful and constructive engagement. More ethnographic work would help to understand further their nature and scope and unpack the social and political prerogatives that underlie them.[301]

---

[297] *Ibid*.

[298] [Singeo 2007, 133] and compare [Strauss 2001, 1940]

[299] [International HapMap Project website]

[300] An interesting example of information dissemination strategies is in the case of recruitment in Japan, where, having met apathy or distrust in some places, the organisers "broadened their plan" by holding "information seminars" in places with groups of people with an interest in medicine and science [Macer 2003]

[301] See also recent commentary by [Reardon 2007] on the use of participatory narratives in such projects as alleged processes of "democratisation" and wishes to investigate their underlying logics and practices further, towards building mechanisms that hold them accountable.

3. Community participatory research theories

Proposals for 'group consent' in HGDP and 'community engagement' in HapMap have not been the only attempts to develop protections for collective consultation of identifiable groups in research. Several participatory models for group approval and review have been proposed since the HGSP debates emerged, as supplemental to individual consent. These vary in context, scale and terminology, from 'community review', to 'community consultation' and 'community dialogue'. They reveal a variety of participatory methods and goals,[302] and seek to introduce *contextualised* and *local* approaches for effective group recruitment. To this date, they have not been incorporated into legal protocols for genetic research but to a very limited extent. It is hoped by some that their emergence, mainly stemming from work of anthropologists, bioethicists, and sociologists in the US and Canada,[303] can lead to their incorporation into legal scholarship about the organisation of research consultation and recruitment practices.

These interdisciplinary theories bear a methodological advantage over their predecessor theory of group consent; they make use of legal, ethical and anthropological research in order to incorporate group-specific perspectives in the design of research.[304] A key element to these approaches is a more refined understanding of the contextual and structural diversity of groups.[305] These theories are useful when seeking to identify elements of group cohesion and structure; they often include the study of group characteristics such as common history, geographical location, shared values, culture and/or lifestyle, and a sense of common identity or responsibility. They help develop ways to define parameters for the

[302] [Foster & Sharp 2000] [Godard et al. 2004] [O'Fallon & Dearry 2002] [Sharp & Foster 2002]
[303] [Bowekaty 2002] [Brunger & Burgess 2005] [Burhansstipanov et al. 2002] [Sharp & Foster 2007]
[304] [Brugge & Missaghian 2006] [Macaulay et al. 1999] [Macaulay et al. 1998]
[305] *Ibid.*

recognition of how group members share their experience, and how they organise themselves into forms of collective action. [306]

These approaches contribute to the quest for tailored community communication and management strategies to help anticipate and ultimately reduce research risks and protect broader group interests at group level.[307] Community consultation and review theories help develop ways to understand the needs of groups such as indigenous peoples, whose cultures are inherently based on collective understandings of identity. They can also be useful for other types of group participation in research, in as much as they help researchers understand particular ethical, political and cultural circumstances and group beliefs. By focussing on 'local' factors, commonalities as well as differences across groups, these interdisciplinary theories offer valuable insight into group beliefs relevant to the control of research knowledge and related ideology on the status of the human body.

A number of successful examples from participatory research with indigenous peoples exist in the form of research ethics guidelines developed to protect native groups in Canada and Australia to ensure effective conduct of research with such groups.[308] These may focus on the emerging tribal models of communication and participation, but I contend that they can also help shape models of governance of research with non-native groups whichi are highly cohesive (e.g. Amish) but also

[306] [Brunger & Burgess 2005] [Kaufert et al. 2004]

[307] [Brunger & Burgess 2005] [Weijer et al. 1999]

[308] [Aboriginal Health Research Ethics Committee of South Australia 1998] [American Indian Law Center 1994] [Australia National Health and Medical Research Council 1991] [Canada Royal Commission on Aboriginal Peoples 1993] [CIHR 2007] [Kahnawake Schools Diabetes Prevention Project 1996] [Medical Research Council of Canada et al., *Tri-Council Policy Statement* 1998] [Menzies School of Health Research 1989]

groups who are less clearly bonded (e.g. ethnic groups) as they allow for flexibility. A few of their advantages are discussed in the next two sections.[309]

4. Communication and engagement

To what extent do participatory interdisciplinary paradigms offer useful suggestions on how to secure meaningful consent in group involvement? What are the necessary conditions to ensure appropriate and timely group consultation in research design, direction and conduct? When and who to speak to? What structures can optimise the representation of group interests? This section discusses different kinds of conditions for communication, understanding and representation of group interests and risks, in order to introduce a basic but flexible model of *engagement* between researchers and group participants.

I argue that effective collaborations between groups and researchers require a shift from traditional practices to an approach which involves:

- improving *communication*
- valuing *respect* and group diversity
- assisting groups in *educating* and *training* their members in research oversight[310] creating opportunities for acknowledgement of group *contributions*
- *consulting* with groups about desired benefits to be derived from research

This approach emphasises the importance of group consultation prior to, and throughout research. This means that the need to communicate and understand the

[309] [Burchansstipanov et al. 2002] *cf.* [Weijer et al. 1999, 275-280]

objectives, intentions and expectations of group members and researchers to the research process must be realised early in that process, in order to build a *trust relationship* between the parties that promotes the transparent representation of their interests.[311]

Obtaining the approval and collaboration of groups at the *outset* of the research process serves several purposes: i) it protects both the group and individual members from research-related harms, to the extent that the consent process as a continuum, gives the group the fullest possible understanding by focusing on its collective implications;[312] ii) it shows recognition and respect for a group's *decision-making structure* by submitting the consent process to the group decision-making process and not just to individual decision-making;[313] iii) it shows respect *for the group*, and not just for members as individuals.[314]

For example, social researchers have found – through interviews and research with focus groups – that the moral authority of the group is undermined when 'outsiders' ask individuals to make decisions about community issues, even when those individuals are recognised moral or political group leaders. If members voice their

---

[310] [Burhansstipanov et al. 2002, 154-155]

[311] [Fisher & Ball 2003] [Freeman 1998] [Norton & Manson 1996] [Schrag 2006]

[312] Anthropologists note that many concepts of risk and harm are culturally defined. Research participants might perceive risks that are unique to the social organisations of their community that outsiders might not be able to anticipate. These risks take several forms, such as risks to shared identities (e.g. traditional conceptions of religion and tribal identities), risks to social equilibria (e.g. disruption of family relationships because of the communication of genetic information about certain family members) and risks to cultural and moral authority (e.g. the undermining of group authority when outsiders try to bypass a group's established decision-making procedures by relying exclusively on individual consent, especially in indigenous contexts, where processes of collective decision-making are required prior to any individual choice) [Burhansstipanov et al. 2002, 154-155] [Foster 1997, 277] [Foster & Sharp 2000, 94-95]

[313] [Foster & Sharp 2000, 94-95] [Foster 1997, 277]

[314] [Foster 1997, 277]

individual opinions before a community consensus is achieved, this can challenge the authority of that consensus as well as the collective decision-making process that produced it, by threatening "the very heart of what keeps localised communities together: namely, the obligations of their members to one another and to collective social structures".[315]

These considerations are relevant and useful both in the context of claims made by indigenous groups regarding group identity and authority but also in the case of protections for members of cultural groups that are less cohesively defined such as ethnic groups. They allow for a more refined understanding of circumstances that give rise to articulations of respect for members' affiliation within particular cultural or ethnic groups.[316]

5. Possible criteria for group-based consent

Since many groups are morally or culturally distinct and are often self-defined, at an ontological level what is defined by a group could be the following:[317]

- a group of persons with *shared culture and, shared way of life and a set geographical location* (e.g. any geographically isolated tribe)
- a group of persons with the above characteristics, except in that they are not isolated (e.g. Native American groups who live in various places but share the same representative council)

---

[315] *Ibid.*

[316] [Schrag 2006]

[317] For the following considerations, I turn to a very useful typology originally proposed by [Schrag 2006] with a few modifications, also in line with a recent theory by [Wall 2007] who, similarly, proposes four criteria of: a) shared history and culture, b) common interests, c) some degree of political authority, and d) shared territory as the key set of variables to help define the degree of cohesion of a particular group.

- a group of persons *who share a common cultural heritage and some kind of collective decision-making structures* that enable them to discuss and decide whether or not to give consent as a group (e.g. a family group or patient advocacy group)[318]
- a group of persons *who at least share some common cultural heritage, but do not have procedures for making group decisions* (e.g. African Americans involved in the testing for sickle cell anaemia; women of Ashkenazi descent who share the BRCA mutation)[319]

These can be classified in the following table which is proposed to show how these criteria can be linked to the justification of various degrees of group consent approaches tailored to examples of groups. They can be used as variables that reflect the degree of cohesion of particular group types.

PTO

[318] As is for example, the interesting case of the association of the descendants of the liaison between Sally Hemmings and Thomas Jefferson, where researchers were interested in determining if DNA testing would establish the link with the couple; the members of the association, the Thomas Woodson Family Association, originally organised to maintain contact and plan family reunions, were not clear whether their organisation could function as a collective decision-making body to give consent for research on the group. Commentators discuss that the association has gradually evolved into such a representative body [Davis 2004] [Schrag 2006] [Williams 2005]

[319] [Abbott 2005, 12]

Table 3. Justification for group-based consent: criteria

Group	Shared culture	Shared way of life	Shared geography	Shared decision-making	Justification
Amish families	**X**	**X**	**X**	**X**	strongest
Native Americans in reservations	**X**	**X**	**X**	**X**	strongest
Native Americans in cities	X	X	-	**X**	limited
Patient advocacy group	(X)	X	-	**X**	strong
Family	X	X	(X)	**X**	strong
African Americans	X	-	-	-	weakest
Ashkenazi women	X	-	-	-	weakest

The above categories allow two broad kinds of collective decision-making:

- If one means by a group simply a collection of individuals who have in common only the quality that the researcher wishes to investigate, group consent amounts to a *limited* kind of group consent since each individual independently agrees to the research without any group discussion or collective decision[320]

[320] [Kaufert et al. 2004, 22] [Schrag 2006]

- If, on the other hand, consent is given as a result of a collective decision-making process, then the result is *full* (group) consent in the sense that it is either a majority or unanimous consent, or in any case, the result of a decision according to the representation rules of the group

According to the four criteria – discussed above – of geographical location, shared way of life, common decision-making process, and some common culture, a few further categorisations are possible. Group-based consent can involve group members with a shared cultural background, a shared way of life, common decision-making procedures and shared geographical location; the *shared geographical location* increases the likelihood that members will have direct face-to-face discussions with each other before consent is given.

Group-based consent can also involve group members with a shared cultural background, *shared way of life*, and a common decision-making procedure. The sense of community is tighter in that members of the group not only have a shared cultural heritage but also a shared way of life, and deliberations about participation in a research project may well take into account its impact on their way of life.

Group-based consent can also mean consent of group members who share not only a *common culture but also a common decision-making process*. One might argue that the feature of a common decision-making mechanism is a necessary condition of group consent; it may not necessarily involve unanimous consent but it can involve a majority rule or a decision taken by a representative body.

Group-based consent might be the unanimous consent of group members who just share *some common culture*. Presumably they might make their decisions based not only on the basis of individual self interest but also on the impact that they perceive

this might have on their cultural group (e.g. in the case of sickle cell testing on African Americans or breast cancer screening for Ashkenazi women).[321]

The *strongest* level of justification would come from the consent of a group whose members live together in the same geographical location, share the same cultural beliefs, the same lifestyle and have a decision-making process that leads to a unanimous decision to cooperate in research which directly affects only members of the group.[322] If all members are in the same geographical area, they are most likely to engage in full decision-making discussion with others in the group, and are most likely to consider the impact of the research on their community, cultural life and beliefs. This level of interaction arguably maximises the likelihood of consent of group members; its strength is derived from the high degree of understanding of the purpose, implications and design of the proposed research.

If the decision is not achieved by unanimous consensus, group majority or by the decision of a representative body, the normative appeal for group-based consent would decrease accordingly. If there is no clear decision-making body within the group, or if there are competing decision-making groups, the issue becomes more difficult; the justification is even weaker if the group shares a common way of life and cultural beliefs, but members are not in a single location, yet they make decisions on the basis of some representative body. The justification is weakest in the case of a group with no common decision-making structure, no shared way of life or common geographical location, but mainly a shared ancestry or cultural affinity.

In tailoring various requirements from literature on community participatory theories with the criteria mentioned above, four possible flexible levels of group consent

---

[321] *Ibid.*

[322] See also [Wall 2007]

strategies were proposed recently, in the form of community dialogue, consultation, approval and partnership.[323] These can be defined in a preliminary way, as:

- community *dialogue*: it includes formal and informal discussions with group members about the proposed research study for example, with the use of focus groups;
- community *consultation*: it is as a more structured way to review the proposed research, enabling representative members to provide their views to an independent research ethics committee;
- community *approval*: it is a formal agreement between researchers and a group, according to which group members or representatives give collective permission for a project on behalf of the group;
- a community *partnership*: it is a model which warrants early and continuous group involvement in the design and review of the research project, to help define project goals, methodology and management

The model of partnership is key for the purposes of this thesis yet overall, these four levels of communication help clarify corresponding levels of collective (group-based) consent processes that could be complementary to individual protections. They can serve as a guide in communicating and assessing particular group needs, for example, for more or less extensive consultation and various group approval mechanisms. This section shows that varying degrees of group cohesion are likely to influence the ways in which communication and representation priorities are viewed by different groups.

The corresponding diversity is indicative of the complexity of group decision-making processes. An interesting theoretical approach with regard to groups in research, considers group research in three ways: a) research *on the group*, in which

[323] [Brugge et al. 2006] [Khanlou & Peters 2005] and especially [Schrag 2006]

participants are not involved except as research subjects; b) *collaborative* research, involving a joint effort by researchers and community c) *research consulting*, in which the researcher is hired by the community[324]. In this thesis, I discuss these notions by progressing from the first type, with mere reliance on consent, to the second in considering participatory models, to the third, in examining contract and property models in details; and back, to propose a reciprocal model of engagement in my last chapter

6. Limitations

Key limitations of group-based approaches rest on: i) identifying who the groups are, as discussed earlier in this section and in the previous chapter; ii) identifying what decision-making structures may be appropriate, iii) risking that mechanisms for group decision-making may impinge on the rights of the individuals involved. These pose a difficult philosophical, social and legal problem in that they require the development of balancing mechanisms, for example, communitarian theories and sovereign rights, to help resolve who can possibly decide on behalf of groups and what the power of individual decision is within those groups. In each of these types of discourse, the balance of relevant rights will vary, for example, on the basis of the level of authority assigned by law to the relevant governing bodies, whether these are bound by public interest clauses, communitarian mantras, or group self-determination rights – which, for example, would allow the application of tribal-specific laws, in the case of indigenous tribe members being bound by the decision of the tribal council.

Furthermore, in the case where a group decided not to participate in a research project but a few members still wanted to do so, there should be ways to prevent this on the basis of binding majority rules, in the interest of certainty and fairness to the

[324] [Burgess & Brunger 2000]

whole.[325] In such hard cases, it is also worth drawing a distinction between group-based – or collective – 'consent' and group-based – or collective – 'acceptability' of the research. In the former, consent by the group's governing body is required for the research to proceed whereas the latter involves meaningful discussions between researchers and members and leaders of the community, and relies on the participation of the broader community.[326] A central problem in group consent is that it is not necessarily true that a political process can provide the same moral authority to a group decision as autonomy does in the case of individual consent. For example, individuals may agree to the group's participation but decline participation themselves, for a variety of reasons; while they may not want to use those reasons to block the group's participation, their individual consent could not be implied from the group consent.[327]

I would like to return to the central point that I am mostly interested in considering in this thesis; even if the models that I examined in this section can facilitate communication and representation of group interest, the question is, to what extent can they help ensure appropriate conduct of research *once consent is given*? How strong can group involvement be at different stages of the research process? Are there any further elements that should be included in the list of criteria for meaningful group consultation or approval apart from considerations of group cohesion? What else is desirable to make the case of groups achieving meaningful engagement, defined as a dynamic, continuous process?

---

[325] The other way around is even more difficult to resolve, as it would seem that, if available, group-based consent would "allow to accept risks on behalf of dissenters", if their individual informed consent was deemed insufficient to protect them from the risks to which they would be exposed to by the participation of other group members to the research [Burgess & Brunger 2000, 125] – This is why authors caution that individual consent "cannot be implied" by group consent [Godard et al. 2003b]

[326] [Burgess & Brunger 2000]

[327] [Godard et al. 2003b]

IV. Group involvement in research oversight and conduct

The sections above examined factors for communication, consultation and representation. Further issues are contested, some of which have already been debated in the context of individual participation in research but they are highly relevant in group research. These are questions of withdrawal from research, destruction of data or samples and mechanisms for feedback given to participants about the conduct and use of research, especially in the case of large-scale research that involves future, unanticipated uses.

1. Withdrawal

The right to *withdraw* was discussed in the UK Biobank 'Ethics and Governance Framework' with a view to ensuring that "participants … have the right to withdraw at any time without having to explain why and without penalty… [as] essential to preserve and demonstrate the voluntary nature of participation".[328] But, if one considers this provision carefully, they would realise that in fact, it does not recognise an active interest in the way the overall project is conducted; it is merely an entitlement to stop being part of the project.[329]

This absence of recognition of power to participants is connected with the issue of one-off consent, discussed further below. Most of the issues raised for groups in this context are similar to problems seen in individual withdrawal provisions. But, there is a major difference, in that the *withdrawal of the group* can have far-reaching consequences for the stability and viability of the project. The aggregate power of

[328] [UK Biobank EGF 2003, section I.B.6] and see [Gertz 2008, 383] who clarifies that the project allows three withdrawal options: 'no further contact', 'no further access' and 'no further use'. For the purposes of this section, I refer to withdrawal covering all options.

[329] [Laurie 2002, 312] [McHale 2004, 85]

group members signing off could have a devastating effect on the fate of a research project, fact which makes the need for transparency and trust in the research even more compelling, at least from a utilitarian point of view!

2. Destruction or Return

Particular issues arise when a group wishes the destruction or return of research samples. For example, in the case of the Havasupai – the Native American Tribe in Arizona who sued University researchers over unauthorised uses of blood samples for research – the tribe felt duped and defrauded because the researchers conducted research on schizophrenia with samples collected from group members for the study of diabetes. In their lawsuit, the tribe claimed *inter alia* the return of samples to them to be buried in their ancestral land – or their destruction, if their return was not possible.[330]

Such interests are not new in native contexts, where disputes to reclaim retained blood samples have been persisting for years. Yet, native group attitudes towards such practices tend to vary, sometimes according to how much contact they may have had with researchers, and also new narratives emerge, for example, about "sacred blood" to be returned to the group – as compared with "contaminated blood" not to be returned but to be destroyed instead.[331]

The main question is whether research samples that groups do not want to see used further in research can be destroyed appropriately and whether consent is a suitable mechanism – or not – to ensure that the samples will be destroyed according to group requirements. Consent, as it stands, is simply not sufficient to protect these interests. As a result, novel ways are being devised by, for example, native scholars to define

[330] [*Tilousi et al. v. Arizona* 2005]
[331] [Rohter 2007]

the nature of relevant interests as cultural and proprietary in the broadest sense, in order to assert a degree of control not available through consent.[332] I examine a few examples of these initiatives in the next chapter. It is important to note that this type of research-related claims – for destruction or return of samples – is not necessarily particular to non-Western contexts. Judging by the furore in the aftermath of the organ retention scandals in the 1990s, in the UK, it is not hard to imagine comparable situations where people may have a similar continuing interest in the body of a family member or their own.[333]

3. Feedback

Another issue that is being widely debated at the moment, especially in biobanking research, is participants' entitlement to feedback. For the purposes of this thesis, it is important to consider its implications for groups, as opposed to the general discussion on its ramifications for individuals.[334] I consider the obligation to feedback as an important aspect of researchers' responsibility to develop opportunities for ongoing engagement with groups.[335]

Different kinds of mechanisms have been proposed so far, as ways to create and maintain continuous communication between groups and researchers. For example,

---

[332] Some of these interests could also be viewed as dignitary, so not necessarily proprietary but this merits separate consideration which may be pursued as part of subsequent work; see also discussion in the Court of Appeals case of the Havasupai Tribe [*Havasupai Tribe v. Arizona Board of Regents* 2008]

[333] For another example, [Lock 1997a] discusses instances of "animism" observed in both western and non-western medical contexts, based on beliefs that 'within all creatures and objects there exists a soul or personality'. Lock provides a very useful commentary on the implications of animism in the case of the alienation of body tissue for research not only on the part of participants but also on the part of researchers and sometimes, even medical practitioners.

[334] For that discussion see [Johnston & Kaye 2004] [McHale 2004] and also [Haddow et al. 2008, 144] who helpfully raise the issue of choice discussed along the issue of DNA feedback, as they call it – whether participants could choose, or had a right to choose to receive it or not.

[335] See also [Winickoff 2007]

in the case of UK Biobank, suggestions have included, among others, the idea of a regular electronic newsletter, a website, a complaints helpline, open days, the option for a participants' panel and opportunities to sit on the oversight body of the project.[336] Some of these proposals echo the practices that are being used in the HapMap, discussed in earlier sections of this chapter.

In the HapMap project, feedback is coordinated by community advisory groups (CAGs) set up as intermediary bodies in charge of communication outputs to participants about the research that is generated from the project. The CAGs are liaisons between the research institutes where the research samples are being stored, and participant groups. Their remit is to keep communities informed of research developments via newsletters and quarterly reports. Each CAG has its own membership and leadership structure, consistent with local cultural norms. They help to facilitate the communication of information about the project, about future uses of the samples, and about genetic variation research and its societal implications more generally.[337] As discussed earlier, their creation is part of the "community engagement" strategy of HapMap planners who have claimed that their engagement efforts are much more than the transfer of information from the researchers to participant groups, in that they involve an "interactive bioethics" process.[338]

This interactive process is worth considering further. Generally, it seeks to communicate information from the project to participants but it is not certain whether this process provides organised opportunities for input the other way round. Further more, the collective implications of feedback are different than in the case of individuals and have not been discussed. The information that is being revealed

---

[336] [Sumner 2007] comments that the UK Biobank Ethics and Governance Council considered that web communications may not be sufficient.

[337] [International HapMap Project website]

[338] As per [Macer & Kent 2004] although the extent to which this interactive process can be guaranteed is open to scrutiny.

raises issues of concern about groups as a whole – as it applies to all members automatically. It has been noted that some researchers are in support of the obligation to feedback in the case where this indicates real health dangers but clear guidelines for its boundaries have not been developed. I contend that, to the extent that such guidelines can be developed both for individuals and for groups, it is advisable that these are designed in consultation with public and group stakeholders, and in consideration of the nature of possible harms from research to these groups.

By revisiting the kinds of emerging claims in modern research with groups, it becomes clear that consent provisions are insufficient to protect continuous group interests in research oversight and conduct. Consent in current frameworks is primarily considered as a safeguard for the *communication of information* to help participants make an informed decision, rather than a means to retain control over samples and research results. So far, I have examined basic criteria that can be used to develop research agreements with groups. I have suggested that partnership models are desirable, in order to communicate group interests and to establish collaborative interactions with researchers. I have proposed new ways in which consent provisions can be complemented to incorporate group interests. I have also assessed that there is an urgent need for developing further protections beyond consent, and that consent is not a panacea for every claim under research.

In seeking to evaluate the overall role of consent in protecting group interests, a few further considerations must be made. Does consent provide sufficient safeguards for participants' claims in influence, oversight or control of research? What further issues should be taken into account while reviewing consent practices in group research? These questions focus on the *scope* of consent. In the next part, I discuss that they are inextricably linked with the *purpose* and *overall function* of consent.

V. Group influence and control in research?

As it was mentioned earlier, apart from the difficulties with consultation, communication and representation, complexities persist with consent viewed as a *merely informational* instrument. These complexities become further entangled due to uncertainty entrenched in the unsufficiency of consent to protect group interests in the use of collected samples and data for *future unanticipated purposes*. For example, relevant group claims are linked to concerns about whether consent should include disclosure of potential *commercialisation* of research. It is argued that unless consent models can guarantee ways for groups to exert continuous influence over the conduct and use of research, they cannot protect these interests alone.

A. Future unanticipated uses and consent

A major ethical problem for research projects of prospective nature – as the case in most genomic banking projects – is how to assure participants' consent when what they are consenting to in terms of future research is not known. Proposals for one-off, broad, and presumed consent options have been forwarded in recent years as a way to bypass difficulties with traditional consent protections that require specific consent.[339] These new broad forms of consent include a cascade of consent options on when consent is given, what it can contain, how it is managed and the extent of protection if offers.

A spectrum of options has been debated in the context of several projects which involve different combinations of recruitment strategies on the basis of two ratios; an

[339] For example, in Iceland, the consent approach that the ISHD database adopted became the focus of major criticisms worldwide. For a discussion of the different options, see key texts by [Annas 2000] [Beskow et al. 2001] [Elger & Caplan 2006] [Wendler & Emanuel 2002] among many others.

opt-in and an opt-out approach.[340] This is due to strategic policy reasons including concerns about the costs of specific consent options, practical difficulties in dedicating resources to tracing and re-contacting participants many years later on with the risk of rates of participation at later stages dropping to unsustainable numbers, but also considerations in favour of extending analogies between rhetorics of donation in the use of biological samples in research, according to which participants stop having control over donated samples at the moment of collection.[341]

There is general debate about whether, in their effort to create viable scientific endeavours, current regulations develop options that are in touch – or not – with the types of research conducted and the risks that can result; also, whether there exist acceptable levels of public trust that match recent regulatory trends for 'lesser' protective frameworks. For example, empirical research reveals that the public generally distinguishes acceptable and unacceptable uses on the basis of who is conducting the research.[342] It also seems that clarification of the 'public good' may need further debate in this context, as large genetic databases are being set up in that name. Similarly, there seems to be a need for developing new ways that can help secure and maintain public input in the governance process.[343]

Many of these criticisms also pertain to problems with individual participation in research. Criticisms are being forwarded against one-off consent approaches primarily due to their lack of full-blown protections as these depart from traditional notions of such protections established post-war, as it was discussed in earlier

---

[340] *Ibid.*

[341] As above and see also [McHale 2004] – An extensive commentary of donation models is made in following chapters.

[342] [Sumner 2007]

[343] For example, in focus groups research in the UK, research participants sought clarification of notions of the "public good", asking *who determines* what falls within the public good and *whether they (as participants) would have any involvement* in that process [Sumner 2007]

parts.[344] Contemporary research rationales for lesser consent support that participants might hardly be facing a personal risk against the backdrop of legislation to guarantee data protection issues, where the point of anonymisation of samples becomes the key that allows samples to no longer be considered as identifiable, and hence posing risks for individuals. This is precisely where the stakes become different between the interests of individuals and the interests of groups, as the anonymity of the individual does *not* imply the anonymity of groups.[345] This applies *par excellence*, in the case of groups who have a small size and therefore are potentially socially identifiable. Current consent protections do not guarantee that samples are not identifiable at collective level. Particular research uses can be problematic to different groups; for example, Ashkenazi Jewish communities are concerned about research that may reveal stereotypical or potentially stigmatising traits; small native tribes have also real concerns about inferred bias because of their size.[346] It is therefore paramount to recognise that some populations can still harmed *as a group* and that consent or data protections options do not suffice to protect them.[347]

Further complications about the adequacy of consent in this context relate to concerns about the *surrender* of interests in any future control over research samples and data and the *disempowerment* that this entails.[348] Critics of consent view one-off consent as a cloaking device which ultimately permits the continuation of practices that do not meet participants' interests. They see it as leading to a formalisation of the relationship between participants and researchers, which ultimately fails to

---

[344] For a critical overview [Greenhough 2007]

[345] See most eloquently [Elger & Caplan 2006, 664]

[346] This is nicely rounded off by [Tsosie 2007, 367]: "… [w]ith small isolated populations such as the Havasupai, individual identification could fairly easily be inferred by a limited amount of information about the person's sample… [a]gain this type of research not only poses risks to individuals but to the group itself… [t[he samples are deidentified from the individual but not necessarily the group…"

[347] See also [Taylor 2007/2008]

[348] [Kaye 2004] [Laurie 2002] [Liddell 2003]

address the complexity of ethical, social and political issues at stake; or else, as a *normalisation* device in the absence of broader visions on research governance.[349]

I argue that current applications of consent fail to make group participants visible, deny groups influence over the conduct and use of research, and ultimately entrench *unequal* – rather than enabling – *relationships* between participants and researchers. I discuss possible ways to redress these inequalities in the following chapters, by focussing on the role and contribution of groups in the research process. The tension between the potential for commercialisation and the use of altruistic rhetoric in current regulatory guidelines for the use of human biological material in research are debated in detail.

In sum, current difficulties with consent can thus be divided in problems with: a) the concept of *group consent* itself, its content and limitations, and b) systemic problems about its purpose, in that consent arguably operates as *disempowerment* because it prevents groups from asserting continuous control over the research process. The latter problem poses questions for the effectiveness of consent as a means to protect group interests. Not only is consent not tailored to facilitate the communication of group needs, but it also allows the perpetuation of current regulatory sympathy for altruistic models that ignore group participants' interests in what happens to research samples and data that they contribute to research.

This analysis is informed by current critiques about the application of consent protections in the individual context, but, as it was discussed in this chapter, it obtains new meaning in the context of groups, precisely because *groups are separate and different to individuals and they have influence that individuals cannot*. Power, or control-based conflicts in group research arise in many cases, for example, about

[349] [Greenhough 2007]

subsequent unauthorised use by researchers of samples collected for purposes other than the ones originally agreed with the group, return of samples to the group, feedback of research information to the group or group review of research findings, as well as the control of the use of large-scale research outcomes that may later become commercially profitable.

B. Commercialisation of research

The widespread acknowledgement of consent as a non-negotiable yet unsatisfactory protection seems to give space to increasingly egalitarian views on the nature and status of researcher and group relationships.[350] Group participants not only expect to have their rights recognised but also seek to be treated as full partners in a relationship of *moral equals*.[351] In the light of such views towards redefining the relationship between researchers and research participants, it can be argued that groups no longer consider their consent to the use of their biological material in biomedical research as fully informed unless potential commercial applications of the material are discussed and disclosed. One then wonders, given that research has increasing and considerable economic and commercial value for some, why should group participants not be provided with information about commercialisation, as this might affect their decision to participate or refrain from participating?[352]

There is resistance among researchers to disclosing commercialisation information out of fear that potential participants will not donate tissue for research or that they will demand some form of compensation or agreement or even that they may become confused by the disclosure of economic and financial interests. But, in the case of

[350] [Merz et al. 2002]

[351] [Carson 1998, 205] [Terry et al. 2007]

[352] [Resnik 2003]

groups, such reservations are not compelling enough to justify failure to disclose this information.

On one hand, empirical sociological research increasingly indicates that people want to be informed of the financial and commercial aspects of biomedical research.[353] Furthermore, many experts now contend that, in the absence of provisions for financial compensation, potential research participants who become aware of the potential commercialisation of biological material may be discouraged from giving biological material to research.[354]

On the other hand, particular groups increasingly mobilise themselves into developing networks and resources, and even private agreements, in attempts to direct and influence the course and outcomes of research, according to their interests. In the following parts, I argue that any delay or reluctance to regulate continuing group interests in the use of research samples and outcomes risks eroding public trust further, with detrimental effects on willingness to participate in research.

C. The contribution of groups in research

In the following parts I argue that the resolution of concerns about commercialisation of research depends on the extent to which the *contribution* of groups in research is acknowledged, in the broadest sense. This is particularly important because, as I

---

[353] [Haddow et al. 2007] [Hadgood, Shickle, Kent 2001] [HGC 2001] [People Science & Policy Ltd 2002] [Resnik 2003] and also compare the discussion in [McHale 2004, 90] in that the court acknowledged patients' discontent towards the pharmaceutical use of their prescribing habits, which had been sold by doctors and pharmacists to pharmaceutical industry agents, as per brief commentary on the *Source Informatics* case [*R v The Department of Health, ex p Source Informatics Ltd* 2000]

[354] [Laurie 2002] discusses public concerns over growing commercialisation practices that have caused decline in public trust and confidence in the research enterprise; see also [Haddow et al. 2007]

discuss later, this contribution can be *constitutive* of groups and it is linked to their value and power in research.

In the past, targeting of populations in isolated areas or developing economies has often given rise to indignation against pharmaceutical research ventures seeking to develop commercially profitable products, without sharing research outcomes, health benefits or profits with peoples who provide the raw materials, and natural resources, in the first place.[355] These "bio-piracy" debates eventually raised awareness for the development of initiatives in the search for local control of group biological material.[356]

More recently, these debates have led to policies and agreements with *cooperative* examples respectful of the motivation of particular groups to participate in research,[357] but also in the quest for developing practical mechanisms for benefit sharing and other strategies for participatory research in developed and developing countries.[358] Many scholars argue in favour of empowering participants to take a more equal role in the partnership that is formed when they participate in research.[359] There exist increasing examples of groups formed to support and protect collective interests in influencing the direction and outcomes of research. I discuss that these initiatives can help shape new agendas for collaborative research and encourage a 'social contract' view of researcher-participant relationships.[360]

---

[355] See [Pottage 1998] and also [Amani & Coombe 2005] [Dickenson 2005] [Dickenson 2004] [Lock 1997a]

[356] [Dutfield & Leverve 2003] [ETC Group 2001] [IPCB 2000] [Posey & Dutfield, 1996]

[357] [Dutfield, 2003] [Schroeder 2007] [Schuklenk & Kleinsmidt 2006]

[358] [Haddow et al. 2007] [Pullman & Latus 2002] [Terry et al. 2007]

[359] [Kent 2006] [Laurie 2002, 309] [Nelkin & Andrews 1999] [Winickoff 2007]

[360] As discussed in following chapters; see also [Kaye 2004, 133] [Terry et al. 2007] among others.

D. Conclusions on consent

This part aimed to explain that consent, on one hand offers an irreplaceable opportunity for *communication and consultation* if supplemented by mechanisms for consultation and engagement with groups, and it can thus have a key informative role, as part of an ongoing collaborative process, if applied in line with group prerogatives; and that on the other hand, consent as it stands, fails to protect group interests in *continuous influence and oversight* of research. It therefore needs to be complemented by further protections – discussed in following chapters.

A few examples from current research indicate that higher degrees of public trust may facilitate participation in large-scale genetics research without major opposition to consent options such as presumed consent.[361] This may mean that different social contexts possibly allow for better acceptance of 'lessened' consent options, and that this depends on differentiated degrees of public trust towards research institutions. This evidence might help develop socially and culturally-tailored approaches and a rethink of consent processes in order to achieve a less problematic co-existence of public health interests with private economical incentives, and healthy levels of trust. But overall, presumed consent options do not help achieve high levels of trust, as empirical evidence from the Icelandic debate shows, unless high levels of trust are already present.[362]

In conclusion, this chapter examined the ways in which consent models do not suffice to protect the interests of group participants in genomic research. Problems with limitations in the application of individualistic notions of consent in group research were identified as problems in consultation, communication, and

[361] [Einsiedel 2003]

[362] [Arnason 2004] [Greenhough 2007]

representation of group interests, concerns about continuous involvement, ethical conduct of research, oversight and feedback, and emerging concerns about future unanticipated research uses, continuous influence and commercialisation. In the next part, I discuss cooperative initiatives which have been developing their own frameworks in order to acknowledge participants' continuing interests in the management and use of research data and samples. These alternative models seek to secure *collaborative mechanisms* in managing research data and samples by which to address concerns in research custodianship, ethical oversight, property articulations and the sharing of benefits. Arguably, as more incidents of perceived inequalities in group-researcher interactions become widely known and more group initiatives to control research appear, concerns will persist that no appropriate mechanisms are in place to safely *empower* group participants to influence the uses of samples and data that groups contribute to research.

Some of these recent models reject the regulatory adoption of the language of altruism in research recruitment, because this language fosters limited acknowledgement of participants' continuous interests in what happens to research samples and how the benefits to be derived from research can be shared. Further debates in this direction highlight the pivotal role of *trust* in fostering social and cultural acceptability of particular research governance models, and the value of public engagement with science and research. Concerns within these debates are inextricably linked with how 'altruism', 'self interest' and 'public good' are articulated in current frameworks. In the following chapters, I discuss the nature of interests that emerge in the protection of 'donation' for research purposes, the reasons why the law should protect such interests and ways in which the law can help provide continuous group influence over samples collected for research purposes.

Examples of models to follow include property models, patient advocacy and benefit sharing models[363] where the advantages of a reciprocal and symmetrical approach in assessing the role of groups in facilitating research will be considered. As part of this discussion, I propose a new conceptual model of *group empowerment* as a novel approach towards developing equitable group research protections.

[363] E.g. [Anderlik 2002] [Andrews 2006] [Merz 2002] [Terry et al. 2007] [Winickoff 2007]

Chapter 4

Finding a Balance? From Free Gift to Property

I. In search of a balance

This chapter examines four legal mechanisms in regulating the use of human biological material for research purposes. It discusses current ambiguities in the UK regulatory endorsement of altruism in research, by drawing on paradoxes that beleaguer the legal status of human biological material and its use in biomedical research. By revealing the limitations of current regulatory endorsement of altruism, this work is in search of a balance between altruism and possible viable models for reciprocal engagement between researchers and participants in the research process.

The chapter examines the strengths and weaknesses of the exclusive application of the donation model in research, problems in the establishment of property rights in the body, advantageous elements of advocacy strategies and conceptual approaches in benefit sharing models, the last two forming part of novel initiatives recently used to promote group interests in research. These models are inspired by group motivations to steer and secure better group oversight in the direction and outputs of research. These models also have particular limitations as regards the degree of *empowerment* that they can help achieve as universal solutions. A close examination of these models provides valuable insights in shaping legal mechanisms for group empowerment, and in developing a better understanding of group structures, values and needs in the modern research context.

Since the mid-1940s when biomedical research protections on humans were formulated, several countries developed research protections, guidelines and legislation in several ways. Yet, when it comes to issues of empowerment, judges and legislators across several jurisdictions tend to shy away from assigning any kind of substantial control to research participants on the conduct or the direction of research. They acknowledge only limited control to individuals, within the scope of what consent protections offer (the latter were discussed in detail in the previous

chapter). It is only very recently that initiatives for group oversight and better control developed successfully (e.g. the PXE advocacy and following examples). The jurisprudential timidity to address participants' claims to better oversight and control can be linked to policy uses of 'altruism' rhetoric in several areas of public health policy related to prospective biomedical research. In this part, I discuss the regulatory situation in the UK both because existing guidance on the use of human biological material for research reflects a regulatory desire to rely exclusively on charitable giving for research as a laudable, 'good thing', but also because, when translated in the legal field, this interpretation leads to paradoxes in urgent need of clarification.

II. Regulatory appeal for altruism

A. Definition of 'altruism'

There is an extensive use of 'altruism' in the regulation of genetic research in the UK which seeks to promote charitable and beneficent dispositions of potential participants towards biomedical research. Throughout this thesis, I understand and refer to altruism as "action in the interests of another or the disposition to act *in the interests of another*".[364] In this chapter in particular, I discuss the use of language employed by current UK guidance on the use of human biological samples in research in order to highlight a persistent and particular *enclosure* of motivations of participants in research. A number of reports were commissioned in the UK since the mid-1990s to address legal and ethical issues in the use of human tissue samples for research purposes. These advisory bodies frame the relation between potential

[364] [Birks 2000, 14]

participants and research as *solely altruistic*, in various ways, and proceed to name the removal of tissue for research purposes as a 'genetic gift'.[365]

For example, in its 1995 report examining the ethical and legal aspects of human tissue, the Nuffield Council of Bioethics proposed that:

> "… The act of providing tissue… clearly indicates what is involved is a *gift*…" [which is] "… *free of all claims*…"[366] (my emphasis)

The report advocated the:

> "... *surrender* of all interests…" in the removed tissue on the part of the person from it was removed[367] (my emphasis)

The report further assumed that the person from whom the tissue is removed does not have:

> "… [not] *the slightest interest in making a claim* to [the donated sample] once it is removed…"[368] (my emphasis)

According to the analysis of the Nuffield report, the 'genetic gift' would have to be considered as:

> "… a *gratuitous voluntary* transfer from the true owner in possession with *no expectation of its return*…"[369] (my emphasis)

---

[365] In the next chapter, I discuss the implications of this definition in more detail. For the purposes of this chapter, it is useful to introduce key concepts such as 'altruism', 'genetic gift' and 'gift relationship' and their connection to current discourses of research participants' disempowerment.

[366] [Nuffield Council of Bioethics1995, 68]

[367] *Ibid.*

[368] *Ibid.*

In their 2001 report, advising on the use of human tissue and biological samples in research, the Medical Research Council Working Group on Human Tissue and Biological Samples reiterated the legal position proposed in the 1995 Nuffield report and explicitly recommended that:

> "… tissue samples donated for research be treated as *gifts* or *donations*…"[370] (my emphasis)

The MRC Working Group further suggested that:

> "… [t]his is preferable from a moral and ethical point of view, as it promotes the "*gift relationship*" between research participants and scientists, and underlines the *altruistic motivation* for participation in research…" [371] (my emphasis)

The term "gift relationship" was originally used in social research studies investigating patterns of exchange in primitive societies.[372] In the UK, in the 1960s, these studies were used by scholars responsible for the elaboration of theories and policies on voluntary blood donation.[373] These policies paved the way for subsequent development of voluntary models for organ donation.[374] I perceive the use of these early discourses about donation (unconditional giving) in the context of genetic research to be misconstrued. The relevant bodies mistakenly conceptualise the transfer of DNA tissue for research as a one-way, altruistic transaction, chiefly with the view to facilitate unproblematic and free supply of biological material for research purposes – and not necessarily to protect emerging interests in the

---

[369] *Ibid.*
[370] [MRC 2001, para 2.2]
[371] *Ibid.*
[372] [Mauss 1990]
[373] [Titmuss 1970]

management and use of human tissue in research.[375] In the next chapter, I discuss controversial aspects and implications of the altruistic misconception in more detail. For the purposes of this chapter, it is useful to introduce key contested notions in current donation models and their connection to property debates.

B. The reinvention of 'genetic solidarity'

Drawing further on the significance of promoting altruism in genetic research, in their 2002 report on *Inside Information*, the UK Human Genetics Commission proposes an interpretation of what they term as 'genetic solidarity':

> "…we all share the same basic human genome, although there are individual variations which distinguish us from other people. Most of our genetic characteristics will be present in others. This sharing of our genetic constitution not only gives rise to *opportunities to help others* but it also highlights our *common interest in the fruits* of medically-based genetic research…"[376]

In their reference to notions of *sharedness* of our genetic constitution, the Commission seeks to emphasise a "special moral relationship".[377] The HGC seems to think that key elements in support of such obligation, within the aim of promoting research, are "opportunities to help others" and a "common interest in the fruits" of research but critical questions remain unanswered, for example, whether there is such a special moral relationship that links us to one another; and, if there is, whether it ought to be reinvented as a unidirectional giving to public (and private) entities for some long-term, intangible common good. Further questions that need to be analysed

---

[374] [Waldby & Mitchell, 2006]

[375] See also [Laurie 2002, 313]

[376] [HGC 2002, 38]

[377] This view was also warmly adopted by the UK Department of Health in their 2003 White Paper on genetics [Department of Health 2003, para 6.26]

further are whether there is such a common interest in the fruits of research that is 'shared by all', and if so, on what grounds and in what terms this interest should be properly defined and understood. Shouldn't this be debated further before any importation into mainstream discussions of how this area can be regulated?

By constructing 'genetic solidarity' in a limited way, the HGC reiterates the interaction between potential "donors" and researchers as essentially a "free-gift relationship" that raises obligations on the part of the former primarily. This is problematic because both the gift metaphor and the genetic solidarity metaphor can be used strategically to *enclose* the research relationship as a positive moral responsibility of potential donors towards the wider public who may possibly benefit,[378] and thereby ignore any broader claims on the part of the "donors" which may *de facto* exist and may have some legitimate basis.

C. Normative assumptions and exclusion

By relying on articulations of 'moral obligations' and 'gift relationships', current advisory guidance frames the transfer of samples solely as a question of altruism. Why is such language used? What is it meant to preserve? Why must one give a tissue sample to research only as a free gift? One can comfortably argue that there is a comfortable social appeal in the use of charitable, 'feel-good' discourses and laudable acts. On a more practical note however, substantial utility considerations are involved in instituting free, gratuitous and therefore unconditional gifts, precisely in order to allow an unhindered and wide scope of possible future uses, without further interference. As it has been rightly pointed out, the invocation of *surrender* or

[378] [Ratto & Beaulieu 2007, 184] [Waldby & Mitchell 2006] – I return to this point at the end of this chapter with a brief critique on definitions of solidarity from a philosophical and economic perspective.

abandonment – briefly mentioned earlier and discussed directly below – strengthens this last claim.[379]

It seems that by appealing to discourses of moral obligations, gift relationships, solidarity and common interests, the regulatory discourse employs themes of *disempowerment* – introduced in the previous chapter – by encouraging the exclusion of participants from retaining an interest in the fate and use of 'their' samples in research. This discourse could, for example, extend to the exclusion of possible moral and social interests in receiving feedback, despite empirical evidence to the contrary, as suggested in the MRC 2000 consultation.[380]

There are a number of objections to treating the relationship between researchers and participants as a gratuitous gift relationship. These are discussed at length in the last chapter of the thesis in order to draw on the political and economic transformations of the value of human tissue and its use in modern research, the changing interests of participant groups, and key notions of empowerment for group research participants can obtain in particular cases.[381] But for the moment, let us look at the ambiguities and inconsistencies in the use of the language of *abandonment* more closely.

---

[379] [Mason & Laurie 2001, 725]

[380] [MRC 2000b, para 6.9] where "… [v]irtually everyone said that if they donated a sample they would appreciate feedback on what the research using their samples had discovered or achieved". The difficulties with feedback are both morally and technically challenging (see previous chapter) and further problematic as relevant information may be significant for family members, and not simply the individual [Chadwick, Levitt, Shickle 1997] [Kaye & Johnston 2004, 252] [Laurie 2002, 264] [McHale 2004, 92]

[381] [Tutton 2004]

III. Ambiguities in property

A. The rejection of property

Even though there is a range of values which can be applied to the body and its parts,[382] there is uncertainty in the law relating to human material. The current regulatory model for the removal, retention and use of human biological material relies mainly on consent and rejects property as a possible model, at first instance. The new UK Human Tissue Act (HT Act) 2004 establishes consent as "the fundamental principle underpinning the lawful storage and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes".[383]

In UK, there is a legal maxim of "no property in the body" (dead, buried, human body) which was established on shaky grounds in the nineteenth century.[384] Interestingly, it seems that the rule sought to disallow trading in the body as an "indignity" on the basis of beliefs that some dignity remained in the body after death.[385] This maxim has cast a shadow in UK courts' willingness to introduce property rights in the body for the person from whom these body parts were taken, in particular.[386]

---

[382] [Dickenson 2004] [Waldby & Mitchell 2006]

[383] [HTA website] The Human Tissue (Scotland) Act 2006 is based on authorisation rather than consent, but these are both expressions of the same principle, according to the HT Act 2004.

[384] [Mason & Laurie 2001, 714]

[385] In [Mason & Laurie 2001, 714] the authors also comment that the rule back-fired in that one now cannot steal a body, since theft requires appropriation of property belonging to another.

[386] I am not unaware of the differences between post-mortem bodies and buried bodies, retained organs, and human tissue removed for research, and their differentiation from material taken from the bodies of the living, yet a thorough analysis lies outside the scope of this thesis. For a very useful examination of these categories and their implications for the consideration of property rights see [Andrews 2006, 398] [Boulier 1995, 693] [Hardcastle 2007] [Harris 1996] [Matthews 1995, 251]

The common law to date has refused to recognise a general principle that people own their removed tissue bodily material (living or dead material). As things stand at the moment, it is only when others have invested "work and skill" on removed bodily material that property rights can arise from it but only in favour of the person doing the work and skill, not the person from whom the material originates.[387] Arguably, even if the position were to change in the future, it is not likely that these rights would be vested in the latter.[388]

In this light, it is possible for research scientists to gain property rights in developing a new research product from 'donated' genetic material, e.g. cell lines for use in diagnosis and treatment and the original donor source has no property rights, in the interest of the unhindered advancement of medical research.[389] An increasing number of scholars comment that the denial of property rights is a fundamental denial of the value that we attach to individuals and their autonomy, and that the position is inconsistent in that property rights are allowed to a number of other agents interested in the use and commercialisation of human tissue, except the source of the tissue herself.[390] Some scholars have wondered whether individuals (or groups, depending on the case, to be discussed later in this chapter) should be awarded some type of

---

[387] [*R v Kelly* 1999] [*Dobson v North Tyneside Health Authority* 1996] [*AB v Leeds Teaching Hospital NHS Trust* 2004]

[388] See discussion in [Mason & Laurie 2006, 526-529]

[389] The precedent was set in *Moore v University of California* (1990) and has not changed since [McHale 2004, 94]

[390] [Andrews 2006, 398] [Gitter 2004, 257] [Hardiman 1986, 214] [Harris 1996, 351] [Mason & Laurie 2006, 528] [Whitty 2005, 227] – A recently proposed approach is that because the central interest in these claims is the *control* of the *use* of the body, relevant rights would be better protected if they were classified as protecting *non-proprietary* interests [Hardcastle 2007, 46] and compare with [Whitty 2005, 227]

property rights in removed tissue; also, whether it should be theft if another person takes this tissue with the intention of permanently depriving them of it.[391]

B. The abandonment paradox

Despite the fact that the current system relies on consent as a fundamental principle to regulate the removal, retention and use of human tissue, arguably, this same system uses an underlying property model, since one can only give as a gift what one owns.[392] This abandonment paradox leaves the status of property rights unclear. How is the "no property rule" compatible with the possibility to give a gift? The stipulation seems inconsistent when considered carefully. Medical law scholars have called this an "incongruous" position[393]. There is an inappropriate contradiction in disallowing 'property' and in instituting 'gift', since the gift arguably *presupposes* an underlying property right, but also because property rights can be acknowledged by *others* on the same material further down the production line.[394]

The paradoxical reliance on property creates undeniable ambiguity but institutional reluctance to address the question systematically remains. The tradition of the 'no property in the body' rule has been deeply entrenched in English law and the Courts have suggested that it would take a decision by the Parliament to change it.[395] Two related examples perpetuate this ambiguity in current UK guidance – and in the latter case, now also in law:

---

[391] [Skene 2003, 3]

[392] [Beyleveld & Brownsword 2004, 88] for example, discuss that the consent strategy presupposes the very property thesis and also [Laurie 2004, 88] in that in legal terms the invocation of a *gift* presupposes underlying property rights in the subject matter that constitutes the gift.

[393] [Mason & Laurie 2006]

[394] [Laurie 2002]

[395] See [Mason & Laurie 2006] [McHale 2004, 90]

i) the 'surrender' provision in the use of human biological samples for research purposes, as discussed directly below, and

ii) the more recent provision that criminalised non-consensual DNA analysis as an offence under the HT Act 2004, often inaccurately mentioned as "DNA theft"[396]

For the purposes of this thesis, I would like to concentrate on the implications of the 'surrender' provision specifically.

1. The 'surrender' provision

It was mentioned briefly earlier that according to the current UK position, the transfer of samples from donors to researchers should be considered as free and voluntary 'gift' with no expectation of return and that *any* proprietary rights that the donor might have (in their tissue) should be considered as *transferred with the control over the use* of the tissue to the recipient of the gift.[397] This position considers the value of tissue to be limited and potential participants having no interest in it.[398] The position aims to tie with the European Convention on Human Rights and Biomedicine position that "the human body and its parts shall not, as such, give rise to *financial* gain" stated in its Article 21.[399]

It is useful to consider the following valuable point; Art. 21 prohibits commerce in the human body or its parts whereas Art. 22 requires a regime of informed consent to be applied where, following a medical intervention, a human body part is stored or

---

[396] See [HT Act 2004, s.45] [Department of Health 2003] [HGC 2002] [ALRC 2003] – Graeme Laurie helpfully comments that it is wrong to talk of the new offences as "DNA theft", as theft is the misappropriation of the *property* of another and no country recognises property interests for individuals in their own DNA [Laurie 2003, 583]

[397] [MRC 2001 para 2.2]

[398] [Tutton 2004] [Waldby &Mitchell 2006]

used for a purpose other than that for which it was removed. This position is associated with one or other of two underlying claims: either that humans have no proprietary rights in their own bodies or body parts (including body tissue and fluids); or that, insofar as humans do have such proprietary rights, they have no right to exploit the commercial value of their bodies or body parts.[400]

In the MRC 2001 report, the members of the Working Group advise that:

> "… [they] fully support the principle: the *sale* of human biological samples for research is not ethically acceptable. Therefore, while reasonable expenses (e.g travel expenses) may be reimbursed, research participants should never be offered any *financial or material* inducement to donate biological samples for research…"[401] (emphasis in original)

In seeking to adopt the approach of the international document, the report casts off (financial) inducement and sale of samples on the part of the participants as ethically unacceptable gain. Interestingly, it also expands the notion of unacceptable gain from 'financial' to other 'material' gain as well, although there is no such disclaimer anywhere else in the relevant articles of the Convention or of its Explanatory Report which states that:

> "…[u]nder this provision organs and tissues proper, including blood, should not be bought or sold or give rise to *financial* gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital…"

---

[399] [CHRB 1997 Article 21]

[400] [Beyleveld & Brownsword 2004, 88]

[401] [MRC 2001, para 2.5]

The Explanatory Report mentions no other type of gain.[402] By considering that any proprietary rights that the donor might have (in their tissue) should be transferred with the control over the use of the tissue to their recipient, the UK position seems to imply that property rights exist. It stipulates that any relevant rights are given away upon removal of the tissue, and does not discuss any further what these rights are or what their scope would be. The current position is ambiguous and it also ignores the significance of other, not necessarily financial (or material) interests of 'donors' in the samples.[403]

On the part of the researchers, the MRC report clarifies that "they may not sell for profit (in cash or in kind) samples … collected with MRC funding" but it does not omit to mention that intellectual property rights to derive from research with tissue samples can be sold, licensed or transferred upon agreement of funding institutions, researchers and their host institutions:

> "… A clear distinction can be drawn between samples of human material and intellectual property rights arising from research making use of such samples. Such intellectual property may be sold or licensed in the usual way…"[404]

There is no mention of any possible rights of participants over such rights. No such differentiation is made between rights over the samples of the human material and any other that may arise from such research on the part of participants; the distinction is important to remember, but one is to presume that these have also been

[402] [CHRB Explanatory Report, para 132, 1997]

[403] This position has been criticised for its ambiguity by several scholars increasingly interested in the ramification of similar approaches for the efficiency of legal regimes on human tissue [Mahoney 2000]

[404] [MRC 2001, para 2.5]

"surrendered" upon removal.[405] Arguably, these articulations further deny the possibility to accommodate any possible interests "in the fruits of the research" on behalf of participants who provided the material, also by dedicating time and effort for the purposes of such research.

Furthermore, in the case of groups in particular, considerable resources may have been created by groups themselves (e.g. data registries and tissue banks). These can be seen as vital resources without which research may not have been possible.[406] A persistent question for the protection of group interests in this instance is whether groups can have *better control* over particular uses of samples in research, and whether *other legitimate claims* of groups can get recognised, e.g. compensation for their active performance, time, effort and valuable resources that they often contribute to research. Group claims of this nature can include interest in the kinds of research *uses* to be made prospectively but also interests in the *return* of samples to the group after use, and in the *destruction* of samples after use.[407] Significant questions arise as to what the law can do to address such interests, and to what extent these protections are of use to groups.

---

[405] This distinction is contained in the same paragraph that discussed the support to the prohibition of financial gain stated in the Council of Europe Convention on Human Rights and Biomedicine. [MRC 2001, para 2.5] No further analysis is given to the relevant article of the Convention, but the corresponding paragraph of the Explanatory Report states that "…[t]he question of patents was not considered in connection with this provision; accordingly *the latter was not intended to apply to the question of the patentability of biotechnological inventions*…" (emphasis added) [CHRB Explanatory Report, para 134, 1997]

[406] [Terry et al. 2007, 157]

[407] Arguably these interests are non-proprietary and could be dealt with outside property models - see also [Hardcastle 2007, 46]. These claims could include protections for the transfer of group samples to third parties, provisions for the return of samples to the group, or the destruction of samples after use. Such claims have been made by groups, e.g. in the law suit filed by members of the Havasupai tribe against the University of Arizona, who asked for blood samples to be returned to them for burial in their own ground [*Tilousi v. Arizona* 2005]

C. Bodies and bundles of protection

It is useful to turn to other jurisdictions to discuss the issue of property further and attempt to clarify whether the concept of property is helpful for developing group protections – or not. In the US, there exist only a few reported legal disputes over property rights to human biological material. Until the late 1990s, the only legal case that had addressed whether tissue donors can have property interests in 'their' excised tissue was the California Supreme Court decision in *Moore*.[408] Even though this case involved the rights of an individual patient, this case set the precedent for subsequent disputes, which has influenced jurisprudential attitudes to property also in the context of groups.

1. The Moore case

In 1976, John Moore underwent treatment for a rare form of leukaemia at the Medical Centre of the University of California, Los Angeles. Dr Golde, his physician, recommended surgical removal of his abnormally large spleen, without disclosing to Moore his intent to obtain portions of the spleen for research purposes. In a series of postoperative visits, Golde withdrew substantial amounts of blood and other samples. He cultured a cell line from Moore's T-lymphocytes and discovered that the cells had a unique ability to produce a protein that might be used to develop an anti-cancer agent.

While the Regents of the University of California filed a patent application for the cell line, Golde, in spite of repeated representations to Moore that there was no commercial value to his bodily substances, negotiated agreements for commercial development of the line, worth, according to many commentators, millions of dollars. When Moore found out what had happened to the spleen cells, he filed suit against

[408] [*Moore v. Regents of the University of California* 1990]

Dr Golde and the University of California. Moore claimed, *inter alia*, an interest in the products developed by using his tissue, on the basis of a tort of conversion, which gives one dominion and control over personal property against the right of another to control that property so that the tortfeasor may justly be required to pay the other the full value of the property.[409]

In examining whether Moore had an interest akin to property in his removed cells the Court considered that it was not necessary to recognise property rights in Moore's cells to Moore in order to provide him with an appropriate remedy (the court turned to consent and fiduciary duty as ways of protection); that it was a matter for the legislature to decide on Moore's proprietary interest and it would not be appropriate for the courts to do so; that there was nothing unique about Moore's cells, and that, if Moore were to be granted a property right, this would set a precedent that would inhibit medical research.[410]

The Supreme Court of California did not accept the argument made by the Court of Appeals that "[a] patient must have the ultimate power to control what becomes of his or her tissues".[411] The court further argued that the patented cell line was both factually and legally distinct from the cells taken from Moore's body and that the patented cell line and the products derived from it could not be Moore's property.[412] Broussard, J., dissenting, sharply pointed at the fact that the court was treating Moore's removed body part as property on behalf of the researcher (Golde) and the University, but not for Moore.[413]

---

[409] *Ibid.*

[410] Some commentators cleverly rebut in that this view could rather be an over-reaction to the *possible* consequences of applying property law to the human body [Mason & Laurie 2006, 522]

[411] [*Moore* CA 494, 508]

[412] [*Moore v. Regents of the University of* California 1990, 492]

[413] Quoting that: "… the majority's analysis cannot rest on the broad proposition that a removed part is not property, but … on the proposition that a *patient* retains no ownership interest in a body part

2. The Greenberg (Canavan) case

Approximately ten years later, in 2000, a case involving groups of families and an advocacy foundation against a Miami research hospital, the *Greenberg* (Canavan) case in Florida, brought some of the ownership issues to the fore again, in the context of an intellectual property dispute over exclusive licensing of a gene test that was developed with the help of disease advocates and families. The Greenbergs, parents of children suffering from Canavan disease, together with the Canavan Foundation, the National Tay-Sachs & Allied Diseases Association (NTSAD) and Dor Yeshorim representatives, filed a lawsuit against Miami Children's Hospital Research Institute Inc. (MCH) and Dr Reuben Matalon.[414]

In 1987, the Greenbergs had made arrangements with a small team of researchers to pursue research into Canavan disease, a rare and fatal degenerative brain disease that leads to loss of body control and death, usually before ten years of age, with no known cure. Using blood, urine and tissue samples, confidential medical information, registry data and financial resources contributed by Canavan patients and families worldwide, the NTSAD and Dor Yeshorim, the researchers identified the Canavan gene mutation and developed a genetic screening test for the disease. By that time, Matalon had joined the Miami Children's Hospital Research Institute which decided to file a patent application for the gene, its various mutations and related applications, including carrier and prenatal testing, and to pursue non-exclusive as well as exclusive licensing plans to commercialise the test. Upon issue of the patent, the hospital warned diagnostic centres offering Canavan testing of

---

once the body part has been removed" (emphasis added) [*Moore v. Regents of the University of* California 1990, 492] – See also [Mason & Laurie 2006, 522] and extensive commentary by [Rao 2007, 376]

[414] [*Greenberg v. Miami Children's Hospital* 2003]

possible enforcement actions, restricted public accessibility to testing and sought to negotiate exclusive licensing agreements and impose royalty fees for testing.[415]

In their lawsuit the families asserted *inter alia* that the hospital and the researcher were exercising the patent rights that they had obtained over the Canavan gene and the license rights they had pursued over the associated diagnostic test, to whose breakthrough discovery the families had contributed substantially, in ways that were unacceptable to the patient families – following the issue of the patents, MCH had asked laboratories that were already offering the test for royalties to continue to offer the test, and had sought to enforce the patent so that some labs already providing the test had to end the practice.[416] The plaintiffs protested that MCH and the researcher had not informed them about the patent and that their contribution to the discovery was neither acknowledged nor compensated. They were rather disenchanted that the defendants used group members' tissue samples and genetic information without acknowledgment, for their own exclusive economic benefit.[417] They sought to block Miami Children's Hospital's commercial use of the Canavan gene and recover damages of more than $75,000 derived from royalties collected for the gene test.

The plaintiffs claimed a property interest in their body tissue and genetic information, that they owned the Canavan registry which contained contact information, pedigree information and family information of Canavan families worldwide. However, at a preliminary hearing, the Florida District Court held that these were research donations without any expectations of return and declined to recognise a property interest in the bodily tissue and genetic information voluntarily

[415] [Merz 2002, 102-106]

[416] The Canavan Foundation had offered genetic testing free of charge but had to stop after they were advised that they would be required to pay royalties to the patent holder and to comply with set license terms if it wished to continue offering the Canavan test [Bernier et al. 2004, 33]

[417] [Merz 2002, 102-106]

given to the hospital. The court reasoned that the property right in blood and tissue samples evaporates once the sample is voluntarily given to a third party.[418]

The Canavan plaintiffs used an additional argument based on a corn seed company case, the *Pioneer* case,[419] where the Southern District Court of Iowa previously held that a company's property interest in the genetic message contained in a corn seed variety is property protected by the laws of conversion. The *Greenberg* court noted the reasoning of the *Pioneer* court in that "where information is gathered and arranged at some cost and sold as a commodity on the market, it is properly protected as property" but they saw this recognition as "more support for property rights inherent *in the hospital's research* rather than the donations of plaintiffs' DNA"![420] As far as the conversion claim was concerned, the court also held that the plaintiffs did not allege how the hospital's use of the Canavan Registry was an expressly unauthorised act, and that the plaintiffs failed to allege the circumstances or conditions that were attached to the defendants' use of the Canavan Registry.

The irony in the comparison between this case and the *Moore* case is palpable: in the *Moore* the court rejected the patient's property claim to his excised cells considering that, if granted, such claims would hinder research by restricting access to the necessary raw materials and would create a litigation lottery for researchers.[421] In *Greenberg*, the group wanted the research information and outcomes to be freely available, against the wishes of the University to privatise and commercialise them, and hence restrict access to them that would potentially hinder research![422]

---

[418] The court cited the *Moore* Supreme Court stipulation that a donor has no property interest in the removed tissue after they have made the donation.

[419] [*Pioneer Hi-Bred v. Holden Foundation* 1994]

[420] [*Greenberg* 2003, 1075] and see comment by [Bovenberg 2004, 8]

[421] [*Moore v. Regents of the University of* California 1990, 492] [Mason & Laurie 2006, 521]

[422] Some commentators note the quirk, see notably [Mason & Laurie 2006, 523] and more recently [Rao 2007, 378] who sharply sums it up as follows: "…[i]ronically, not only did the court reject the

The *Greenberg* court further rejected the plaintiffs' claims for a continuing right of donors to possess the results of research conducted by the hospital on the material provided by Canavan families, including patented applications, and it reaffirmed their status as "donations".[423] The court stated that "[i]f adopted, the expansive theory would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital. At the core, these were donations to research without any contemporaneous expectations of return".[424]

Interestingly, as regards to the thorny issue of the *contribution* of the families to the research process and the gene discovery, the court permitted a cause of action for unjust enrichment, by recognising that there existed "a *continuing research collaboration* that involved plaintiffs also investing time and significant resources in the race to isolate the Canavan gene"[emphasis added].[425] As a result, in September 2003, the parties reached a confidential settlement which permitted a research exemption for royalty-free research by institutions and researchers in search for a cure; and entitled the Miami Children's Hospital to continue to license and collect royalty fees for clinical testing by certain licensed laboratories for the Canavan gene mutation.[426]

Greenberg's argument that the Canavan gene patent should remain part of the public domain because that was their intent, but instead [it] ruled that it was their bodies and their genes – and *not* the gene isolated by Dr. Matalon – that were in the public domain, free for appropriation by the first researcher who came along and reduced them to private possession…"]

[423] [*Greenberg* 2003, 1075]

[424] *Ibid.*

[425] [*Greenberg* 2003, 1075]

[426] [Bernier 2004, 33] [Canavan Foundation 2003] [Oberdorfer 2004] [Rao 2007]

A key problem stemming from this case – and related to subsequent cases where the courts have denied acknowledging property interests to the sources of tissue material – is the basis on which the "material contribution" of the group will be assessed.[427] Did the court in the *Greenberg* case allow the unjust enrichment claim only because the patient families contributed considerable monetary resources to the research? Did it disregard their contribution of biological tissues and related information? How ought the court's stipulation on "investing time and significant resources" to be analysed further? What is the extent to which future patients and research participants can have a say in the use of potential future commercial applications of research to which they have "contributed materially"?[428] This key issue was addressed – albeit in a *sui generis* fashion discussed below – by another patient advocacy group, PXE International, again in the US, somewhat contemporaneously to the *Greenberg* developments.

3. The PXE International case

In 2000, a novel example followed with PXE International, an advocacy group who successfully negotiated intellectual property rights over research done with the tissue samples and that data they contributed.[429] The group is a non-profit patient advocacy organisation representing the interests of families affected by pseudoxanthoma elasticum, a rare genetic disorder that affects elastic tissue and skin cells.[430] PXE provides patient support, funds and coordinates a consortium of research labs, directs a blood and tissue bank and maintains a database of thousands of members worldwide.

---

[427] [Kanellopoulou, forthcoming]

[428] [Anderlik & Rothstein 2004, 450] [Oberdorfer 2004, 365] [Rao 2007, 371]

[429] [PXE International website]

[430] [PXE International website]

PXE entered into a *contract* with researchers to steer research in finding the gene associated with PXE disease. In accordance with the contract, PXE is entitled to ownership rights in any patent application arising from the research and a profit share in any revenue to be generated by such inventions, a right of control ensuring broad and affordable availability of genetic tests, and a right to influence future licensing of the intellectual property.[431] To date, neither party to the contract has challenged its enforceability on the ground that the members do not have a property right in their removed material – as in *Moore* (as individuals) – and the PXE example has been followed by other patient groups in subsequent years.[432]

A few commentators have so far highlighted the inconsistency between the precedents established in *Moore* and *Greenberg* on the one hand, and the later *PXE agreement* on the other, and a combined approach has been suggested. This approach has been proposed as part of a model that would grant participants property rights in the use of their biological material by negotiating *in advance* (in line with the property-by-contract approach based on the PXE model); and, that, where such rights were not negotiated in advance and researchers withheld crucial information which would have helped participants to bargain for such rights, this model would enable participants to bring an action for conversion and liability.[433]

By comparison, in the case of the *Havasupai* tribe against the University of Arizona, the court missed the opportunity to clarify whether a similar approach could be used. As it was discussed earlier, in this case, Havasupai Tribe members alleged that researchers of Arizona State University and the University of Arizona collected blood samples from them for researching diabetes but that additional unauthorised

---

[431] [Bovenberg 2004, 7] [Gitter 2004, 317]

[432] Examples are associations such as Cure Autism Now, Juvenile Diabetes Research Foundation, Alpha-1 Foundation [Gitter 2004, 317] [Terry 2007]

[433] [Bovernberg 2006] [Gitter 2004]

research was undertaken on those samples regarding schizophrenia, inbreeding, and population migration.[434]

As part of their many causes of action which included breach of fiduciary duty and lack of informed consent, fraud and misrepresentation, infliction of emotional distress, conversion by using another's possessions as one's own, and violation of civil rights an negligence), the *Havasupai* plaintiffs stated a claim for conversion and a right to immediate possession, on the basis that the defendant researchers committed conversion by intentionally obtaining possession of their blood samples and hand prints, by fraud.[435] The Arizona District Court said that "… the plaintiffs' voluntary donation of blood samples… suggests [they] had no right to immediate possession of the blood"; [436] the court stated further that according to Federal Rules of Civil Procedure that apply to the claim grounded in fraud, plaintiffs were required to allege the who, what, when, where and how of the alleged fraud; the plaintiffs failing to comply with these requirements, the court dismissed the conversion claim in its entirety. Hence the chance was missed to track how the court could have discussed the conversion claim further.

4. The Catalona case

A more recent case on property rights in human bodily material is *Washington University v. Catalona*, with the lawsuit filed in 2003, in St Louis. The University sought to prevent Dr. William Catalona, an internationally known prostate cancer surgeon and researcher, who had developed a large repository of (30,000) samples for the specific purposes of prostate cancer research with the consent of his patients, from moving the repository to his new institution. Washington University saw the

[434] [Andrews 2004] and see relevant discussion in chapter two of this thesis.
[435] [*Tilousi v. Arizona* 2005, 10]
[436] *Ibid.*

repository not solely as a resource for prostate cancer research advances, but additionally as a capital resource.[437]

When Dr Catalona left to take a place at another University, he asked his patient-donors to write to Washington University requesting that their tissue samples be sent to his new place of employment, and most of them did. Washington University refused to send the samples, and a dispute arose about the patients' right to control the tissue, where the University sought to assert its sole right of ownership of the collection.[438]

On the basis of the terms of the consent documents signed when Dr Catalona's patients originally gave their tissue, the St Louis Federal District Court ruled that control belonged to Washington University and that, although patients might ask that their samples be destroyed, patients could not instruct that the samples be delivered to Catalona or to another university.[439] It was left unclear whether the patients ever had a property interest in their tissues. One reading suggests they did but that they relinquished it upon donation; another suggests that they never had such an interest, even while the tissues were in their living bodies.[440]

---

[437] [Andrews 2006, 398]

[438] [*Washington University v Catalona* 2006] – In his correspondence with *JAMA*, the Journal of the Americal Medical Association, Dr Catalona states: "It is understandable that, given the potential commercial value of human tissue and blood samples, universities would like to assert sole right of ownership. However, this case is about patients' and other human research participants' rights and their sometimes *highly personal relationship* with their physician-researcher. Universities cannot assert sole ownership to samples that participants can withdraw at any time for any reason. There is also an important distinction in that … previously litigated cases … relate to secondary commercialized products derived from samples and related patent rights, not rights relating to the primary raw samples that are at issue in this litigation" [Catalona 2005, 1325]

[439] [*Washington University v Catalona* 2006]

[440] [Charo 2006, 1517]

It is fair to argue that if no property rights on excised tissue are recognised, then the *Catalona* decision is not a question of the abandonment of a property interest after donation but rather a stipulation that we have no property right to our tissues, before or after they leave our bodies. In such case, any possibility to control the use of such tissue would depend on other protections, as part of biomedical research ethics protections (i.e. consent and data protection). These are not adequate to protect other interests, such as interests in the destruction, or return of samples, which, according to recent commentators, may be better protected if they are treated as non-proprietary.[441] I agree that, if such rights exist, the balancing on whether donation is relinquishment at least depends on the 'fairness' of the transaction and the quality of the information provided before consent is given.[442]

How are these to be measured then? In so far as the issue of control goes, courts find that state law provides little basis for granting patients a property interest in their voluntarily removed tissue. A commentator recently said that the case of *Catalona* seems to indicate that when patients' preferences about the kinds of research that may be performed on their tissue are ascertained, this is done "as a courtesy" rather than as recognition of patients' rights to prohibit the use of their tissues for purposes of which they disapprove.[443] So far, the discourse in favour of participants' disempowerment remains entrenched in common law jurisdictions both as lack of resolve to clarify the ambiguities and as absence of will to address the significance of interests involved.[444]

[441] [Hardcastle 2007, 46]
[442] [Healy 2006]
[443] *Ibid.*
[444] [Nelkin & Andrews 1999]

5. Bundles of rights?

These controversies warrant an evaluation of what can be characterised as property in the human body in this context. I return to the UK and European context with US considerations in mind. Since the procurement of financial gain and profit from the sale of samples on the part of participants is prohibited, what rights may be applicable, if any?

I discussed early in this chapter that the current situation is not clear whilst implying that property rights exist. Several scholars propose the consideration of property rights through the increasingly popular idea of the notion of bundles of rights. Calling something property does not necessarily mean that the owner has all possible rights to its exclusive use, donation, sale, alteration, and destruction, but that there is a set of rights associated with it. Scholars who support the use of the theory in the handling and use of human tissue are in favour of the need to disaggregate and distinguish these rights.[445]

The bundles correspond to sets of relations as incidents of the right of ownership. The most influential analysis most commentators refer to when considering the core components of the bundle of ownership entitlements and duties is attributed to Honoré although there exist several proponents of different systematic accounts of the components of the bundles of right that constitute ownership.[446] According to Honoré, these bundles are:

1) the right to exclusive *possession* (exclusive physical control)
2) the right to *use* (personal use and enjoyment)

[445] [Björkman & Hansson 2004] [Bovenberg 2004] [Dickenson 2005, 49] [Munzer 1990]

[446] [Honoré 1961] – For a philosophical analysis see [Björkman & Hansson 2004] and for a comparative legal analysis see [Jaffey 2007, 88]

3) the right to *manage* use (decide how and by whom the thing owned shall be used by others)
4) the right to *income* (forego personal use and reap the benefits from allowing use to others;
5) the right to the *capital* (right to alienation, consumption, waste, destruction)
6) the right to *security* (indefinite ownership, immunity from expropriation)
7) the incident of *transmissibility* by gift, devise, or descent (to the one's successors)
8) the incident of *absence of term* on these rights (indeterminable, unlimited duration except for contingency)
9) the duty to refrain from using the object in ways that harm others (prohibition of *harmful use*)
10) the liability to *execution* for repayment of debt
11) *residual* rights upon reversion of lapsed ownership rights held by others

One may consider these rights to be a 'package deal', as goods which are related to each other but can be enjoyed and managed separately. A few attempts have been made in recent years by scholars to determine which of these rights may be applicable in handling and managing human bodily material. According to one of the most interesting ones, the application of some rights from the core bundle to human material is conceivable but human biological material does not necessarily fit comfortably in a number of rights from the property bundle; [447] some of them give rise to contradictions and potentially adverse implications, and additional difficulties arise in deciding which rights are the core rights in the bundle.[448]

[447] E.g. the right to alienate, the right to security and the liability to execution [Bovenberg 2004] [Munzer 1990]
[448] *Ibid.*

For example, one could hypothesise that in order to protect groups under a property model, the key may be to develop ways to award guarantees of possession (1), management of use (3), indefinite security (6), and indeterminate duration (8);[449] but then again, what about the controversial right to capital (5) and the negotiation of transmissibility entitlements (7)? Given the disempowering and expansive works of current guidance and the precedent that favours narrow interpretations of participants' control rights, it is difficult for such rights to be implemented and enforced. In the absence of clear statutory provisions, uncertainty remains as to how to regulate such options! Furthermore, it is essential to determine where these considerations lead to in the discussion about what kinds of rights groups could assert towards securing better control on the use of samples and resources that they contribute to research, and on what basis. I examine these in the following section.

IV. Groups and property?

There exist no positive examples of judicial acknowledgment of group property rights in genetic research context. In the previous section, I discussed the judicial antipathy to property, as far as research participants, as the sources of tissue samples, are concerned. Group property rights are generally ignored, despite recent claims to the contrary.[450] Let us take a closer look at the kinds of claims that have been asserted by different kinds of groups in research. These include claims in controlling the use of body samples given to research but they further extend to claims over products of group intellectual and material labour, as well as claims for respect to particular group values or beliefs, e.g. for the return of samples to the group, depending on what kind of group is involved.

---

[449] [Bovenberg 2004]

[450] A notable very recent example is the case of the *Havasupai* Tribe, where two lawsuits were filed, one from particular tribal members and the second on behalf of the Havasupai Tribe as a whole,

Debates in this context have been developing since the mid 1990s and can be divided in two different strands. The first is of particular concern to indigenous populations; and the second relates to patient advocacy activities. For example, particular patient advocacy activities of the PXE International [hence, the PXE] patient advocacy group helped secure the recognition of a group's contribution and interests in controlling relevant research. The PXE secured contractually-agreed protections which took the form of joint IP authorship rights and are being adhered to on the basis of a private agreement, based on contract. To many commentators, the agreement implies that the PXE and its members possess a property right in their biological material. [451]

The reason I examine the claims of these two categories of groups under the same section is that in both types of cases, groups invoke *sui generis* claims themselves, seen as necessary for the protection of their interests which are not necessarily enforceable outside the parameters of the group's agreement with the researcher (as in the case of advocates who agree private contracts with researchers and universities), or jurisdiction (as in the case of sovereign native tribes, who seek to develop frameworks in order to defend rights on their genetic material).

In the case of indigenous groups, questions about property or related claims for control and respectful use of tribal DNA tissue samples and data are closely linked with their cultural views on the nature of DNA material, their history and experience of marginalisation or exploitation. These crucial factors affect the ways in which many indigenous peoples view participation in research and are considered in more detail, in the section below.

---

claiming conversion of samples to property [*Havasupai Tribe v. Arizona* 2004] and [*Tilousi v. Arizona* 2005]

[451] [Bovenberg 2004, 7] [Gitter 2004, 317] [Hardcastle 2007, 5] [Terry & Boyd 2001, 178]

A. Indigenous peoples and appropriation of human genetic material

There are several instances of indigenous opposition to the appropriation of what they perceive to be collective genetic material against researchers' activities who sought to obtain intellectual property rights on such material. Before discussing the intricacies of such discourses, it is important to reiterate that the references to 'indigenous peoples' contained in this chapter, are based on internationally recognised definitions in international human rights law, used worldwide by experts including indigenous activists and scholars.[452]

I discussed these definitions in an earlier chapter, but it is worth reminding the reader that the term 'indigenous peoples' is an umbrella term, denoting both the diversity of indigenous cultures and local contexts but also the many common characteristics that indigenous peoples share. The term is used to define such groups as those "indigenous communities, peoples and nations… which…, having a historical continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves *distinct* from other sectors of the society now prevailing on those territories, of parts of them. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their *ancestral territories*, and their *ethnic identity*, as the basis of their continued existence as peoples, in accordance with their *own cultural* patterns, social institutions and legal systems" [emphasis added].[453] Key traits captured in this definition are the *non-dominance* and marginalisation of indigenous peoples, their cultural *distinctiveness*, and their long-standing links to *land*, traits which do not

[452] For a good comprehensive overview on the evolution of international human rights standards for the protection of indigenous claims, see [Xanthaki 2007]

[453] In [Eversole, McNeish, Cimadamore 2005, 5] and see also [Greene 2002] [Gregory 2003] [Guenther et al. 2006] [Quane 2005, 658]

necessarily occur together but are part of a fluid shared identity, that is also used strategically as a collective resource, to help reflect on the kinds of basic similarities in peoples' histories and identities, and to describe real commonalities of interest among diverse peoples themselves.[454]

These common interests have been the impetus for the emergence of a broad range of organisations and movements for indigenous peoples' rights, many of which are active and visible internationally. As an example, several organisations of indigenous peoples have consultative status with the United Nations Economic and Social Council and hundreds of representatives of indigenous peoples and their organisations participate at international meetings of the United Nations. Indigenous organisations may be specific to certain *peoples* (e.g. Inuit, Mapuche), certain geographic *regions* (e.g. South and Meso American Indian Rights Center, Asian Indigenous and Tribal Peoples Network) or they may be *pan-indigenist* organisations (e.g. Indigenous World Association, International Indian Treaty Council). The specific mandates and composition of these organisations vary, yet by adopting the language of 'indigenous peoples' and 'indigenous rights', they recognise common interests, build alliances and celebrate the value of their collective identity, also seen as a strategic resource in their work for change towards self-determination and self-identification.[455]

In light of these common interests, research narratives about the nature and treatment of human biological material become highly contested. Historically, for indigenous peoples worldwide, the discussion on property entitlements and genetic resources is often framed in rather negative terms. Concerns over the fate of genetic resources become linked with a tradition of unmet indigenous claims about self-determination, disputes of land rights, environmental politics, and cultural appropriation seen as

[454] [Eversole, McNeish, Cimadamore 2005, 8]

[455] [Brysk 2000] [Field 2003] [Harry & Kanehe 2006] [Johnston 1989] [Tallbear 2001]

'western' exploitation.[456] For example, scholars who work together with American Indian and Alaskan Native people to formulate policies for genetic research with these communities, caution researchers interested in working with native people to keep these histories of "theft" and "respect" carefully in mind.[457] Consequently, in controversies on research with indigenous human genetic material and its potential commercialisation, debates about property have been linked with narratives of prior long-term exploitation and colonisation. This historical connection has been made by many indigenous commentators and is also highlighted by anthropologists who work with indigenous human populations.[458]

Controversy about the patenting of indigenous genetic material peaked in the early 1990s when two parallel kinds of activities occurred: a) the filing of patent claims on indigenous cell lines at the US Patent Office (USPTO) by US-based researchers, and b) the proposal for the creation of the Human Genetic Diversity Project.

1. Opposition to the Human Genome Diversity Project (HGDP)

I discussed briefly at an earlier chapter the rise and demise of the HGDP project for a worldwide survey of human genetic diversity among the world's peoples, proposed by US population geneticists and evolutionary biologists. The project faced a number of difficulties including vociferous opposition by indigenous activists and representatives who reacted to it as an inappropriate instance of biopiracy. They feared that researchers seeking to collect indigenous tissue and DNA were not interested in their welfare and could exploit them for 'western' profit and commercial gain. As one author put it: "… [t]hey [ha]ve come to take our blood and tissues *for their own interests, not for ours*".[459]

---

[456] [Brown 1998, 193] [Dove 2006, 191] [Greene 2004, 211] [Johnston 1989]

[457] [Bowekaty & Davis 2003, 12] [IPCB 2000, 7]

[458] [Foster 1999, 348] [Lock 1997a, 86]

[459] [Whitt 2000, 432]

To indigenous representatives, the issue of control over what would happen to their tissue and information was a fundamental issue of social justice and survival against others' political and economic re-ordering of project priorities. They deemed those priorities exploitative, disrespectful and insulting in that in them, indigenous existence did not seem to have any particular value, adding to historical frustration to that fact.[460] Moreover, there was no indication that the diseases to be studied or the treatments likely to be developed from the project would benefit indigenous groups themselves. Various commentators now discuss how native peoples, having long been exploited for others' academic and financial advancement, become increasingly wary of research, especially when they are not assured that there is a strong likelihood that their group will benefit from participating research, rather than simply contributing to generalised knowledge or to the researcher's career. According to this literature, *benefits to the tribe* must be defined together with the tribe. [461]

Furthermore, in the use of marginalising, alienating language of HGDP advertisements that named indigenous groups as "vanishing human isolates", "rapidly disappearing populations", "in danger of dying out or being assimilated", indigenous peoples read a lack of respect to their *cultures and sacred values of the body*, which further fuelled their opposition to the project.[462] It is thus fair to say that the critiques to the project were directed at something quite fundamental: the *clash of knowledge and value systems between indigenous and western culture*. Diverse local traditions of indigenous peoples across the world relate to different cultural beliefs on, for example, how the indigenous groups may wish 'their' biological materials to be treated, but many groups worldwide share similar concerns and basic concepts

[460] [Amani & Coombe 2005] [Freeman 1998] [Hamilton 2001] [Mgbeoji 2007] [Whitt 2000]
[461] [Bowekaty & Davis 2003, 13] [AI/AN Genetics Research Policy 2001] [Davis 2000, 38]
[462] [Amani & Coombe 2005, 155] [Whelan 2006]

and beliefs about the human body and its connection to nature.[463] For the great majority of indigenous groups worldwide their genetic materials hold traditional and spiritual significance.[464] A revealing quote on this matter, by Dr Dukepoo, a well-established geneticist of Hopi and Lacuna ancestry (American Indian ancestry), can be used here:

> "[t]o us, any part of ourselves is sacred. Scientists say it's just DNA. For an Indian, it is not just DNA, it is part of a person, it is sacred, with deep religious significance. It is part of the essence of person".[465]

A related major indigenous concern against HGDP was the researchers' ambition to reconstruct migration and settlement patterns of populations: "… many consider further research into our origins and migration patterns based on genetic mapping as … *unwarranted tampering* with *whakapapa* processes which have already settled these questions to our satisfaction".[466] The claim was not negligible at all; indigenous peoples were concerned that it would be difficult to have control against particular governments attempting to use genetic information concerning migration and settlement patterns as 'evidence' to deny native groups land rights and other human right claims.[467] These conflicts show that detailed investigation is necessary in order to agree what research can be pursued with group material and on what basis, taken in sensitive cultural contexts. Failure to do so perpetuates problematic ignorance of

---

[463] Emerging scholarly work highlights potential problems in the generalisation of particular beliefs as pan-indigenous approaches and the need to develop specific tribal approaches. Yet overall, there is rising consensus on the importance of a more unifying discourse that indigenous peoples and their representatives could pursue to further their interests in self-determination [Brysk 2000] [IPCB 2000] [TallBear 2001]

[464] [Arbour & Cook 2006] [Tallbear 2005]

[465] [IPCB 2000]

[466] [Mead 1995, 129]

[467] [Dutfield & Posey 1996, 170]

the psychological, social and religious impact of undermining the integrity of particular groups, and its cultural, political and legal implications.[468]

A relevant case that highlights the traditional and spiritual significance attributed by many indigenous peoples to their own beliefs about nature and their relationship is the example of the beliefs of Maori peoples in Aotearoa/New Zealand. It is worth mentioning it here, as it helps stress particular points about the role that tribal histories and beliefs in affecting indigenous understandings of body and property. According to Maori beliefs, references to 'human genes' are often translated as close to *ira tangata* (life force or life spirit of mortals); [469] references to 'human genes' are inextricably linked with references to genealogy, for which the word is *whakapapa*; it incorporates genealogical succession and tribal histories and denotes the fundamental connection that Maori perceive to exist among themselves, their ancestors and future generations.[470]

Studies on these beliefs reveal that to the Maori, a gene and a genome are imbued with a life spirit handed down by the ancestors and passed on to future generations,[471] and, that it is not, and *cannot be the property of individuals*. Experts assert that according to *whakapapa*, genetic information is not within the domain of the individual but "deeply related to the group who are the current representatives of their lineage".[472] In such contexts, the concept of gene as something that can be

---

[468] [Nelkin and Andrews 1999, 4]

[469] [Dickenson 2007]

[470] [Gillett & McKergow 2007]

[471] These interpretations are proposed by Professor Donna Dickenson, a bioethics scholar who pursues work on global ethics and genetic research [Dickenson 2007] – It is also worth comparing another case from the study of global ethics, the case of Hawai'ian peoples; they believe that every piece of the body contains *mana* or life force which 'flows through the universe', and that its *disruption* (e.g. by a researcher who is unaware of their world views and takes pieces of it to study) causes disease; see also [Bowekaty & Davis 2003, 14]

[472] [Arbour & Cook 2006] and see [Gillett & McKergow 2007, 2096-2097]

commodified and commercialised is often at odds with some indigenous understandings of what the body is and what it represents to indigenous peoples.[473]

These positions have a direct impact on how patenting practices are viewed by many indigenous groups and their representatives.[474] In return, the HGDP project was an opportunity for such groups to express their disdain in the way the proposed project practices clashed fundamentally with indigenous knowledge and value systems in many native contexts. Several indigenous representatives voiced concerns that individualistic intellectual property rights on the body were inappropriate.[475] For example, the first international agreement formulated by indigenous peoples on cultural and intellectual property rights issues, known as the 1993 Mataatua Declaration on the Cultural and Intellectual Property Rights of Indigenous Peoples, called for a *global moratorium* on any further commercialisation of traditional plants, medicines and human genetic materials until indigenous peoples and the international community have developed appropriate protection mechanisms. The declaration asserted that existing Western intellectual property rights mechanisms are *not capable of providing adequate or appropriate* protection of indigenous knowledge and resources. They are deemed to be so because their rationale goes against indigenous *communitarian* cultural beliefs evidenced in the quote below:

> "… we assert that our identity and our rights are *not reducible to the rights of individuals*… With its cult of the individual and its emphasis on individual rights, non-indigenous people in the western world have failed to

[473] [Dickenson 2007] [Lock 1997b] [Whitt 1998, 240]

[474] [Dickenson 2007] [Harry & Kanehe 2006] [Lock 1997a] [Mead 1996]

[475] The declaration calls for more *co-operative* arrangements between indigenous communities and researchers, such as codes of ethics and research agreements. The declaration was presented to the 1993 UN Working Group on Indigenous Peoples in Geneva and has since been signed by over 800 indigenous nations and organisations, as well as non-indigenous organisations. It was named after the nine Maori tribes of the Mataatua region who hosted the meeting [Mataatua Declaration 1993] [Mead 1997]

> acknowledge the *collective nature* of indigenous societies, and have provided inadequate protection for the group rights of peoples"[476]

This fundamental clash cannot be translated easily into legal structures primarily designed to accommodate individual rights and interests. I referred to some of these problems in previous chapters, but this section offers a unique opportunity to examine intellectual property-related issues further. It was unaccommodating, for example, for the creators of HGDP that a) the year before the project was proposed, unrelated teams of researchers working with indigenous tribes in Polynesia had filed patent claims on indigenous cell lines, developed as a result of collection and culture of samples taken from tribes in the Western and South Pacific, or that b) their proposal was tabled at the aftermath of the introduction of the Native American Graves Protection and Repatriation Act (NAGPRA) in the US. These developments are discussed further below.

2. The patent on the Hagahai cell line

In the early 1990s, the US National Institutes of Health filed a patent claim over a cell line developed on an isolated T-lymphotrophic virus found in the blood of the Hagahai people in New Guinea.[477] In the course of anthropological research on the

---

[476] [Whitt 1998, 240]

[477] In fact, two claims were filed in 1990 and 1991 by the US National Institutes of Health (NIH) on two cell lines infected with HTLV-1 variants; the second line (Solomon Islands) was developed in the course of research for the Hagahai cell line (PNG), used to determine the genetic sequence of the virus. The virus in the PNG sample was a genetically distinct variant of HTLV-1 found elsewhere in the world, so the laboratory sought out blood samples from other populations in the region (Western Pacific). In the Solomon Islands they found another population infected with another distinct strain of HTLV-1, and then they developed the second line. The patent application for the Solomon Islands cell line was withdrawn in 1994 by NIH, after being challenged in court by a lawyer representing the interests of the Solomon Islanders. According to commentators, the demand for commercial products to be produced from this cell line was low. However – according to the same commentator – the patent on PNG-1 was not withdrawn, at the request of the anthropologist who was working with the tribe and was a co-inventor on the patent. The PNG-1 cell line was granted a patent by the USPTO in

effects of contact to the tribe's biological and cultural survival, a genetic study was developed to research the distribution of virus variants.[478] Lab analysis revealed the existence of antibodies to a variant of a leukaemia virus (HTLV-1) in the blood of Hagahai people. The Hagahai at the time were a small, 260-member, hunter-horticulturist group who had first made sustained contact with government and missionary workers in 1984. They were of particular interest to the NIH because the gene that they carried predisposes humans to leukaemia, but they did not manifest symptoms of the illness.[479]

Researchers collected and used samples from tribe members to develop an immortal T-cell line (PNG-1), which was used as a basis for a successful patent application for the cell line, the virus, and the set of diagnostic tools or vaccine that could develop. The researchers claimed that they negotiated a profit-sharing agreement with the Hagahai when some tribe members sought help for an illness that afflicted the group, and that an (unspecified) share of commercial profits from the prospective invention had been agreed with Hagahai leaders. Controversial issues in ensuing debate were questions of inappropriate, passive representation and adequate understanding of the science represented to them as an 'insect in their blood', the claim over agreed returns to share commercial profit and the issue of whose patrimony this would be.[480]

Despite public controversy and outcry by activists and public interest groups on the exploitative nature of the enterprise, the USPTO granted the Hagahai patent to the US National Institute of Health (NIH).[481] The patent was later disclaimed, as it produced very little commercial rewards and NIH abandoned the rights in late 1996.

March 1995, with patent number 5,397,696 for a Papua New Guinea human T-lymphotrophic virus [Bhat 1996] [Lock 1999] [Mead1996]

[478] [Pottage 1998]

[479] [Lacy 1998, 794]

[480] [Lock 1997a] [Pottage 1998] ['US patent on tribesman's blood raises ethical questions' 1996]

[481] [Bhat 1996] [Lock 1999] [Mead 1996]

Empirical research reveals that when they were asked to comment on the acceptability of the overall arrangement, the Hagahai placed emphasis on their *relationship* to the anthropologist associated with the patent.[482] When they agreed to the donation of the tissue samples, the creation of the T-cell line, subsequent patenting, and a return of the portion of the profits – according to commentators of this case, if money resulted from a vaccine or other product then all members with Hagahai ethnicity would receive half the profits – the Hagahai considered the proposals in terms of the social practices through which persons "make claims on one another" – and not on the basis of what was profitable on the basis of Euro-American property regimes.[483] This emphasis is of particular relevant for the central argument of this thesis that the law should focus on defining the nature of the relationship between groups and researchers, as opposed to that of the samples transferred alone.

The Hagahai patent case is indicative of the diversity of worldviews about the nature and function of personal and property relations from an indigenous point of view, as well as the potential advantages of novel approaches that would enable such *relational* understandings of group-researcher interactions. It is important to note that the fact that the patent was vigorously opposed by Melanesian public intellectuals could possibly indicate that not all indigenous peoples may share the same views on what can be transacted or patented and why. On the other hand, it could simply denote concern for the absence of appropriate communication and other safeguards in the tribe's interaction with researchers. It is difficult to assert which is the case while reviewing the relevant literature.[484] Moreover, this case presents an opportunity to discuss the issue of research benefits further in two ways: in that indeed, no guidelines are in place to ensure that possible benefits from the research can flow back to groups, or to guarantee that negotiated benefits can be agreed to

[482] [Lock 1997a]

[483] [Kirsch 2004, 23-25]

[484] [Kirsch 2004] [Liloqula 1996] [Lock 2001] [Pottage 1998] [Sengi 1996]

help solve pressing health problems in communities where groups cannot afford to pay for basic medicines.[485]

3. The patent claim on the Guaymi Indians cell line

Meanwhile, in 1992, another team of researchers filed for a patent on behalf of the US Department of Commerce on a cell line developed from samples collected from a woman in the native tribe of the Guaymi Indians, in Panama. The researchers alleged that the woman gave "oral informed consent" to the collection of blood samples for research on a human T-lymphotropic virus but neither the tribe nor the woman knew anything about the cultured cell line or the patent application.[486]

In response to the patent filing, the President of the Guaymi General Congress wrote a letter to the U.S. Secretary of Commerce and demanded that the application be withdrawn on the grounds that a) it had been made without consultation with the Guaymi community; b) this was not an invention but rather a discovery of an antibody that is part of the blood of a Guaymi woman, and c) he asked what benefits – if any – the Guaymi people would gain from the proposed patent application. Protests from numerous interest groups and from the Rural Advancement Foundation International (RAFI) followed until the application was withdrawn.

These failed attempts to patent indigenous cell lines and gene sequences are part of the most contentious issue in the history of human genome diversity research, with serious practical implications on how research may be commissioned and conducted. As asserted by the Committee on Human Genetic Diversity, established to assess the scientific value of technical aspects, organisational requirements and the ethical, legal, social issues that would be raised by HGDP as a systematic worldwide survey

[485] [Kambu 2007] – A discussion of benefit-related claims is made in the last section of this chapter.
[486] [Whelan 2006]

of human genetic variability, in 1997, many indigenous groups had become "so averse to patenting" that researchers would not only have to state that they will refuse commercial funding for genetic diversity research, but also explicitly promise not to patent or profit from any potentially profitable discoveries that might be made.[487] The Committee acknowledged that researchers can speak only for themselves and others might obtain patents on related inventions but did not provide substantive recommendations for urgent changes in patent law itself.

4. Blood and bones in Native American experience

The patenting incidents with the Hagahai, the Solomon Islands and the Guaymi tribes came to public consciousness at the same time as the HGDP advertised widely its intentions to collect samples from "vanishing" indigenous groups worldwide.[488] The precedent affected indigenous perceptions about the planning of HGDP and scientists' intentions to collect samples. But there were further factors that HGDP scientists and fellow planners failed to take into account, whose proper acknowledgment in the planning of the project might have made a difference.

I mentioned previously that indigenous communities have been increasingly reluctant to get involved in genetic research ever since. Native reluctance has become part of a long-held history of colonial practices, which they see endure today, in the forms of cultural disrespect, economic exploitation, and political extinction.[489] Native efforts to repatriate human bone collections and regain control of blood samples collected for research constitutes a big part of this history. Extensive medical, historical, anthropological, sociological studies analyse how these histories impact on how native peoples come to face the prospect of involvement with further research.[490]

---

[487] [Committee on Human Genetic Diversity 1997, 66]

[488] [Cavalli-Sforza et al. 1991]

[489] [Guerrero 2003] [IPCB 2000] [Kirsch 2004] [Lock 1999] [Mead 1996]

[490] [Marks 2005, 32]

In indigenous peoples' minds, the HGDP narratives became associated with the echo of attempts for the repatriation of Native American human remains under the US Native American Graves and Repatriation Act (NAGPRA), which had just been announced the year before the HGDP was proposed. The Act was passed after a decade of strenuous and heated debates during which native groups sought to regain control of osteological repositories and sample collections of Indian human remains from museums.[491]

The possibility of native association of the HGDP as a yet another colonialist exercise given its proximity to the debates about NAGPRA, never registered to be ethically or socially relevant to scientists developing the HGDP proposal. As I mentioned earlier, commentators stress that ethical and legal considerations during HGDP planning strategy meetings were addressed rather reactively and mainly in response to concerns of external critics, and not as part of an elaborate strategy in *anticipation* of constructive and wide ethical debate.[492] Jon Marks, a molecular anthropologist who became interested early in the debate, observed that "the ties between blood and bones… were intimate", and that "one need hardly look far" to find the relevance of the connection.[493] Two bioethics scholars, Malcolm Bowekaty and Dena Davis have stressed the same point and usefully put this tension forward as:

> "[f]or centuries white people have dug up the bones and sacred possessions of native people and *used them in ways they would never have used the bones of their own people*: selling them and displaying them. Researchers

[491] [NAGPRA 1990] NAGPRA is a US federal law. It provides a process for museums and federal agencies to return certain Native American cultural items, human remains, funerary objects, sacred objects and objects of cultural patrimony, to lineal descendants, culturally affiliated Indian tribes, and Native Hawaiian organisations.

[492] [Reardon 2006] [Marks 2005]

[493] [Marks 2005, 33]

> need to be aware when they approach a tribe and ask for body parts, such as blood, hair … that *their requests will be framed by this experience*. The tribe will certainly want to know if their body parts will be treated with *respect*, who will have ultimate *control* over stored biological samples and how the tribe will be *identified* and *portrayed* in subsequent publications"[494]

These considerations are important in thinking about designing appropriate protections in that they reinforce the need for provisions that take account of these broader questions, in the search for meaningful involvement of native groups in research. I maintain that flexible terms and mutually agreed conditions are essential in order to enable groups to *trust* that the researchers will be respectful to their particular cultural, religious, historical and political concerns.[495] In designing adequate frameworks, building awareness of indigenous history and worldviews is of paramount importance.[496]

It is thus vital that researchers and science, law and ethics scholars involved in developing protections for native groups actively acquire insights into the histories and practices of what anthropologists call "colonial science"; [497] these insights can be achieved through interdisciplinary study, honest commitment, and communication with tribes.[498] In these understandings, the meanings of body parts and remains are not under-estimated; they do not necessarily denote hypersensitive indigenous cultural reactions or views;[499] on the contrary, they are highly relevant to, and

---

[494] [Bowekaty & Davis 2003, 12]

[495] On the importance of tribal approaches, see [TallBear 2001] and of agreements on conditions, see [Harry & Kanehe 2006]

[496] [Harry & Kanehe 2006] [McGregor 2007] [Tsosie 2007]

[497] [Marks 2005]

[498] These points are stressed by scholars like [Schmidt 2001, A219]; they recently have found their way into legal thinking on the matter [Tsosie 2007] but it remains to be seen how instruments can be developed to accommodate these requirements, in a systematic way. This thesis proposes a conceptual model in this direction, described in the next chapter.

[499] As, for example, the reaction of the Havasupai to researchers' activities in the recent case has been referred to by some of the researchers involved in the lawsuit [Harry & Kanehe 2006]

arguably even constitutive of indigenous beliefs as well as attitudes about research, and consequently, critical in forging trust towards researchers – and more generally towards research *per se*.[500]

5. Native research proposals in the US

Recent proposals have been suggested by native scholars to develop appropriate protections, under "culturally informed" frameworks[501] or mechanisms such as model tribal laws, with the aim to assert tribal sovereignty on indigenous DNA, for the protection of indigenous DNA material and related knowledge as ***cultural property***.[502] In the latter case, the concept of cultural property is described as a notion of cultural heritage,[503] with the authors stating that "although [they] have chosen to use the term 'property', [they] do *not* use it in a Western-law sense as something that is used for the purpose of extracting economic benefits".[504]

These notions also evoke notions of indigenous responsibility to maintain "a reciprocal relationship with the human beings, animals, plants and places with which the song, story or medicine is connected". In these proposals, cultural heritage is understood as "everything that belongs to the distinct identity of a people… which includes inheritance from the past and from nature, such as human remains, the natural features of the landscape, and naturally-occurring species of plants and animals with which a people has long been connected…" – in short, "everything that indigenous peoples have a relationship with and responsibility to show respect to".[505]

---

[500] [Sharp & Foster 2002, 180] [Tallbear 2005]

[501] [Tsosie 2007]

[502] [Harry & Kanehe 2006] [Riley 2005]

[503] [Harry & Kanehe 2006, 32]

[504] Interestingly, the authors conclude that 'indigenous peoples' cultural property can be conceived as a "bundle of *relationships*, rather than a bundle of economic rights" (my emphasis) [Harry & Kanehe 2006] citing the UN Rapporteur [Daes 1995]

[505] *Ibid.*

According to this indigenous understanding of cultural heritage, "cultural property rights are rights to property that are held communally"; "only the group as a whole can consent to sharing the property", and [property] "can never be alienated, surrendered, or sold"; "if and when it is shared, it comes *with conditions*" (my emphasis).[506]

These claims extend understandings of property beyond the individualistic 'Western' notions of property rights as rights of control over economic transactions and things in new ways. To me, these ideas seem to be forwarding two kinds of claims: a) the need for respect to cultural views and values of tribes, and b) a strong interest in the stipulation of reciprocity (in the form of conditions) in their dealings with researchers. Both of these elements are key elements in the model that I propose in the next chapter. It is very interesting to note that these interests are presented within the vocabulary of (indigenous) 'property'. In my vocabulary, these would be classified as non-proprietary, given that they seem to be more concerned with issues of identity, culture, dignity, and control of the use of material, rather than owning it *per se*, in legal terms. With my (Western) understanding of property as an individual right of control over things, I eschew any property paradigm as unfortunate but I am aware that native understandings of native property may be very different than western ones. I thus believe that further conceptual work is required in this area, to develop these discourses further, in any sustainable way.

For an example on the diversity of possible approaches, there is an interesting discussion on Navajo views on property, which describes the interplay between traditional Indian norms in the application of Navajo common law approaches to

[506] *Ibid.*

intellectual property law and genetic research. [507] According to this discussion, "a Navajo clan might not 'own' material property, [but] it 'owned' its clan members"; in the clan, "disputes among clan members are the business of other clan members". It is suggested that the clan has an interest in a clan member disposing of blood, saliva, or skin samples for genetic research, and that it is the clan which defines what kinds of such disposal are appropriate.[508]

Another model that is keen to forward property-based claims in research with native genetic material is a set of ***DNA on loan*** proposals currently formulated within some native communities in Canada.[509] They are the product of collaboration between a medical geneticist and a health policy analyst in British Columbia, working with First Nations families and communities affected by genetic conditions. The model has adopted an approach of community participatory action research in establishing three basic parameters for respecting communities that researchers should commit to: a) respect for the family or community members and their needs; b) respect for the participatory method of involvement which stipulates, among others, early and ongoing commitment to learn and value cultural, social and political perspectives of the community in research; and, c) respect for the biological samples that researchers may collect.[510] Under this model, it is proposed that samples are owned by the community (or mutually owned with the researcher) and that the community agrees with the researcher that the latter will be the steward of the DNA material, to hold and to use only for purposes designated by the community, via consent.

---

[507] [Zion 2001] cites Berard Haile, a Fransiscan priest who worked with Navajos for six decades until the 1960s, who spoke their language, has written on their property concepts and is considered a reliable source on writing about group, or rather, clan ownership.

[508] *Ibid.*

[509] [Arbour & Cooke 2006]

[510] *Ibid.*

It seems to me that this model aims to establish two key protections: i) an ongoing commitment to a collaboration that is accountable, respectful and beneficial to the community, and ii) the ability of the community to retain the power to determine the future handling and use of research. In the context of non-therapeutic research, the model has some merit. It helpfully points at the differences between medical research that is geared toward the needs of patients and the nature of prospective biomedical research where the goal is generalisable, scientific knowledge and the stakes are different. This observation raises awareness that workable approaches which are respectful to aboriginal worldviews (the topic debated in this section of the thesis) exist and they are being used widely in other research areas, such as public health or epidemiology; hopefully, then, lessons can be learned from them.

The emphasis on a *continuing*, *respectful*, *reciprocal* relationship is inspiring. It offers workable ways to incorporate opportunities for training and engaging researchers early in the research process. It furthers transparency, accountability and sensitivity in that it requires that research is tailored to community needs, benefits the community and is authorised by appropriate review structures. Hence, from an empowerment point of view (as it will be discussed in the following chapter), this approach is of significance.

While I find the 'DNA on loan' approach useful, I also find it disenchanting in that its reliance on property regimes is rather unhelpful. It is uncertain or rather unlikely that the model would be enforceable in the event of a legal challenge, since property rights to tissue sources are considered with great antipathy by the courts, and no laws have been enacted to change this situation either. The authors themselves acknowledge that "there is currently no governing body which enforces such as

concept", and also when they stipulate that the written agreement "that the DNA is on loan requires legal adherence".[511]

This makes one wonder whether the appeal to this leg of the model is no more than a metaphor, a property metaphor ('loan'), accompanied by a contract metaphor (written agreement, questionably enforceable). I believe that in the quest for viable and sustainable legal models, we need to look further than that. The question remains open as to what extent regimes that call for property rights seen as part of self-determination claims are compatible with mainstream protection models, especially since the latter do not acknowledge property rights to tissue sources.

6. The Tongan opposition to a private commercial research biobank

All the above considerations pertain to debates over control of indigenous resources for the group sources of tissue materials. These are associated with a long history of biopiracy on indigenous plant resources, where large agricultural firms make considerable profits without rewarding or sharing them with these communities.[512] As it was already indicated on a few occasions in this chapter, concerns about appropriation of native resources are pervasive in indigenous scholars' writings. It is no surprise that such concerns found their way in indigenous reactions to biobanking project proposals as well.

An example of a biobanking project proposal which was met with criticism, and ultimately failed, was the case of the Kingdom of Tonga. The quote below is characteristic of a cynical stance that indigenous activists adopted at the time:

[511] [Arbour & Cooke 2006, 156]
[512] [Fraboni & Lenzerini 2006]

> "Existing intellectual property right laws favour those with the technology, the expertise and the capital. All we have is the raw material – our blood. We should not sell our children's blood so cheaply"[513]

The quote refers to a 2000 proposal by Autogen Ltd., an Australian-based biotechnology company (now part of ChemGenex Pharmaceuticals Ltd, Geelong, Victoria, Australia) to build a gene database in Tonga Island, by collecting tissue samples for genomics research into the causes of diabetes, which affects about 14% of the Tongan population, in Polynesia. Autogen was interested in developing drug research on the genetic basis of diabetes; they offered a package of benefits to the Tongans, which included free provision of drugs from future discoveries, annual research funding for the Tongan Ministry of Health, royalties from any commercially successful products that would be developed to the Tongan government, and building a research laboratory next to a government-owned hospital.[514] According to commentators, Autogen planned to offer Tongan authorities a profit-sharing deal for drugs that would be developed from this research, while the database would "remain Tongan property".[515] Autogen's plan was to also negotiate similar deals with other Pacific nations to allow for genetic studies of the entire Polynesia.

Despite the seemingly worthwhile benefits, the proposal faced fierce protests in Tonga and neighbouring countries, with the collaboration of church leaders with human rights groups, a) on grounds of insufficiency of individual informed consent to function within Tongan family decision-making structures, but also b) upon realisation that Autogen stood to gain much higher venture capital profit whether any drug therapies were developed or not.[516] In Tonga, extended family groupings (*matakalí*) determine whether individual members are permitted to give consent, in

---

[513] [Dickenson 2005, 45]
[514] [Pálsson 2007, 102]
[515] *Ibid.*
[516] *Ibid.*

that genetic research implicates family genetic make-up. This makes the rights of extended family groupings and the value of intra-generational relationships important in Tonga. This is why individually-based consent was deemed inadequate.[517] Furthermore, this indicated a discord between concepts of individual genetic property and notions of shared economic and cultural assets which are integral to Tongan society. The Tongans saw that the promised royalties and provision of therapeutics "were prefaced by a huge 'IF'".[518] In 2002, Autogen announced that it no longer had any immediate interest in Tonga and that they would concentrate resources into investigating the Tasmanian population.[519]

Commentators have wondered whether, had the benefits agreement been designed better and had consent provisions been tailored to meet the extended Tongan family needs, the project would have taken a different course.[520] Would the project still go against fundamental Tongan values? According to their cultural values, it is "inconceivable" that some person or company or government could own property rights over a human person's body or parts thereof; scholars have pointed at comments by Tongan governmental officials saying that, to do so would be against notions of dignity of the human person; dignity is derived from "whoever the Tongans believe to be their Creator", as human tissue materials would be considered living tissue and thus imbued with life force ("*mauri*") and sanctity of the person ("*tapu*"), not to be violated.[521] Yet one wonders if any kinds of balancing could have been proposed in order to justify the health benefits of the proposed research, in that they would enrich and thus respect Tongan's spiritual values, and not diminish them.[522]

---

[517] [Kegley 2004, 835] [Senituli & Boyes 2002]

[518] [Senituli & Boyes 2002] and see also [Dickenson 2005, 45]

[519] [Burton 2002b]

[520] [Dickenson 2005, 47] [Dickenson 2007, 167-170]

[521] [Dickenson 2005, 47-48]

[522] [Dickenson 2007, 170]

The ways of property do not seem to indicate a viable way forward in developing group protections in controlling research. What other models exist? Perhaps a model that is tailored to the *will of the parties*, who would then be seeking to ensure better influence or control in research, could secure flexibility in group collaborations with researchers, with the development of agreeable conditions and limitations.[523] On what basis would these be agreed? Might the outcome depend on the initiative and organisational capability of the group? In the next section I discuss whether such a model, as part of models seeking to establish new forms of group *contribution* are a better basis for group claims about influencing research than property is – or not.

B. The advocacy model

1. Introduction

As it has already been discussed on several occasions, the realisation that genomic research is *collective* research which does *not affect just individuals* has led to increasing proactive attempts to develop protections for groups.[524] Emerging interest in patient group activities is nurtured by strategies to encourage participation in the interest of science, paired with efforts to cultivate a climate of willingness and trust towards research;[525] practical approaches to promote particular group interests by means of influencing the direction of research, via active contributions by groups and the development of group resources. These raise questions of how group control over those resources as well as the relevant research outcomes will be secured.[526]

---

[523] [Nelkin & Andrews 1999]

[524] e.g. [Knoppers 2000b] [Merz 2002] [Weijer 2000] and see discussion in chapter two.

[525] [Chadwick & Berg 2001]

[526] [Anderlik & Rothstein 2003] [Merz 2002]

Many of these initiatives are tailored to the needs of particular groups. They reveal innovative thinking and help further reflection on the nature of group protections *in toto*, and the development of conceptual models for group *empowerment*, which are central for this thesis. In the following part, I discuss how research has been facilitated and accelerated by advocacy groups with the *creation of resources* and the *negotiation of conditions* to establish group influence in the management of research.

2. Patient advocates and their interests

Patient advocacy groups nowadays organise themselves in supportive clusters of disease families to steer research towards the identification of particular disease genes.[527] The first patient support organisations for genetic diseases appeared in the late 1960s to provide emotional and social help to affected patients and families. These initiatives were encouraged by a pre-existing culture of patient support groups that had been forming in the US since the 1930s, inspired by an ethos of "self-reliance, familiarity, informality and pioneer mentality".[528] Over time, they developed into organisations aimed at providing more than psychosocial sustenance, between the 1970s and early 1990s, by starting to work together with scientists towards the identification of genetic markers.[529] It was not until the mid-1990s that family advocates started to seek to initiate and fund research.[530]

By the late 1990s, new forms developed with focus on catching researchers' attention as many of the rare diseases that affected patient group families were not attracting the interest of national funding agencies neither of private biotechnology or

---

[527] E.g. Cystic Fibrosis Foundation, Tay Sachs and Allied Diseases Foundation, PXE International, Consumer Advocacy Genomic Health Inc. [Terry 2007, 158]

[528] *Ibid*.

[529] E.g. Hereditary Disease Foundation for families affected by Huntington's disease [Terry, as above]

[530] E.g. AT (ataxia telangiectasia), Children's Project Chromosome 18 Registry and Research Society [Terry, as above] For notions of support and professionalism in the definition of advocacy and related pressure group activism, see [Boyd, Higgs, Pinching 1997, 8 and 195-196]

pharmaceutical industry. The new model of advocacy group combines the pursuit of progress in basic genetic science, epidemiological and clinical studies – via ongoing cooperation of families affected by a particular disease – and the facilitation of development of technologies and access to treatment for those families. Their approaches to translational research include the pathway from research on the genetic basis of a rare disease to the pursuit of prognostic, diagnostic and therapeutic strategies of direct benefit to patients. Thus the primary agenda of current alliances is the acceleration of research and its translation to new therapies for patient families.[531]

Key advantages of these groups are their ability to engage large numbers of patient families in research by tracing affected families, organising the collection of health data and samples in disease registries and tissue banks, developing close collaborative relationships with academic science and industry researchers and taking risks in translational research. Advocacy groups operate as *gatekeepers* and make decisions about which researchers may get access to affected people, by fund-raising, funding research and organising research workshops, or by networking with other volunteer groups.[532]

Their appeal to both researchers and policy makers is manifold. By identifying and providing access to affected families, securing data and samples, sharing the costs of research, developing research resources and clinical outcomes, advocacy groups greatly facilitate both research and its translation to healthcare.[533] They increase credibility and trust towards researchers who commit to collaborate with them; and they encourage public confidence in the capacity of genetics to improve human

---

[531] [Rajan 2006]

[532] *Ibid.*

[533] For a chronological table with examples of advocacy organisation achievements see [Terry 2007, 159] Major achievements include research consortia, sample collection, donor registries, clinical databases, biorepositories and tissue banks, gene discoveries, gene tests and testing programmes, clinical trial networks and clinical trial recruitment, among others.

health.[534] Numerous examples of advocacy groups now provide valuable resources for the realisation of studies that may not have otherwise been possible.[535] Their role is increasingly valuable as they become essential in encouraging research on rare diseases, fostering alliances and accelerating provision of therapies.[536]

More recently, advocacy activities have evolved further into the formation of coalitions of several patient organisations worldwide and contribute to centralised biorepositories, and help maximise training, research and funding opportunities, in the search for positive health outcomes for people affected by rare diseases.[537] Commentators – including advocates themselves – have highlighted the increasing role of advocate groups as innovators.[538] Undeniably, the new breed of advocacy groups uses a variety of strategies in promoting research and accelerating the possibility of therapies for their members. These can be summarised under the following five strands of activities:

a) *coordination* of families (community engagement)
b) ongoing *engagement* with scientists
c) creation of *resources* throughout the research process and its applications
d) *negotiation* of conditions with partners at the outset of collaborations
e) pursuit of *joint intellectual property* rights with laboratories and industry

Many groups followed the model that PXE International pioneered, by setting up representative structures, blood and tissue banks as first step, maintaining member

---

[534] For a comparative example from UK, see GIG (Genetic Interest Group)

[535] E.g. Canavan, PXE International, NAPE, Alpha-1, DebRA International [Rajan 2006]

[536] *Ibid.*

[537] For example, the Genetic Alliance Biobank founded in 2003; interestingly, the three mandates of Genetic Alliance, a coalition of over 600 disease advocacy organisation, are advocacy, education and empowerment [Genetic Alliance website]

[538] [Rajan 2006] [Rose & Novas 2002] [Terry 2007] [Terry 2003]

databases, establishing registries and biorepositories, providing research infrastructure, funding and coordinating research, contributing to gene discoveries, testing and clinical trial recruitment, to name a few.[539]

In the words of one of the protagonists of PXE International:

> "… [e]arly on, [we] knew that there was a need to incentivize research into PXE by *leveraging the available resources*. It seemed that this would be best achieved by establishing a community,[[540]] developing a commodity through this community,[[541]] making the foundation an essential part of the academic enterprise,[[542]] and aiming towards the industrialization of a treatment or technology, with the goal of improving the lives of affected individuals…"[543] [emphasis added]

The initial creation of the community was achieved by the use of language that allowed affected family members to share their experiences and no longer feel alone in the way that patients with rare disorders can be. The process of becoming engaged was not reduced to the use of informed consent but instead it involved an informal decision-making process tailored to engage with individual patient needs, who in return donated samples and necessary related medical record, health questionnaire and longitudinal data. Their first step was the PXE International Blood and Tissue Bank, then the formation of the PXE International Research Consortium, the creation of memoranda of understanding with scientists, member engagement with bench science as research team members and assistance in gene and gene mutations discovery.

---

[539] [Terry 2007]

[540] [Terry 2007, 160]

[541] Their first step was the PXE International Blood and Tissue Bank.

[542] With the formation of the PXE International Research Consortium, the creation of memoranda of understanding with scientists, member engagement with bench science as research team members and assistance in gene and gene mutations discovery [Terry 2007]

[543] *Ibid.*

PXE International evolved from the concern of determined parents who acted not only as advocates but also as mentors for advocates for other conditions.[544] They adapted their practices to the needs of the families they represented, by establishing an active multi-cultural membership, an international research consortium and internationally networked patient support offices, a patient registry, a biobank, and by actively working together with researchers, eventually to become gene co-discoverers and joint intellectual property inventors.[545] In late 2003, one of the founders of PXE International during an international conference in Canada advised that the skills required for them to succeed and the strategies which worked best were 'commitment, strategic planning abilities, organisational skills, ability to understand the *ambient milieu* [which helped build] a unique international alliance of interested persons'.[546]

I discussed earlier the case of another advocacy group who gained jurisprudential attention in the early 2000s, the *Greenberg* case (Canavan Foundation). They had the commitment, planning and organisation skills but they failed to understand the *milieu*; as a (partial) consequence, the property claims – including intellectual property – that the Greenbergs forwarded were rejected by the court. As it was discussed earlier, intriguing comparisons can be drawn between the ways in which the Greenbergs and PXE International (the PXE) went on about building their communities and shaped their activities respectively. These highlight the differences in their outcomes, when looking at how each group worked towards acquiring the necessary information, seeking cooperation with members or external partners and pursuing ways to translate 'their' research to affordable therapies for their members.

[544] [Terry 2003, 377]
[545] [Rajan 2006, 194-196]
[546] [Terry 2003, 377]

Commentators have commented that "the Canavan experience [wa]s perhaps an extreme example of what can go wrong with patents and medicine".[547] Certainly the Greenberg case seems to suggest that patient groups should be "more *aggressive*" in pursuing collaborations with researchers by negotiating and retaining rights, including IP rights, in order to ensure broad and availability of diagnostic tests and therapies.[548] The next section offers a closer look at the merits of advocates' different *modus operandi* in these cases.

3. Patient control and 'entrepreneurship'

Was the PXE a unique and 'miraculous' international alliance of interested persons, or rather an intelligent consumer management and business model?[549] Or is it both? Early while setting up the International PXE research consortium, the PXE advocates agreed memoranda of understanding (MOUs) with researchers which allowed them to work together, without sacrificing funding and publication advantages.[550] The terms of the MOUs were in fact research collaboration agreements and included terms on:

a) what constitutes *acceptable uses* of sole and joint data and materials
b) the use of particular *material transfer agreements* (for biological or other relevant materials, chemical compounds and software)
c) clear *authorship* and *acknowledgement* procedures to be decided *well before* the research commences and the manuscript is written
d) specific *timelines* for public release of newly generated data and materials

---

[547] [Merz 2002, 111]; see also [USA Today 2003] quoting the case as a "tale of successful research collaboration gone sour", "a bad example of the way not to do it", highlighting persistent problems in diagnostic tests being tied up against the interests of patients when exclusively licensed. See also "[t]his case is the ultimate nightmare of how a gene patent can be used against the very families who made possible the discovery of the gene" [Gorner 2003]

[548] *Ibid.*

[549] [Rajan 2006]

[550] [Rajan 2006] [Stockdale & Terry 2002] [Terry 2007, 160-161]

e) detailed description of research projects, *role* and *responsibilities* of each party
f) criteria for *intellectual property* co-authorship and co-inventorship, payees of patenting *costs* and *future licensing* negotiations determined *upfront*[551]

The MOUs were used as platforms to ensure clear understanding of the parties' commitments and to agree common lines of action. The rights that the PXE became entitled to included patent ownership rights in applications that arose from that research, profit shares in revenue generated by inventions, and crucially, the rights to ensure and to control broad and affordable availability of genetic tests that might be developed and rights to influence future licensing terms on them.[552]

The PXE did get to be named as co-inventor in the patent that was obtained for the *ABCC6* gene and its mutations that cause PXE.[553] Commentators on the case discuss that when the gene for PXE was discovered by collaborating researchers at the University of Hawaii, the technology transfer unit at the University of Hawaii was initially reluctant to yield patent rights to PXE International. But, as the PXE had already negotiated the terms and conditions of access to their blood and tissue bank, in addition to one of their founders being named as a co-inventor, they were able to make an arrangement with the University to share royalties and to be able to have a say on licensing deals. They managed to ensure that any medical treatments for the research would be affordable and accessible to PXE patients.[554]

[551] [Terry 2007, 160]
[552] [Bovenberg 2004, 7] [Gitter 2004, 317] [Terry 2007, 160]
[553] [Marshall 2004, 1226]
[554] [Fleisher 2001] [Rose & Novas 2002]

The founders of the PXE were awarded inventorship and were named co-inventors on the patent because they had *participated materially* in that discovery.[555] They assigned their rights to the PXE foundation, together with the scientists involved in identifying the gene. The PXE considered the organisation to be the *custodian*, or *steward* of the gene, in direct representation of the interests of the PXE families towards moving from the gene discovery stage to commercialisation for diagnostics and therapeutics.[556] So, as one of the two PXE founders put it, "with a gene patent and a myriad of peer-reviewed publications authored, PXE International is in a position to *require that the research enterprise serves the paramount stakeholders, individuals with PXE and their families*".[557]

Interestingly, in pursuing these strategies, the PXE adopted a proprietary language and aggressive negotiation practices, mirroring the way innovation and market relations operate. Patrick Terry contended in 2003 that the US patent law is robust and a more than sufficient vehicle for a "rational approach", which clashes with advocates discussions in the *Greenberg* deliberations.[558] The PXE advocates adopted a language that was aware of healthcare financial management and called their approach a model of "disruptive innovation", "similar to changes in the marketplace that redefine solutions, pushing to accelerate the research enterprise beyond its usual pace and involving new players, the advocates".[559]

I mentioned earlier that several commentators consider the PXE agreement model to imply that PXE and its members possess a property right in their biological material. I understand the PXE model as a *hybrid* model for advancing research. It adopted

---

[555] [Fleischer 2001] [Smaglik 2000] [Spier 2001]

[556] [Spier 2001] [Terry 2007, 161]

[557] [Terry 2003, 377]

[558] [Terry 2003, 377] *cf.* [Merz 2002, 111] [USA Today 2003]

[559] [Terry 2007, 160] – An online commentator and patent lawyer swiftly called the PXE approach as a "do-it-yourself patenting" [Fleischer 2001]

aspects of a) academic models of rigorous science, b) commercial business (with commodification and accountability), and c) advocacy organisations (trust and agility) in establishing and maintaining ongoing cooperation between its partners.[560] It is an innovative model also in that it has led to establishment of a common infrastructure and mentoring schemes that enable patient groups to initiate, conduct and accelerate research, and it established itself as a replicable model, in that context.[561]

So, why did Canavan fail and why did PXE succeed? The PXE developed strategies to control their interaction with their partners and its outcomes proactively, by learning the market, and by materially contributing to the research discovery process.[562] The advocates prepared long term planning strategies early and organised themselves in ways that enabled them to stay informed and to control their activities at all stages of their engagement with their research *partners*. They adopted a *community-based facilitative* discourse together with an *entrepreneurial* approach.

The PXE claim that they were not in knowledge of the earlier problematic outcomes of the *Greenberg* experience. They have stated repeatedly that they were not aware

---

[560] [Terry, as above] and compare with criticisms in [Rao 2007] on contract and property being the two sides of the same coin, see discussion later in chapter five, under contracts.

[561] For example, elements of the PXE International model were successfully incorporated in the case of CFC International (cardiofaciocutaneous syndrome) in collaboration with the Genetic Alliance BioBank which eventually led to the stage of establishing clinical trial testing on the Costello syndrome [Terry 2007, 162-163]

[562] According to PXE spokepersons, the PXE did not negotiate for inventorship – contrary to bibliographical accounts that I came across in several publications; they met the inventorship requirement under US Patent Law which does not allow for negotiating. Inventorship is strictly defined by the patent statute, (U.S. Code Title 35) as one "who makes a contribution to the subject matter of the claims of the patent". Sharon Terry obtained the co-inventorship by *participating materially in the research* [Ducor 2000, 873]. In 2003, during a speech at a meeting on benefit sharing at the University in Philadelphia, Sharon Terry stated, interestingly, that "we don't believe [that]

of earlier cases when they conceived their own approach to property rights, that they had actually crafted their agreements before the Canavan case surfaced, that they did not know anything about these Canavan activities.[563]

A few years earlier, the Greenbergs had been actively involved in collecting samples and resource building, with combined efforts of Canavan families and support foundations to create a tissue registry and organise community outreach and testing activities. They operated within a more traditional framework, under the assumption that the researchers involved in their project shared common goals with them. They were unfortunate in that they *did not negotiate in advance* with the researchers they approached; it was more unfortunate that the relevant institutional review boards (IRB) were not able to protect their interests. They did not sign consent forms at the early stage of sample collection (the researcher just sent out Guthrie cards) between 1987 and 1994. It was only upon the families' request in 1994 that the suggestion for a consent form to be used was given to the researcher, who by then was employed at the Miami Children's Hospital. The hospital IRB approved the research with an express waiver of informed consent.[564] These details are necessary in order to give a more comprehensive view of the case and its particular circumstances.

Interestingly, Jon Merz discusses that the Canavan families were "uninformed" and that they became "dumbfounded" when the hospital sought the patent over the genetic test for the Canavan disease.[565] Arguably, their circumstances might have had a different turn, had they sought to negotiate an agreement, in advance of any

---

contributions of samples… entitle anybody to inventorship…" seeking to confirm why the PXE obtained the joint intellectual property rights with the Hawaiian researchers [Terry 2003]

[563] [Stockdale & Terry 2002, 95-96] [Terry 2003]

[564] [Merz 2002, 112]

[565] *Ibid.*

research collection, and had the research been conducted accordingly (e.g. consent was not sought before collection).[566]

In the absence of unambiguous clarification of the law in ways that recognise increasing research participants' concerns, the difference between the entrepreneurial model of PXE International and the *less informed* Canavan families influenced significantly their role-taking and role-making as advocate activists and support networks. It was rather unlucky for the latter that they were hardworking yet uninformed agents conflicting with corporate university managers, whilst the former (the PXE) succeeded in engaging in fruitful collaborations with researchers as proactive and informed patient-managers.

The law system should not leave such matters to 'luck' or to the market alone. The fact that the PXE model operated, to some considerable degree, on the basis of business and commercial strategies might signal that group participants are starting to realise that *the traditional notion of gratuitous altruistic participation in research needs to change*. The fact that it succeeded in safeguarding and promoting the interests of its members made this model a basis for the activities of other groups. It is imaginable that such groups could increasingly act similarly to business and commercial entities in establishing licensing policies. But then, the concern has been expressed that patient advocacy groups might exercise control over 'their' research results in such a way as to maximise their own benefit, while limiting access to these results to people suffering from other disorders, and a similar argument has been forwarded at the level of patient advocacy groups lobbying for funding for the National Institutes of Health in the US. [567]

[566] [Gorner 2003] [Merz 2002, 112]

[567] [Bovenberg 2004, 16] [Gitter 2004, 323] and see also the relevant discussion in chapter five.

The PXE has asserted that their goals with regard to patenting and licensing are "to facilitate useful, timely treatments and to make all tests and treatments accessible and affordable",[568] and that they will "resist bettering off their own fortunes at the expense of patients suffering from other diseases". It is not clear whether this may in the future clash with their prerogative to "insist upon licensing deals that would maximise the access of PXE patients to a future diagnostic test or treatment".[569] The argument could go on and on, until "we might all end up having to swap licenses and set off royalty payment before consulting our physician" as Jasper Bovenberg eloquently puts it.[570]

Still, in view of the approach that the PXE is advocating at present, a good argument in their favour is that they already managed their way through their own mini-anticommons, and they already faced the problem successfully. They have avoided wasting their commonly held scarce resource – that is, intellectual property rights on gene tests developed through their collaboration with researchers – by under-consuming it when compared with a 'social optimum'.[571] To clarify, the notion of the anticommons was developed as a mirror image of commons property by economy theorists. The tragedy of the commons occurs when multiple owners are given the privilege to use a resource with no one having the right to exclude another, and the resource gets overused and exhausted. The tragedy of the anticommons occurs in situations where multiple owners hold rights of exclusion in a scarce resource and they can block its use. In the field of biomedical research with the proliferation of patents on gene sequences and database rights in genomic databases, rights of exclusion bear the danger of blocking, restricting or delaying access to healthcare innovations.

---

[568] [Stockdale & Terry 2002, 95]

[569] *Ibid.*

[570] [Bovenberg 2004, 16]

[571] [Heller & Eisenberg 1998, 698-701]

Political economists and anthropologists studying shifts in the dynamics of postgenomic economies and the generation of biovalue have started to develop theories about the agency and impact of advocacy groups as innovators; they refer to advocacy stories as "stories of miraculous therapeutic intervention", facilitated by the construction of new "networked biosocial communities", through forces of "consumer genomic revolution".[572] From a legal viewpoint, despite the fact that such organisations accelerate research and therapies for rare diseases considerably, there is some way to go towards developing models that can help solve regulatory problems in controlling the use of resources, with long term certainty. These problems include questions on what would apply to groups who do not have the resources, information or capability to upgrade themselves as joint inventors or equivalent collaborators.

The *Greenberg* case and the PXE model are very interesting examples in analysing current views on whether groups can have control of resources, the degree of control that they should have, and whether the basis of their claims can legitimately lie on property. The challenge of regulating the interests of all relevant agents, i.e. patients, families, researchers, research-funders, investors, clinicians, and society as a whole, has not been met yet so as to eliminate potential conflicts. The PXE model agreement has not been challenged in court so far. If the agreement is ever challenged in the future on the ground that the members do not have a property right in their removed material, it would be intriguing to see what the US courts would adjudicate on the group's entitlement to control and to profit from uses of that material or subsequent research derived from it.

One thus wonders whether contractual agreements and property rights are the optimal way to go about protecting group interests, and solving persistent control dilemmas, as conflicts of such nature are likely to increase. This is why novel approaches and regulatory models are needed, in order both to meet the needs and

[572] [Rajan 2006, 193-194] [Rose & Novas 2002]

values of such groups, but also to reconcile these with state ability to exert some degree of control over their activities.

4. A new basis for group protections?

A conceptual basis is needed for the development of group protections, instead of compartmentalised approaches. While it is important to maintain awareness of the specific needs and capabilities of particular groups, this cannot happen in isolation of the articulation of general principles to enable a consistent approach in the regulation of the use of human biological material in research. It is only through the development of such conceptual frameworks that the need for certainty, fairness and cooperation can be accommodated.

The previous sections discussed that property and contractual agreements are not the optimal means to generate conceptual solutions but rather technical tools to be applied in respect of the will of the parties. Participants as parties are traditionally viewed primarily as individual agents rather than members of a whole. In current developments, agents tend to act on the basis of logic of 'let the market decide' but, the market does not take personal, cultural and ethical considerations into account when focusing on commercial, proprietary managerial models. One could argue that the story of the *Greenberg* case was an example of the failure of the market to provide an equitable answer in the conflict that ensued. The proprietary approach of the hospital managers to the conflict may have been inadvertently enabled by the ignorance (or naivety) of participants, but was also furthered by the absence of a principled legal backbone to protect participant contributors.

Would the collaboration have had a happier end for the Greenbergs, had they negotiated in advance? Maybe yes but maybe not. There is no precedent of a test case, the influence of the *Moore v. Regents of the University of California* case aside, nor can one predict with safety how the PXE model may last in the future, especially

if a party challenges advocates with a lawsuit – in this or in any other case of patient groups under the PXE model.

An important difference to consider in this context is the difference between models based on contract and models based on membership or a common connection. There exists a conceptual and practical distinction between the interaction of contractual parties who act as diverse parties with different ends, and cooperation on the basis of membership created in line with a common connection and common pursuit of goals, as part of ongoing relationships.[573] According to philosophical work on group membership theory, duties of connection derive from one being part of something with which they partly identify, e.g. one's family, profession, nation, and within which they develop and define oneself, by sharing common assumptions and beliefs over time; in duties of 'contract' on the other hand, there is no intrinsic connection between contracting parties.[574]

In the advocacy cases examined above, the differences seem blurred. For example, the reliance of the PXE on negotiation may render their model as a *prima facie* contractual model, but, closer consideration reveals that their model could also be understood as a model of connection. The PXE advocates strategically sought to define their roles early in their partnership with researchers; but, at the same time, the PXE helped to bring patients to meetings with lab scientists, and vice versa, they invited researchers to patient family meetings. This reportedly gave scientists the opportunity to understand more deeply the reasons for their work and it enhanced their motivation to work on PXE.[575] On this basis, it is reasonable to argue that PXE advocates used narratives of community-building, which, in turn, are genuine elements of the membership (or common connection) theory. These strategies

[573] [Smith 2001, 176]

[574] *Ibid.* – These views connect well with theories on the use of reciprocity to enhance and maintain ongoing collaborative relationships, as I propose in chapter five.

involved emotional commitment-building towards researchers, early on and during their collaboration with advocates. Such community-building narratives are an intrinsic part of strategies used in the advocacy hybrid approach. They aim precisely to strengthen partners' attitude towards a common-minded ethos and common pursuit. This phenomenon shows an interest and shift in emphasis towards defining not only the roles of the parties involved in research, but the nature of their relationship.

Current approaches in the regulation of the use of human biological materials in research are not foreign to discourses of community-building, albeit in the other way round. For example, existing UK guidance on the use of human biological materials in research proposes a soft version of 'connectedness', in current references to 'altruism' and 'genetic solidarity', as central to understanding the motivations for research participation.[576] Parallel to the fact that these concepts in favour of free donation are being forwarded by advisory bodies, the courts tend to ignore notions of patient synergy and empowerment by contrasting them with concerns about no hindrance of medical research. The irony with the *Greenberg* case is that the patients were the ones who wanted more research done in the public domain, and the University the one who wanted to hinder such access.[577] In light of these ambiguities, it is therefore paramount to consider novel ways to understand the nature of the research relationship between group members and researchers and define how this relationship could be viewed in law.

So, instead of a property model, in the last part of my thesis I will propose a conceptual model, based on the need to foster the 'common connection' between participants and researchers. While I find the hybrid model of advocacy attractive at

---

[575] [Terry 2007, 160]
[576] [HGC 2002]
[577] [Rao 2007]

first instance, I suggest that a more systematic way is needed in order to examine viable mechanisms and to institutionalise effective empowerment models for groups. I maintain that there can be no empowerment if such models do not take account of the participants' needs within their multiple cultural and economic contexts, wherein research inevitably takes place. Further discussion on this is presented in my last chapter, where I propose a new principle of 'group empowerment'. Under such a model, the research relationships are maintained by *conditional*, *reciprocal* gifts, as *returning favours* to all partners. This model draws on notions of engagement, common pursuit and interdependence of the parties involved. But first, it is necessary to examine the advantages of another recent approach, the benefit sharing model, as a model which has conceptual rigour, but lacks in technical application. My interest in this model stems from its emphasis on benefits as a possible way to redress the balance in the power dynamics between researchers and group participants.

V. The push for benefit sharing

A. History

As discussed briefly in earlier chapters, the application of the concept of benefit sharing in human genetic research was first proposed in the early 1990s. In 2000, building on discourses in search of paradigms that could promote notions of human sharedness and solidarity, especially towards disadvantaged populations in developing countries, a first set of principles for benefit sharing were developed.[578] With references to international statements and documents in support of 'justice

[578] [Knoppers 2002b] [HUGO Ethics Committee 2000]

considerations towards vulnerable groups in research, consensus emerged that a principle was needed for some form of *benefits* in research.[579]

In an article published in 1999 discussing 'remuneration' opportunities for participants in genetic research, Bartha Knoppers called for "a more equitable approach that provides *some return of benefits to the community*"[580] [emphasis added]. Following statements by the HUGO Ethics Committee in 1996, the WHO in 1997 and the 1997 UNESCO Declaration on the Human Genome, who called for international and scientific co-operation, solidarity and humanism in biology, medicine and healthcare research, in 2000, the HUGO Ethics Committee suggested a set of principles for benefit sharing to become part of normative frameworks towards achieving some distribution of genetics research benefits to developing countries.[581]

These principles called for acknowledgment of the participation of individuals and communities in research and were based on the recognition that the human genome is part of the common heritage of humanity; that there exists a diversity of human communities; that precedents for benefit sharing existed in other areas (e.g.

---

[579] Few commentators consider these attempts as ways to introduce notions of 'exchange relationships' in the research context; this is open to interpretation [Haimes & Whong-Barr 2004, 69] – Dickenson comments that advisory and policy-making bodies in recent years are turning their attention to ways for strengthening the rights of 'vulnerable' individuals and populations, precisely because of the gaps in the common law that leave property in the body a "confused and confusing concept"; she criticises attempts to rectify current *power imbalance* between researchers and participants primarily by revising consent provisions, as focussed more on procedure rather than substance [Dickenson 2004, 111]

[580] [Knoppers 1999, 24]

[581] [HUGO Ethics Committee 2000] – Interestingly, the WHO Guidelines stated that "[i]f genetic information that results in a patent stems from a *family* or *ethnic group* with a particular variant or disease, there is an *obligation in justice* that donors should receive some benefit or return" [WHO Guidelines 1997]

agriculture).[582] They included a mandate that genetic research should foster health for all human beings, considering health to be a common good to which we all owe each other a share.[583]

In accordance with these prerogatives, HUGO further suggested that benefit-sharing arrangements be planned in discussion with the population involved, e.g. on what potential benefits the population can expect from research and how these can be shared fairly. Prior consultation with the population would be needed to help tailor the benefit-sharing plan to the population's needs and cultural values, as the plan cannot be drawn in the abstract – equity considerations must prevail while making arrangement for the distribution of benefits to the whole population (not only to the participants).[584] At the end of the Statement, the Committee suggested that "profit-making entities dedicate a percentage (e.g. 1% - 3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts" seen as a "*minimal moral guideline* to encourage companies to become good global citizens" in recognition of the need to redress *inequalities* of power and wealth between biotechnology companies, and research participants as possible justification for benefit sharing.[585]

---

[582] E.g. Rio Convention on Biological Diversity (CBD) 1993, FAO International Treaty on Plant Genetic Resources for Food and Agriculture 2001

[583] [HUGO Ethics Committee 2000]

[584] [Cardinal & Deschênes 2003, 61] [Knoppers 2000b, 49]

[585] [HUGO Ethics Committee 2000] – the six recommendations of the Committee were that:

(1) all humanity share in, and have access to, the benefits of genetic research;

(2) benefits not be limited to those individuals who participated in such research;

(3) there be prior discussion with groups or communities on the issue of benefit-sharing;

(4) even in the absence of profits, immediate health benefits as determined by community needs could be provided;

(5) at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation;

(6) profit-making entities dedicate a percentage (e.g. 1–3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.

The HUGO Statement provided a set of non-binding recommendations to frame the main components of the concept. The authors were influenced by notions of resource sharing in other areas such as the CBD; the CBD has excluded human genetic resources from its scope, and there exists no legally binding framework for an international (or national) legal requirement of benefit sharing in human resources today.[586] The recognition of the importance of prior discussion and consultation with participant communities was not a new idea; a number of theories on community consultation and dialogue had been developing in the aftermath of the unsuccessful Human Genome Diversity Project, by researchers with anthropological expertise, working with population epidemiological studies[587]. The attention of benefit sharing scholars turned into the development of ways to get to grips with the concepts of 'benefit sharing' and 'common heritage of mankind', rooted in notions of 'justice' and 'fairness' that are hard to specify.

B. Justification

The concept of the genome as the common heritage of mankind was influenced by international agreements on the law of the sea and laws on celestial bodies in the 1970s and 1980s.[588] In the context of benefit sharing for human resources, there exist multiple justification models for sharing. I will refer to the four options that I find most appropriate, as proposed by a philosopher who has been working on benefit sharing agreements with Sub-Saharan tribes:[589]

- The results of human genetic research provide sufficient benefits for researchers, participants and the public at large (no further rewards)

[586] [Schroeder 2007, 205]

[587] E.g. [Morris & Foster 2000] – These were discussed previously in chapter three on 'Consent for Groups in Genomic Research'.

[588] [Bovenberg 2006] [Ossorio 2007]

[589] [Schroeder 2007, 205]

- Donor participants who cannot benefit directly from genetic research qualify for some form of additional benefits, whereas donors who benefit directly do not (e.g. clinical trial participants)
- All donors qualify for additional benefits (e.g. because of the risks involved or because their property is being used)
- Altruism is the guiding principle for participation

Current benefit-sharing practices tend to be characterised by a combination of the first and last considerations, with emphasis on altruism and pursuit of health as common good. Yet the second and third scenarios are of great relevance for this thesis, and examples of relevant control claims have been discussed, due to continuing imbalances between the recognition of donor interests in rewards and benefit distribution.

The ethical justification for sharing is derived from philosophical and legal considerations of fairness, equity and justice as asserted in international declarations and guidelines.[590] There is an intuitive appeal in such notions and policy actors became interested in developing benefit sharing mandates.[591] An attempted definition could be that, benefit sharing is the giving of a portion of advantages to derive from the use of human genetic resources back to donor sources, who contribute to the research enterprise with no undue inducement. From a procedural point of view, there may be two main ways to view benefit sharing; as claim of *universal* nature in the interest of humanity, or, as a *technical* compensatory tool.[592] The first is a conceptualisation of benefit sharing as a *redistributive* normative framework to

[590] E.g. [HUGO Ethics Committee 2000] [UNESCO 2003] [UNESCO 2007]

[591] For example, in Canada, the Network of Applied Genetic Medicine of Québec used notions of equity in formulating guidance for the ethical conduct of human genetics research involving populations: "[f]or the sake of equity, population research should promote the attribution of benefits to the population" [Cardinal & Deschênes 2003, 61]

[592] [Bernier et al. 2004]

achieve equitable distribution of the benefits to society – on the basis that justice should protect the neediest and the most vulnerable, this is particularly appealing to organisations such as the WHO or UNESCO.

An example of a *compensatory* claim is the *Greenberg* case, which I presented before and in particular the plaintiffs' claims against being excluded from the intellectual property rights on the Canavan gene and testing even though they had contributed considerably to the discovery, while the hospital could exploit patent rights and charge royalty fees. Under a specific benefit sharing arrangement, they might have both claims, depending on the model adopted overall; a claim for Canavan patients to be tested free of charge; a claim for them to be recompensed for contributing to the research; or both. Yet, as discussed in the previous section, it still difficult to give compensatory claims a normative basis in spite of the intuitive attractiveness of the idea of one's proportionate recompense for one's contribution.[593] This is why in the next chapter I propose a new approach to help acknowledge group contribution and award significance in maintaining research relationships long-term on the basis of rules of reciprocity.

C. Benefits and ethics

A number of studies are seeking to specify the main elements of benefit sharing,[594] and more recently, to transfer the principles into practice.[595] These developments raise a lot of issues, worth considering in a separate thesis alone, including:

- What are the benefits?

[593][Castle & Gold 2007, 65-79]

[594] E.g. [Berg 2001] [Harrison 2002] [Knoppers 2000b] [Sheremeta & Knoppers 2003] [Weijer 2000]

- How the benefits will be measured?
- What kinds of resource uses warrant benefit sharing?
- On what basis are benefits agreed?
- Who has the power to agree on what the benefits are?
- How will benefits be distributed and who will be in charge?
- Who gets to share?
- Who will seek remedies in cases something goes wrong?
- How will rights be enforced and so on

For the purposes of this analysis, I will focus on the nature of the benefits to highlight the connectedness of values, motivations, expectations and relationships that shape the backbone of research relationships at a given location, culture and history. In their 2000 statement HUGO provided the following definition (highlighted extracts) of benefits:

> "…a benefit is a good that contributes to the *well being* of an individual and/or a given community (e.g. by region, tribe, disease-group)…"
>
> "… benefits *transcend avoidance of harm* … in so far as they promote the welfare of an individual and/or a community…"
>
> "… [b]enefits are *not identical with profit* in the monetary or economic sense. Determining a benefit depends on *needs, values, priorities* and *cultural expectations* [of populations]…"[596]

[595] E.g. [Haddow et al. 2007] [Hunter 2006] [Nicol 2004] [Pullman & Latus 2003] [Pullman & Latus 2002]

[596] [HUGO Ethics Committee 2000]

The statement prohibits "*undue inducement* through compensation for individual participants, families and populations"; and, it explicitly excludes from the above prohibition the following types of agreements, which then may be possible 'benefits':

> "agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care or of information, infrastructures, reimbursement of costs, or the possible use of a percentage of any royalties for humanitarian purposes"[597]

So, benefits can be of many kinds. Benefits can be categorised in *development* terms, *health* terms or *profit* terms, and in two broad types: *'research-related' benefits*, as benefits that justify the social acceptability of a proposed project, and *'negotiated' benefits*, as consequences of a group's claims to control.[598] In earlier parts of this chapter, I discussed how 'negotiated benefits' are pursued in the advocacy model, according to contract and property rationales. One should not automatically assume that because intellectual property rights are involved, these negotiated benefits were 'profits'. They could be defined as 'health' benefits, because the intention of the advocates was not to make money but to discover a cure and make it widely available and affordable. The benefits that were most valuable to the PXE were the development of the PXE gene test and its broad and affordable use.

The PXE were commercially aware when they developed their strategies in that they developed their own resources, consulted and agreed mutually beneficial collaborative terms with scientists and contributed materially to the research so as to 'deserve' the intellectual property rights that allowed them to control the research.[599] The PXE group was a patient population who enabled themselves from being

---

[597] *Ibid.*

[598] [Tansey & Burgess 2005] and see also elaborate discussion later in chapter five.

[599] [Terry 2003]

'vulnerable', to assuming control of research done with the samples that they contributed and in recapping the benefits. The PXE case was an 'exchange relationship',[600] in the sense that they granted access to their tissue bank and they received the rewards, although they worked for them, and thus they can be seen as an type of extreme benefit sharing (a self-help one).

What about the benefits that other groups would ask for? Different communities have different beliefs about what constitutes a benefit.[601] The cultural, economic and social contexts of groups vary widely, as I demonstrated in earlier parts of this thesis.[602] The example of the Tonga Island raises particularly pertinent issues on the clash of indigenous worldviews against commodification and commercialisation of the human body and its spiritual value. Even though the offer that Autogen Ltd approached the Tongan Ministry of Health with was a profitable deal, the Tongans dismissed it as inadequate. They did note that what the company offered them was 'a drop in the ocean in comparison to what Autogen [was] bound to get if there is any success',[603] but more so because they fundamentally objected to the idea that DNA could be converted into commercial property, as it clashed with their cultural values and religious beliefs.[604]

Where do such conflicts of values leave possible benefit sharing regimes? In spite of considerations of diversity and respect of plurality in the principles establishing benefit sharing, there are no current enforcement mechanisms in cases where researchers might act disrespectfully towards the values or beliefs of indigenous group participants. As scholars have pointed out, issues of cultural diversity and

---

[600] [Haimes & Whong-Barr 2004, 69]

[601] *Ibid.*

[602] See chapter two in particular.

[603] [Cardinal & Deschênes 2003, 60-61]

[604] [Dickenson 2004, 117]

global ethics are highly relevant in considering benefit sharing approaches.[605] What about other cases, for example, of isolated indigenous tribes in deprived areas? These individuals will have different needs that inevitably would shape their expectations from research involvement (e.g. improvement to health care, sanitation, housing, transportation, schooling) – or, when collaborations do not end well, often due to researchers' not keeping to consent processes, not respecting cultural mores and lying to tribes, from litigation that might ensue upon realisation of deceit, as in the case of the Havasupai Tribe. The efforts towards developing acceptable bases for benefit sharing models vary significantly and are linked with additional concerns, e.g. over inducement (or bribery).[606] It might be difficult to draw the line, especially in the developing countries context. This is also due to the diversity of local needs, e.g. immediate benefits such as medical care, technology transfer, or contribution to the local community infrastructure.

Various hypotheses can be drawn on best strategies for developing specific, local, approaches. There are normative differences between health and infrastructure support, compensation for one's contribution and shared proportion of profit. Interestingly, in indigenous contexts where there is strong support for the recognition of shared and sacred notions of what the body is, and where there is no question of profiting from it, if a company stands to earn big gain, native groups may still desire compensation; the desire to remedy inequality owing to an intuitive reaction to the perceived imbalance.

I mentioned earlier that, apart from contracts, there exist no legal mechanisms and binding instruments to implement benefit sharing requirements. Specific approaches are being developed on an *ad hoc* basis, for biobanking projects, in Canada,

[605] For example, in a native context this applies on the basis of different worldview for assessing suitability, nature and scope of benefits (as exchanges) and degree of need for benefits (as future gains from research) [Dickenson 2004, 117]

Scotland, and UK.[607] Current research in the UK tries to assess the extent to which prospective research participants may associate benefits with health benefits or also with wealth benefits translated in monetary terms.[608]

Questions that arise in this research include a) whether health and wealth benefits are considered to be mutually exclusive, b) the diverse ways in which people perceive anticipated benefits, especially in different cultural and ethical contexts, c) the extent to which such concepts link with how people view their contribution to research and d) in what ways the potential for research commercialisation affects people's willingness to participate in research. Efforts to give answers to these questions are based both on a practical and theoretical imperative to consider the *forms* of benefits that could be offered, and explicitly name these rather than focusing on 'educating' participants that they should not expect benefits. As an example, comments were made recently that the benefits of the UK Biobank need to be *more clearly spelled out* and *tangible benefits* need to be reconsidered, to enhance the practicability and viability of the resource which requires long-term *cooperation* and *trust* from both researchers and participants.[609]

There is a shift in legal thinking about benefit sharing mechanisms. It is hoped that with the contribution of empirical research, this will lead to a reflective understanding of patterns of social exchange and engagement, vital in the regulation of areas where personal values and expectations are affected so deeply. It is important to link these next with a discussion of the normative assumptions and conceptual interpretations involved in developing models of 'sharing'. This is because there is a need for paradigms to help assess the role of current models not

---

[606] *Ibid.*

[607] [Haddow et al. 2007] [Pullman & Latus 2003] [UK Biobank IP & Access 2007]

[608] [Haddow et al. 2007]

[609] [Sumner 2007] – These could be clinically significant findings that may result from later research.

only as mere models of 'self-help'; this is a need for developing a conceptual approach towards evaluating the role of groups and their interests.

I contend that current applications of benefit sharing do not provide a unifying principled approach, but rather model options for developing specific proposals tailored to particular research projects. I believe that in order for such projects to be viable long-term, and in view of the absence of balance in preserving continuing interests of participants in the use of samples during research, it will be very helpful *first* to develop a conceptual model that sets out the core set of principles upon which arrangements for transfer and research oversight can be made, and then proceed to implement benefit sharing mechanisms in various ways. In the next section, I examine notions of solidarity, because scholars in benefit sharing ethics suggest particular interpretations of 'solidarity' as a principle that is implicit in benefit sharing.[610]

D. Solidarity and interdependence

The use of terminology of solidarity and common heritage has increased in UK advisory documentation in recent years. I already highlighted the pitfalls of the importation of altruistic assumptions in the governance of human tissue uses, also by briefly discussing the pairing of 'altruism' with 'solidarity' as problematic. I propose that the optimal way to understand the concept of solidarity is to celebrate the *interdependence* it is premised on. This interdependence is evident in philosophical readings of solidarity and its connection with *reciprocity*.[611] I maintain that solidarity in the regulation of human genetic research cannot be understood as a principle that compels one to act *solely* in the interest of everybody else; to do so would be an

[610] [Chadwick & Berg 2001]
[611] [Bayertz 1998]

authoritative requirement of charity, and not solidarity as recognition of fundamental interdependence.[612]

The use of the term 'solidarity' in the ethically and socially sensitive context of human biomedical research requires a systematic consideration of the nature of the engagement between researchers and participants, and the pursuit of common goals; in current guidance about research with human tissue, the concept has been taken to simulate charity and altruism, possibly by echoing religious interpretations of 'solidarity as benevolence', aimed at steering human disposition towards the 'virtuous'.[613] The Human Genetics Commission discussed their view of the concept in 2002:

> "… the concept of *genetic solidarity and altruism* might be summarised as follows: we all share the same basic human genome, although there are individual variations which distinguish us from other people. Most of our genetic characteristics will be present in others. This *sharing of our genetic constitution* not only gives rise to opportunities to help others but it also highlights our *common interest in the fruits* of medically-based genetic research…"[614] (underlining added)

I find the conjunction of 'altruism' with 'genetic solidarity' decidedly vague. The HGC definition does not appeal to the fundamental connections that philosophy scholars recognise as being at the heart of communitarian interpretations of solidarity.[615] Instead, it reiterates a *power asymmetry* between givers and takers; again, consistent with an interpretation of charitable notions of solidarity. To me this is problematic, precisely because of the non-egalitarian way in which the relationship and the roles between researchers and participants are fixed.[616]

---

[612] [Simm 2005, 51-52] and also [Bayertz 1998] [Dickenson 2004]
[613] [Simm 2005, 51]
[614] [HGC 2002, 38]
[615] [Simm 2005, 52]
[616] *Ibid.*

Instead, a *communitarian* understanding of the term would define solidarity as a realisation of value-interdependence, in recognition of sharing interests and values, under which importance is attached to a common good, but not necessarily in opposition to private good; the two can in many ways, overlap.[617] Solidarity can thus be perceived as a jointly pursued principle, built on shared values.[618] The question is how these values are defined, shared and pursued. Communitarian discourses can have their limitations, to the extent that they may become exclusionary to other surrounding discourses but this is a problem of different nature.

In activism terms, the possibilities for collective action and representation of common interests that applications of solidarity involve, arguably, resemble notions of trade unionism. In such case, solidarity is linked historically with political activism, and may take some contractual form, which could, for example, be applied in biobanking politics, for building collective donor management mechanisms.[619] These understandings of solidarity have nuances not seen in the simple of version of 'solidarity' that is currently used by advisory bodies in the UK. This simplification arguably occurs at the expense of rich interpretations which call for *reciprocal reliance* in the common pursuit of mutual goals, stemming from joint effort and labour, common strategy or need.[620] Current frameworks do not encourage conceptualisations of group-researcher interactions as research *engagements*. In the next chapter, I argue that these interactions should be viewed as cooperative engagements between mutually contributing partners.

---

[617] [Bayertz 1998]

[618] *Ibid.*

[619] Winickoff refers to them as a "collective voice" in this recent article on donor management options in the UK Biobank; he draws on this different understanding of solidarity and he uses it to discuss possible donor representation models e.g. a Donor Approval Committee [Winickoff 2007, 450] [Fortun 2003]

[620] [Tenfelde 1998] An analysis of the relationship of the principles of mutuality and reciprocity, as organisational principles that specify requirements of fairness, follows in the next chapter.

The philosophical interpretation of solidarity as a principle for *collective action* is much more complex and different than its current mention in UK guidance. Present discourses are limited in that they do not offer a systematic approach for conceptualising the rights and obligations of participants in ways that match changing social realities and biovalues. In this light, the use of 'solidarity' risks becoming another disempowering device, mistaken for benevolence, in perpetuating models of unconditional participation in research. Such poor interpretations of solidarity seek to steer research policies away from participatory discourses, and introduce external obligations.[621] I contend that instead, solidarity should be used to develop mechanisms for collaboration, negotiation of short- and medium-term benefits anticipated from research, and robust definition of principles for their distribution to the collective. It is critical to balance differing interpretations of solidarity against corresponding social responsibilities and moral obligations on one hand, and one's contribution and benefit on the other.[622] An uncritical adoption of an activist model of solidarity could lead to compartmentalisation of interests of subgroups and might not serve societal interests as a whole. An overzealous adoption of solidarity as a duty, risks confusing solidarity with altruism and is not well-placed to address increasing participants' concerns about the value of research.[623]

I agree with approaches in support of interpreting solidarity on the basis of principles of reciprocity, fairness and global justice. The interpretation of solidarity as a principle which denotes cooperation, justice, and recognition of interdependence is supported by philosophical literature.[624] Solidarity helps build cohesiveness and

---

[621] [Chadwick & Berg 2001, 318]

[622] See also analysis in [Harmon, 2006]

[623] See, for example, the way [Chadwick & Berg 2001, 318] use the principle to emphasise the obligations of potential participants towards the collective public health and biomedical research enterprise [Winickoff 2007, 450]

[624] [Bayertz 1998, 11] [Steinvorth 1998, 54] [Tenfelde 1998, 195] and compare [Harmon 2006]

intra-group cooperation, as well as birth of new groups. When applied to research relationships, 'solidarity' can help control intra-group politics (e.g. patient, family, ethnic groups), and collective action mechanisms. Articulations of solidarity can be thus used as a unifying discourse, and not as a disempowering device.

While there is utility in using the principle of solidarity to build discourses of togetherness and common purposes, I am interested in less complex ways in which to describe the dynamics of current research relationships, in line with models of empowerment and cooperation. In the next chapter, I discuss the advantages of regulating relationships in human tissue research as *reciprocal engagements* and I propose a new model of conditional gift in group research. The chapter discusses the role of reciprocity and cooperation in establishing trust, before introducing a new principle of 'group empowerment' for the protection of group interests in research. It then compares various legal mechanisms that may be better suited to serve the purposes of the group empowerment principle.

Part III.GROUP EMPOWERMENT IN GENOMIC RESEARCH: A NOVEL APPROACH

Chapter 5

Reciprocity and Empowerment in Group Research

I. The problem of unequal relationships

A. Introduction

In this thesis, I discuss that the inequality of legal power between researchers and groups, at the expense of the latter, is problematic for the development of adequate protections for groups in research. I have examined the ways in which inequality is perpetuated in current consent practices,[625] and fostered further by attempts to import the altruistic donation paradigm in the governance of genetic research.[626] In chapter four in particular, I introduced the UK guidelines on the use of human biological samples in research according to which the proposed status of 'donated material' is construed as a (pure) 'gift' considered to be a free and voluntary transfer, with no expectation of return. A key example of this trend is evidenced in the proposal of the Medical Research Council Working Group that donated tissue samples for research should be treated as 'gifts':

> "… this is preferable from a moral and ethical point of view, as it promotes the 'gift relationship' between participants and scientists, and underlines the altruistic motivation for participation in research…"[627]

In this chapter, I draw in detail on the problems that beleaguer direct endorsement of the 'gift relationship', as cited by the MRC Working Group, in the regulation of research using human biological samples. The term 'gift relationship' has been used extensively in studies of social exchange of goods which influenced thinking and subsequent formulation of policies for blood and organ donation in the UK since the 1960s, as mentioned in chapter four. These accounts allow for multiple meanings of

---

[625] In chapter three on 'Consent for Groups in Genomics Research'.

[626] In chapter four on 'Finding a Balance? From Free Gift to Property'.

[627] [MRC 2001, para 2.2]

what gifts are conceptualised and lead to differing interpretations as to whether gifts are in reality 'free'.[628] In the research context in particular, some scholars find that the gift model is not altogether successful and that it instead needs to be supplemented with an element of *mutual obligation*.[629] I translate this interest in developing mutual obligations as a call for introducing *conditions* that will follow transferred sample(s) for the duration of their existence and their use in research. I argue that there is an urgent need for clarification of the notions of 'free' and 'reciprocal' or 'conditional' gifts respectively. I consider this to be central for the development of protective mechanisms that can help redress residual power imbalance in group research relationships.

In the same report and same paragraph, the MRC Working Group recommends that:

> "… tissue samples donated for research be treated as gifts or donations, *although gifts with conditions attached*..."; "… [g]ifts may be conditional (that is, a donor may specify what the recipient can do with a gift)…"[630]

The Working Group does not clarify further what these conditions would be. It merely stipulates that:

> "… nothing will be done that would be *detrimental* to [the donor's] interests, or bring *harm* to him or her…"[631]

This requirement is rather limited in its scope, especially if one wishes to take into account not only considerations of risk or harm to groups but also proactive ways for groups to retain an interest in the use of samples that they provide for research

---

[628] [Healy 2006] [Titmuss 1970] [Waldby & Mitchell 2006]

[629] [Eriksson 2001] [Gottlieb 1998] [Knoppers 1998] [Levitt & Weldon 2005]

[630] [MRC 2001, para 2.2]

[631] *Ibid.*

purposes. In seeking to develop ways to build such protections for groups, I propose a more refined approach which is altogether new. In this last chapter of my thesis, I put forward a conditional gift model in group research, as part of a new approach that can help achieve what I call '*group empowerment*'. This model requires the establishment of *conditions* that groups can undertake and agree to jointly with researchers. Before discussing the details of this novel approach on empowerment, a few clarifications need to be made regarding key problematic aspects and legal ambiguities in this highly complex and controversial area.

B. Two unfortunate assumptions

1. The assumption of relinquishment

As I discussed earlier in chapter four, according to existing guidance in the UK, the legal notion of genetic gift in the use of human biological samples for research purposes would be considered as:

> "… a *gratuitous* voluntary transfer from the true owner in possession with no expectation of its return…"[632] (my emphasis)

This guidance postulates that, once the sample is removed from the giver ('donor'), he or she "… surrender[s] all interests" and does not have "… the slightest interest in making a claim to [the donated sample] once it is removed..."[633] Alternatively, we could call this the assumption of 'disinterestedness'[634] in its dangerous hypothesis – if not presumption – that 'donors' (or rather research participants) do not have a stake in what happens to donated samples once these are separated from their body. I

[632] [Nuffield report 1995]
[633] *Ibid.*
[634] [Carrier 1995, 166]

argue that this inference relies on a second major assumption, the assumption of altruism, which merits separate and careful consideration.

2. The rhetoric of altruism

By describing the decision and act of transfer of human tissue for research purposes as a gratuitous gift, the current framework imports a policy model that sees the transfer of tissue samples solely as a question of altruism. Earlier in chapter four, I introduced the notion of altruism as involving an action or disposition to act in the interests of another.[635] There exist long theoretical debates about altruism as the concept attracts a great deal of attention from a wide range of disciplines, as diverse as sociology, social psychology, neurology, behavioural biology, philosophy, game theory and economics. The concept is used in different and independent ways across these disciplines, fact which highlights that its history is long and complex.[636] Yet,

---

[635] [Birks 2000, 14] – The reason why I choose this legal author's definition over others is because this short definition it clearly indicates the surrender involved in one's action to serve the interests of another.

[636] For a few examples, the concept of altruism was born in the 1850s and coined by Auguste Comte. It fuelled sociological and philosophical debates whether all human action is ultimately driven by self-serving interest or by benevolence viewed as fundamental [Mautner 2000, 16] [Science Encyclopedia]. In moral philosophy, the majority position defines altruism as unselfish behavior designed to promote others' welfare regardless of cost or harm to self [Rachels 1999] and see also [Blum 2001] for a very useful and concise discussion of definitional and conceptual issues regarding altruism in ethics. In evolutionary biology and philosophy of biology, controversial debates in the 1980s questioned the applicability of theories such as 'reciprocal altruism' in humans [Trivers 1971] by referring to the survival value of altruism that is "by helping another, one increases the likelihood that the other will help them back in the future" [Stanford Encyclopaedia of Philosophy on Biological Altruism]. In the 1990s, these debates were followed by theories favoring the distinction between 'biological altruism' and real or true altruism as theories that describe independent relationships and circumstances. The former was defined in terms of its consequences for species' fitness whereas the latter was defined in terms of one's conscious intentions to help others [Sober & Wilson 1998] [Stanford Encyclopaedia of Philosophy on Biological Altruism] [Science Encyclopedia]. In contemporary debates, such independent concepts have been crystallised under three strands of 'psychological, behavorial, and ethical altruism respectively. These signify that 'psychological altruism' is "any set of inclinations or intentional motivation to help others for their own sakes"; 'behavioral altruism' is defined in terms of consequences rather than intentions and refers to any

however interesting, an analysis of these relevant debates lies beyond the scope of this legal thesis. For the purposes of this thesis, I refer to altruism as it is used in current policy documents on the management of human biological samples for research purposes, especially in the UK. In this context, it seems that altruism is indeed understood as unselfish regard for the welfare of others and denotes the provision of a benefit to another without expectation of payment, compensation or recognition.

The 'genetic altruism' model thus makes a second assumption about the altruism of 'helpful strangers' as named by some critics.[637] By referring to 'genetic altruism' as a social obligation[638] this policy model employs a language of solidarity inspired by the organ transplantation paradigm, which in turn is derived from the blood donation paradigm in the UK. According to medico-sociological literature, the paradigm of blood donation can be seen as a key way to express and maintain solidarity as denoting an altruistic gift exchange.[639] However it must be noted that the altruistic UK model is not universal and different approaches have been developed in other countries, as for example in the US, where two systems of altruistic and paid

---

action that benefits others (normally with the additional condition that there is some cost to the agent – for example, 'evolutionary' or 'biological altruism' is a form of behavioral altruism defined solely in terms of consequences rather than intentions as it refers to any behavior that reduces the fitness of the organism performing it and increases the fitness of another organism; and, 'ethical altruism' is an ideology stating that "the happiness of others should be the principal goal of one's actions" [Science Encyclopedia]

[637] For example [Arrow 1972]

[638] Notes from HGC open meeting, 24.9.2001, Edinburgh – the HGC commenting on their general principles stated that 'there are already accepted principles in place on the use of genetic information in medicine… [with] two overarching conditions: respect for the person, an important central principle to build regulation on; and 'genetic altruism', a social obligation which would include, for example donating samples for medical research.

[639] [Arrow 1972] [Busby 2004] [Keown 1997] [Tutton 2004]

donation exist in parallel.[640] As I mentioned in the previous chapter, the rationales of policies that were introduced in the UK in the 1960s and favoured the use of altruism as paramount in the regulation of blood donation are now being used as a template to encourage the public provision of tissues samples to genetic research.[641] Recent critics point out that these more recent accounts fail to elucidate that the 1960s models were underpinned by particular ideas on the role of welfare state, within a specific socio-political climate. These accounts conflate the unconditional gift (donation) with the gift relationship – which instead should be understood as part of a chain of exchanges that encapsulate giving, receiving and reciprocating.[642]

Several criticisms have been expressed about the shortcomings of the assumption of genetic altruism. I argue that this conjecture is unfortunate in at least four counts:

- The erroneous hypothesis that the same circumstances apply in blood donation, organ transplantation and genetic research which ignores the 'polysemic' nature of gifts in these contexts[643]
- The lack of evidence that the participants act solely for charitable reasons[644]

[640] [Healy 2006] [Katz 2006] [Mason & Laurie 2006] [Oberman 2006] [Waldby & Mitchell 2006] – Healy insightfully suggests that successful systems rest on the *fairness of the exchange* rather than the purity of a donor's altruism or the size of a financial incentive!

[641] [Shaw 2008]

[642] [Hayden 2007] [Shaw 2008] [Tutton 2004]

[643] The term is usefully coined by [Shaw 2008]; for a few examples of different ways that donors and recipients conceptualise the notion of the gift and multiple meanings in these contexts see also [Haddow 2006] [Healy 2004] [Waldby & Michell 2006]. [Dixon-Woods et al. 2008] offers an additional perspective on the poor fit of the 'gift' model for blood donation: the 'gift' metaphor provoked considerable discomfort or even offence among participants in cancer tissue research but this analysis offers useful insights in the study of key notions of gift, consent and control in 'DNA donation', as it is sometimes termed.

[644] See also [Merz et al. 2002, 969]

- The failure to acknowledge other interests that become engaged, apart from any charitable ones[645]
- The risk of altruism becoming an exploitative device[646]

This multiple failure has grave implications for the future success of research with human tissue, as it is intimately linked with the motivations and trust of group participants as the necessary tissue-sources in research. Ultimately, such altruistic rhetoric is owed to institutional fear of shackling medical progress, accompanied by reluctance to recognise sources' interests in research – or both – especially since such interests have been claimed, more recently as being of proprietary nature.[647]

The implications of this unsupported altruistic rhetoric are profound for the regulation of the use of human tissue in research. By assuming that altruism is the only reason why participants agree to participate in research and by ordering the surrender of rights over biological samples to research, current guidance on the use of human biological samples in research creates *barriers* in the power balance between researchers and participants that limit the latter's interests.[648]

I contend that there exist serious and several normative and practical reasons why the transfer of human biological samples in group genetic research should not be considered as a 'gift' that is free of all claims. The group research 'gift' should not be considered automatically to be a 'pure' gift for the following reasons because of:

---

[645] As these are discussed and debated in various parts of this thesis through key case studies.

[646] [Dickenson 2004] and [Tutton 2004] among other scholars discuss the implications of the use of altruism as a 'boundary-setting exercise' and as 'exploitative device' respectively.

[647] As discussed extensively in the previous chapter on property.

[648] [Tutton 2004] as above and see also [Andrews 2006] – For a very useful and detailed analysis on the political economy of human tissue research and related drivers, see [Waldby & Mitchell 2006]

Participants' fears not to be 'suckered': Under the pure altruistic model, participants would be required to participate 'for nothing' yet contribute to private profit which furthers interests other than their own. Hank Greely discusses this as a major emerging problem in group research:

> "… I actually think that it's not so much an ethical obligation to share some of the profits, as it is a desire to avoid having people feel that they're suckers. You know, 'I gave away something for free that you got awfully rich from. You took me for a ride. You mistreated me. I was a sucker', which, whether or not it's a strong ethical argument, doesn't have good political consequences for support of research…"[649]

There is emerging evidence of negative reactions to such lack of balance, encouraged by concern that participants may be exploited.[650] This can be defined as the *injustice in using one's gift to make another's profit*.[651] The importation of purely altruistic models imposes problematic obligations on participants to give *unconditionally* to research precisely because the language of altruism implies no obligation on the part of the researchers and/or other profiteers with respect to the donated material.[652]

Other interests (that) take precedence: A number of interests are not being taken into account by the purely altruistic model, such as the interests of participants in influencing the use of samples for research purposes. These include interests for the use of the sample not to be contrary to the belief-system of possible givers and interests in obtaining information about illness in the family or about one's descent.[653] These can also be reservations about commercialisation of future research

---

[649] [Greely 2005]

[650] [Katz 2006] – This lack of balance can also be seen as a failure to adopt and carry through practices based on the principle of mutuality, as it will be discussed further below.

[651] [PropEur Final Report 2006, Discussion] and see also [HGC 2001]

[652] [Katz 2006] – Donna Dickenson puts it as "altruism has too often tended to be one-way – from research populations to researchers – and one-way altruism is better called exploitation" [Dickenson 2004, 113]

[653] [Wendler 2002]

or about the level of control that participants may have on the direction of such research.[654] Concerns over participants' power and/or control in research are critical in developing mechanisms of empowerment, as it is discussed further below. They are linked inextricably both with ethical principles of fairness but also practical considerations on willingness to participate in research. These questions call for clarity over the nature and function of research participation as a process and the rights that derive from it.

***Principles of fairness*:** the principle of distributive justice requires that all legitimate stakeholders receive a fair share of both the benefits and burdens resulting from this research.[655] Ethical principles are used internationally in support of this claim. The fact that they are hard to pin down does not mean that these principles cannot be invoked.[656] By the same token, this does not imply that it is currently possible for stakeholders to receive an *equal* share nor that research-related benefits need only be measured on monetary terms. In proposals for benefit-sharing, for example, provisions are anticipated for groups to share research benefits through health care, hospital, and other community facility improvements.[657] The critical question then is whether existing approaches are enough and furthermore, according to what metrics group contribution and return can be assessed.

---

[654] [PropEur Final Report 2006, Cunningham-Burley response] and [Haddow et al. 2004] [HGC 2001]

[655] See [Pullman & Latus 2002] and also argument made by Greely that 'fair' treatment of prospective research participants should require a discussion of whether the research involves, directly or indirectly, commercial interests; also that prospective research participants should be able to take that information into account when considering whether to participate; more importantly, that commercial benefits should be shared 'in some manner' with the group who took part in the research and thus "made the commercial benefits possible". Greely assesses that this sharing could be through giving benefits to the group, e.g. health care, hospital, and other community facility improvements. He contends that because of the rise of commercial interests in large-scale resources, rethinking is required both about the *process* and the *substance* of the relationship between researchers and research participants – and I agree! [Greely 2001b, 227]

[656] [Knoppers 2000c]

[657] [HUGO Ethics Committee 2000]

There is no absolute gift: the transfer involved in the genetic research gift is not an absolute one; as it has already been noted by various scholars in very recent years, the right to withdraw from research at any time is acknowledged by current advisory guidance.[658] This signals a possible shift in research participation. The fact that the gift is revocable could mean that it cannot be treated as a free and unconditional transfer. The possibility of withdrawal of samples from research possibly raises a critical difference between the paradigm of pure donation and the case of genetic research.[659] Some scholars support that the firm protection of withdrawal rights is a positive feature that indicates a good faith attempt to endow participants with *limited but real rights of control* over (their) tissues.[660] I agree that the right to withdraw at any time from the research without having to explain why, and without penalty, preserves the voluntary nature of participation and awards participants with 'real' rights to some extent only. Indeed the possibility of withdrawal may imply some degree of recognition of participants' interests against abuse of (their) tissues – this approach arguably advocates against the importation of the paradigm of pure donation in genetic research, but ironically, when combined with one-off consent, falls short of empowering participants in having a say in the overall endeavour.[661]

Lack of flexibility: the current assumption of altruism denies the existence of any other rights or interests but for the charitable intentions of potential donors. A conditional model does not prevent prospective participants from volunteering on the basis of charitable intentions only, as it can include the possibility that the gift would be free of any conditions. This means that, even if one is to assume that prospective

---

[658] [Winickoff 2007, 445] mentioned that the withdrawal feature evinces a *moral sensibility* concerning the relation of participants to their extracted tissues that is currently lacking in US common law.

[659] For a key example, see the withdrawal provision proposed by the Ethics and Governance Council of the UK Biobank in their guidelines for the ethical and legal collection and use of samples in the UK Biobank project.

[660][Eriksson 2001, 43] [Gottlieb 1998, 190] [Tutton 2004, 19] [Winickoff 2003, 218]

[661] The critique of power dynamics that become disrupted by one-off withdrawal is rather eloquently presented by [Laurie 2002, 312] and [McHale 2004, 85]

group participants have only charitable intentions, under the conditional model, their rights and interests are acknowledged and respected. This cannot be said in the case of the model of pure altruism which denies that any other interests exist!

The two assumptions of relinquishment and altruism lay at the heart of disempowerment discourses introduced in chapter three of this thesis. These discourses are increasingly brought forward by scholars in more recent years.[662] As already discussed in chapter four, they are also linked with debates on property rights in the body as rights that could guarantee higher degrees of participant control in the use of samples in research.[663]

In this thesis, I contend that the critical question for the protection of group interests in this context is not whether groups who agree to give biological material for research purposes have property rights over samples but, mainly, whether they can have a degree of better control of the *use* that is made of samples as well as other rightful claims, e.g. for the time, effort and resources that they contribute to research.[664] Relevant group interests include claims about the kinds of research conducted, transfer to their parties, returning samples to the group after use, and rights for the destruction of samples.[665] A property model may be a possible way to address some of these issues, but, as it was already explained in the previous chapter, the property route suffers its own limitations. This thesis proposes a new and better way.

---

[662] For key examples see [Andrews 2004] [Laurie 2002]

[663] [Hardcastle 2007, 46]

[664] [MRC 2001, para 9.2] and see also [Bellivier & Noiville 2006, 99] for a good comparative perspective.

[665] As already forwarded, for example, in the Havasupai tribe claims discussed in chapter two of this thesis.

C. A persistent paradox

1. The gift and property paradox

In order to look at the concept of a gift (conditional or unconditional) one has to consider the question of ownership, since we can reason that one can only give as a gift what one owns.[666] If there can be no ownership in human tissue, how is that compatible with the possibility to give a gift? How can one transfer it to someone as a gift? In chapter four, I introduced key aspects of the paradoxical relationship between gift and property in existing research frameworks. Here it is useful to consider a little further the implications of this contradiction that a gift presupposes an underlying property right.

The MRC Working Group on Human Tissue and Biological Samples report infers that:

> "… *any* proprietary rights that the donor might have in their tissue would be transferred with the control over the use of the tissue to the recipient of the gift…"[667]

The corresponding legal position remains unclear and this is a problem, because when debating who can have control over the transfer and the use of the samples, one needs to be able to ascertain what kinds of rights can be asserted on those samples and by whom! Several scholars criticise the current position on property rights as being ambiguous and seriously incongruous.[668] I argue further that this position, in

[666] See discussion in [Laurie 2002, 313] and references cited therein. The author also provides a very useful comparison between English and Scots law on the concept of the gift, to which I will return.
[667] [MRC 2001, para 9.2]
[668] See for example [Mahoney 2000] and [Laurie 2002, as above]

practice, is a way to circumvent claims for control and current calls for a better balance in the power that is afforded to researchers and research participants respectively. The tension whether participants – that is group participants in the case of what this thesis examines – can attain a better degree of power or control simply remains unaddressed by existing UK frameworks.

I contend that, by employing the altruism rhetoric in regard to the use of biological samples for research, UK guidance as it currently stands, fails to resolve three persistent problems. These problems engender increasing uneasiness towards the viability of participation in group research, on long term basis in particular.[669] The perpetuation of the use of altruism as the only paradigm in the regulation of group research presents the following problems:

- It does *not anticipate fundamental implications* for other rights and interests of group participants[670]
- It becomes a '*boundary-setting' exercise* aiming to avoid potential claims that could disturb the set ways in which research is done[671]
- It relies on the *assumption of an established trust relationship* between participants and researchers that cannot always be validated[672]

Current reliance on altruism is intimately linked with the way in which the interaction between groups and researchers is conceptualised by existing guidance. In current frameworks, confusion exists as to the whether the transfer of human tissue

[669] [Sumner 2007] [Tutton 2007, 175] [Webster et al. 2008]

[670] This lack of anticipation is arguably based on an unsophisticated view of donor participants as being involved in "an uncomplicated one-way act" instead of a more active process of engagement, as reported in [Haimes and Whong-Barr 2004, 60] and also [Tutton 2007, 176]

[671] [Tutton 2004] and see also [Laurie 2002, 313] who comments on the appeal of the continuing use of the unconditional gift model in that "[i]n practice, it has *considerable utility for the recipient* ... [as] [it] provides *broad scope for the future use* or disposal of the gift" (my emphasis).

samples for research purposes can be seen as anything other than free – and it is not disengaged from notions of property, as explained above. For semantic purposes, it would have been consistent if current guidance had adopted an unambiguous term such as 'DNA donation'. Laurie helpfully notes, for example, that in Scots law, gift is more correctly termed 'donation', where he also clarifies that donation cannot be presumed.[673] On the other hand, I contend that a correct use of the term 'gift' could accommodate a novel debate about the conceptualisation of genetic research 'gifts' as constituted within a circle of interactions dependant on broader social *relationships* between research participants and researchers. As a result of enduring confusion, current views on the interaction between researchers and groups are rather narrow. These views do not accommodate an urgently needed broader regulatory focus on the personal character of group research interactions. I contend that a wider perspective is necessary that can lead to a better understanding of the dynamics between them. I propose a new way in the following parts of this chapter.

D. The need for a new approach

1. The transformations of human tissue

There exists a body of interdisciplinary research work interested precisely in the understanding of the nature of interests and the relationship between gift givers and recipients. This work draws on sociological and anthropological theories on the nature of gifts, exchanges and ensuing obligations.[674] In this literature, gifts are studied as constitutive of positive social relations. Contemporary theorists who research these systems highlight that in these systems of "giving, receiving and

---

[672] [Chalmers & Nicol 2004]

[673] [Laurie 2002, 313]

[674] For key examples [Carrier 1991] [Douglas 1990] [Frow 1997] [Mauss 1990] [Osteen 2002] [Titmuss1970]

reciprocating, gifts act more like *loans*",[675] the "… transaction… perhaps bears rather more resemblance to a *loan* than to an absolute gift or the alienation of a property right" (my emphasis).[676]

Political economists who research contemporary trends in the changing economic value of human tissue, its circulation, and its status highlight that there exists a major re-evaluation of the "seemingly mutually exclusive relationship" between gifts and commodities.[677] In these discourses, gifts and commodities are seen as polar terms that define a *continuum* along which one can place existing transactions, friendships or relationships; their realms overlap and interact.[678] These experts highlight that there exist constant transformations of the status of human tissue in and out of waste, gift, and commodity forms, as forms of circulating value.[679] The transformations can be seen as different phases in the change of status of human tissue, defined by the *relationships* in which tissue circulates at a particular time.[680]

Current frameworks are not equipped to address the cultural implications of these status shifts or "regimes of value"[681] and cannot adjust protections accordingly. This

---

[675] [Waldby & Mitchell 2006, 15]

[676] [Frow 1997, 110]

[677] [Waldby & Mitchell 2006, 24]

[678] [Carrier 1995, 190]

[679] [Appadurai 1986] coined the term of 'value tournaments' as processes determining not only the economic value of things but also forming the context in which other symbolic and social meanings of things are developed; see also [Lock 1997a]

[680] This understanding is supported by developments in anthropological scholarship since the mid-1980s, studying the circulation of gifts, commodities and modes of production. These studies led to the formation of a new, culturally informed economic anthropology to study culture in a way that convincingly relates it to political economy, and analyses political and economic realities in a culturally sensitive way. According to these accounts, culture is seen as a dynamic, shifting, contested terrain, constantly shaped by and shaping a changing political and economic context [Appadurai 1986] [Ferguson 1988, 491] [Kopytoff 1986] [Komter 2005] [Komter 1996] [Rajan 2006] [Waldby & Mitchell 2006]

[681] [Appadurai 1986] [Ferguson 1988, 495]

lack of insight creates misconceptions and difficulties, such as the MRC and HGC approach to regulating genetic research participation by importing the altruistic donation model. I contend that the biggest difficulty in the current regulatory approach to research participation in UK is that it does not question this reliance on altruism, what I thus call the *fallacy of altruism.* As a result, current frameworks have not been able to reduce continuing tensions between altruistic motivation to participate and sources' interests in how samples are used and in what kinds of research are being pursued.[682]

In the following sections of this final chapter, I suggest that a new approach is needed in order to:

- reinforce *reciprocal* understandings of engagement in the research enterprise
- *acknowledge* group interests in the conduct of research with group samples (as groups are the sources of these samples)
- establish mechanisms to *evaluate* source contributions
- enable the distribution of *benefits* according to agreed conditions

My main argument for a better balance of power to be attributed to groups in research is formed with the above criteria in mind.

2. A dynamic engagement

In line with the previous analysis, I support that the transfer between groups and researchers when it comes to participation in research is not just an exchange but that in reality it is the actualisation of a continuous *engagement*. In defining the reasons and obligations derived from group-researcher interaction, altruistic or charitable

[682] [Chalmers & Nicol 2004]

intentions can form part of the reasons for engagement. These intentions are not necessarily the only ones, a fact which current regulation continues to ignore.

I maintain that in order to understand and address current inconsistencies and gaps, relevant law and regulation need to develop ways to appreciate:

- the *nature* of the interests involved
- the collaborative *relationship* between the parties and
- the *expectations* that both parties bear as they engage with each other during the research process

I discussed questions on the nature of groups and their expectations in the first two chapters of this thesis. In this chapter, I discuss new ways for the law to view the *relationship* between research 'givers' and recipients as being dependant on i) the *nature* of the 'gift',[683] ii) the *utility* of the 'gift' to both parties, iii) the *dynamic* between researchers and participants (e.g. how respectful, trustful and cooperative they are), iv) their respective *expectations* and previous history.[684]

---

[683] The MRC remarks that "it is part of our understanding of the *nature* of a gift that the making and reception of it confirm a special *relationship* between donor and donee" [MRC 2001, para 2.2]

[684] Expectations are often affected by history and the same can be said of the overall dynamic between groups and researchers. Several scholars criticise the impact of previous negative experience of genetic research projects on groups (e.g. indigenous tribes in Polynesia, Tuskegee study in the US). These projects met particular resistance or public outcry as exploitative, disrespectful and even demeaning of these particular communities. These and other similar accounts affect current views about group research participation among native and ethnic communities today, as supported by a number of authors such as [Amani and Coombe 2005] [Corbie-Smith et al. 1999] [Dickenson 2004] [Reardon 2006] for a few key examples.

An interesting question to address is how many of these factors can contribute to the development of new frameworks in this area and help establish clear obligations and rights that arise from this relationship. Under the model proposed in this thesis, one can stipulate that the person(s) who accept a conditional gift have certain obligations towards the giver(s), in similar fashion that we already instructed that they have the obligation to use the gift in a way that will not harm the giver(s).[685] The giver(s) could state conditions if so they wish, or instead, make it clear that the gift will be free of any conditions. This means that, a model could be developed to allow the stipulation of *conditions*, under which the rights and interests of giver groups would be acknowledged and respected - not ignored - precisely because the conditional model can be *flexible* where the current model is not.

In the following parts of the thesis, I propose that considerations of *reciprocity* can provide a useful basis for the development of such *conditions* in group research. I propose a novel analysis of reciprocity as a core value in group research and recommend that its use will help achieve appropriate levels of protection for meaningful engagement between researchers and groups.

II. The centrality of reciprocity

A. Reciprocity and cooperation

Reciprocity imposes an obligation to return a favor or resource.[686] In his highly influential piece on the function of reciprocity, Gouldner discusses that the norm of reciprocity makes two demands; that people should help those who have helped

[685] [MRC 2001, para 2.2]
[686] [Gouldner 1960, 171]

them, and that people should not injure those who have helped them.[687] According to the rules of reciprocity, the obligation to return a favour or resource does not necessarily require that the same favour or resource is returned. In many cases, the returned favour or resource can be a return in kind, especially where it is no longer possible, practical or desirable to return that favour or resource, as long as the return is assessed on a fair and mutual basis.[688] However in some cases, it may be required that the same favour or resource is returned, as is the case in the pending lawsuit of the Havasupai tribe in Arizona, US, where the tribe claimed that they wanted tribe samples to be returned to them after research use.[689]

Reciprocity is linked with *mutuality* according to which obligations can be imposed only *contingently in response to the benefits conferred by others*.[690] In accordance with rules of mutuality, the obligations of return are conditional to the value of the benefit received. In accordance with reciprocity, it is proposed that the appropriateness of return can be assessed in proportion to four initial parameters:

- the intensity of recipients' *needs*
- the givers' *resources*
- the givers' *motives*
- other *constraints* that may apply

There is a critical mass of philosophical, economic, biological, anthropological and sociological studies on the function of reciprocity but very little reflection exists from a legal point of view. The interesting question in this context is how we can use this expertise in law in order to achieve *a better balance* between the interests of

---

[687] *Ibid.*

[688] *Ibid.*

[689] [*Tilousi v. Arizona State University* 2005] and see discussion of the case in previous chapters.

[690] [Gouldner 1960] [Watkins 2006]

group participants, researchers and research institutions. I contend that there exists a workable way to integrate such thinking in the development of legal frameworks by focusing on the *collaborative qualities* that this thinking involves. At conceptual level, as the focus of biomedical research is shifting from individuals to populations, such integration is in line with current shifts in emphasis of the relevant ethical questions, which highlight the need to respect diverse cultural values.[691]

In developing thinking to promote the collaborative qualities these emerging trends support, I see it necessary to take account of economic and psychological studies to highlight that reciprocity is achieved with *cooperation*. Cooperation happens when people believe that mutual synergy is generally a beneficial strategy to all, rather than that of the individual action.[692] This means that partners will *collaborate when they think that their partner will cooperate*.[693] I see this as a situation where one party's expectation of another's cooperation is founded on two basic principles, i) general *trust*, and ii) a sense of *control*. Trust is often enhanced by previous positive collaboration and experience between the parties but finds itself at risk in case of previous negative histories of groups as research targets. Trust-building helps achieve heightened levels of a sense of control but is not the only factor that influences one's sense of control.[694]

---

[691] See [HUGO Ethics Committee 2007] – this shift in ethical emphasis goes in pair with shifts within the scientific community, where a new desire exists to invest in long-term and continuous relationships with group research participants as population genomics is increasingly geared to include richer phenotypic and environmental data sets in the study of genotype, taken as one of many significant variables used to explain health outcomes [Winickoff 2007]

[692] [Hayashi et al. 1999]

[693] *Ibid.*

[694] [Kollock 1998]

There exists a plethora of empirical evidence on the pivotal role of cooperation in establishing successful partnerships in several contexts.[695] In the context of genetic research, and in particular in the case of groups, cooperation and communication has been achieved with extremely advantageous results in the formation of advocacy groups and patient groups to facilitate research towards a particular direction of their interest, and to manage group resources for this goal.[696] The majority of these initiatives focused on ways to secure better group influence in the direction and the use of research and further, in the distribution of research results to their community, with the creation of *group resources* which are commonly owned and are used as leverage for research.[697] Not all groups, as analysed earlier in chapter two of this thesis, have managed to develop similar mechanisms of cooperation but current shifts in emphasis towards such developments are likely to help such processes.[698] This thesis aims to be part of such efforts by offering a new conceptual model for cooperation between groups and researchers.

There is evidence that healthy mechanisms of representation and communication can greatly enhance participation rate, participants' trust and, by extension, project sustainability. Attracting and retaining participants requires that participants have trust in that research is managed in a way consistent with their core values and expectations. This is valid both for individual participants and groups as participants. I argue that the levels of cooperation and trust to be achieved largely depend on a proper understanding of *reciprocity* in particular, as the notion of reciprocity can help

---

[695] See especially [Hardin 1993] [Hayashi et al. 1999] [Kollock 1998] for a few very useful examples in economics and psychology research.

[696] See the discussion on the rise and strategies of genetic diseases advocacy groups in my previous chapter, also [Anderlik & Rothstein 2004] [Gitter 2004] [Terry et al. 2007]

[697] E. g. the PXE International tissue bank [Anderlik & Rothstein 2004] [Merz et al. 2002] [Terry et al. 2007]

[698] For example, the advocacy model has attracted the interest of experts developing guidelines for research protections in research with American Indian and Alaska Native communities [American Indian and Alaska Native Genetics Research Policy Formulation Meeting 2001]

address significantly not only the need for joint commitment (mutuality) but also calls for achieving a *balance* in overall group-researcher interactions (reciprocity).[699]

An example from current proposals signalling a move towards such a direction are calls for the development of provisions obliging researchers to disclose any potential commercial interests derived from the use of samples that groups give to research. The application of considerations of mutuality and more importantly, reciprocity would suggest that such proposals be assessed on the basis that i) parties are *jointly bound* in that they should share the risks and benefits from research on a mutual basis; ii) their entitlement and/or influence is contingent to the value of their contribution balanced in accordance with their history, needs and expectations, against all other interests considered to be necessary for the protection of the rights of research parties by research ethics laws and regulations. The ways in which these can be assessed fairly needs critical examination and this is where considerations of reciprocity become necessary in fostering genuine and enduring group-researcher cooperation.

B. Trust-building and interdependency

Reciprocity requires not only that there exists a shared basis for the parties' contribution but also that their response is *balanced* to guarantee ongoing cooperation.[700] Gouldner refers to the norm of reciprocity as a universal but not unconditional element that establishes a configuration of rights realised in the obligation of reciprocation.[701] He notes that reciprocity becomes a trust-building

[699] [Komter 2005] [Levitt & Weldon 2005]

[700] This means that a response is required with the expectation that the parties respond to each other in similar ways: from Latin *reciprocus* meaning returning the same way, alternating [Merriam-Webster Online Dictionary]

[701] [Gouldner 1973, 248]

mechanism that helps stabilise and maintain social relationships exactly because it helps relevant parties to "cope with the disruptive potentialities of power differences".[702] Reciprocity helps achieve stability by circumscribing exploitative relations, the resulting conflicts that undermine social systems, and the power arrangements that make exploitation possible. In this respect, Gouldner successfully recognises the complex *balancing relationship between trust and control* insofar as trust and control are both functionally necessary for the generation and maintenance of social order.[703] The complexity of this balancing act is due to the complexity of another fundamental relationship that is, the engagement between group participants and researchers and the dynamics developed between them, as discussed further below.[704]

In line with these considerations, the understanding of what constitutes appropriate reciprocation will depend on the observance of particular cultural and ethical norms and on the specifics of the dynamic between the parties. The reciprocal obligation need not be a mere 'tit-for-tat' since the gift recipient(s)' means may not be adequate to return the full economic value of the givers' gift.[705] There ought to be some basic criteria that can help us determine what constitutes appropriate reciprocation and bring the group-researcher relationship to a balance. In an influential book on reciprocity, Lawrence Becker proposes a helpful way of evaluating the appropriateness of reciprocal returns at a broad level by putting forward two concepts of "overall relationship" reciprocity and "transactional" reciprocity.[706] Transactional reciprocity requires that *one benefits another person with the recognition that one has been benefited in some specific way*. Overall relationship

---

[702] *Ibid.* – This approach offers a way to interpret principles of fairness and justice invoked by several law scholars [Greely 2001b] [Amani & Coombe 2005]. I will return to this point later.

[703] *Ibid.*

[704] [Mauss 1990] [Douglas 1990] [Frow 1997]

[705] [Schmitdtz 2005, 458] broadly defines the principle of R as "when you can, return good in proportion to good received".

[706] [Becker 1986, 145-147] and also [Blum 1988, 146]

reciprocity is the *reciprocity of the overall balance in one's relationship with another*. According to Becker, if the parties are unequal, the relationship can still work. He explains that transactional reciprocity between unequal parties indeed risks entrenching the inequality between them and that this would constitute a violation of the overall relationship reciprocity.[707]

In his sociological work on gifts and exchanges, Thomas Murray discusses three main obligations that derive from the gift relationship, the first being "grateful conduct", the second being "reciprocation" and the third being "grateful use".[708] He proposes two criteria for this third obligation of grateful use and identifies these to be the nature of the gift and "what we can know of the donor's intention for its use".[709] I suggest that these criteria provide useful guidance for the interpretation of gift-based interactions as reciprocal. I further contend that they should be developed further and be complemented by a clearer understanding of what the dynamics and interaction between groups and researchers can mean in law. I put forward that group-researcher relationships are continuous engagements that create obligations and expectations on both sides and should be recognised as such.

So far, no comprehensive efforts have been made to develop precise criteria for addressing this conceptual problem in group research although limited attempts that propose a re-examination of gift relationships in genetic research have been made by law and philosophy scholars.[710] They entertain preliminary reasons that lend support

---

[707] Becker does not recognise overall relationship reciprocity to be distinct from transactional reciprocity but he acknowledges that the latter can function within unequal relationships. He adds that the problem is not a real one because "an unequal relationship precisely is *not* a reciprocal one"!

[708] [Murray 1987, 32]

[709] *Ibid.*

[710] [Dickenson 2007] [Gottlieb 2004]] [Hoppe 2005a] [Knoppers 1998]

to a re-evaluation of human tissue gifts in law but no one has yet put forward new conceptual and practical ways to take such a model forward.[711]

At first instance, I contend that the criteria to help us determine what constitutes an appropriate reciprocation should be developed on the basis of the following qualities:

- the (giver) group's *relationship* with (recipient) researcher(s)
- the *nature* of the 'gift'
- the group's *intention(s)* for the use of the 'gift', and
- the respective *expectations* of both parties involved

I propose that a thorough rethink of the language of the 'gift' in research is critical and long overdue. A principal objective of this thesis is to develop a coherent, principled way for the law to protect the *relationship* between researchers and groups as both *collaborative* and *less unequal*. In the following parts, my analysis on the nature and function of reciprocity becomes part of my proposal for a new principle of *group empowerment* in research ethics. This principle could become part of research ethics guidelines to influence the development of legal models that protect group research relationships through recognition of the significance of groups as proactive research contributors. One such model is a new *sui generis* model of *conditional group research gift*. I discuss ways in which this model can be an effective mechanism for group empowerment, in the last part of this chapter. I support that this model can provide a genuine opportunity for reciprocity to become an essential component in the process of establishing trust and facilitating research. But first, it is important to explain what group empowerment is, how it fits with current research ethics norms and their history.

[711] These reasons include a desire for mutual relationships with obligations on both sides.

III. The principle of 'Group Empowerment'

A. Introducing a new concept

In the search for a model that acknowledges the significance of groups as research contributors and establishes less unequal relationships between them and researchers, it is time to suggest a new approach. This approach is focussed on ascertaining better levels of group 'control' in research on the basis of a new principle of *group empowerment*.[712] Before embarking on presenting the theory of group empowerment, I believe it helpful for my reader to sum up the key concepts behind this new approach in the following taxonomy, as these are linked with the arguments made in the previous section on the pitfalls of the altruism model and the centrality of reciprocity in developing new mechanisms for group protections in research.

1. Taxonomy of key concepts

***Altruism*:** altruism is exemplified in one's action in the interests of another or one's disposition to act in the interests of another. The concept does not necessarily require that there is detriment to self but often a disadvantage is implied in one's surrender to acting solely for the benefit of another.

[712] 'Control' often sounds somehow too forceful a term, as in 'utter power'; it possibly leaves more nuanced notions of similar options unexplored, but it is often explicitly used in literature promoting group claims, e.g. [Schnarch 2004]

Gift: two possible interpretations of gifts are proposed, based both on legal definitions but also sociological and anthropological theory on *'gifts as relationships'*:

- ***unconditional gift*** has been defined as gratuitous transfer with no expectation of return
- ***conditional gift*** involves the exchange of reciprocal returns, implied by ongoing collaborative interaction and dynamic relations between parties

The notion of *unconditional (or free) gift* is also termed as 'donation' in law. It raises no obligation for reciprocation – although sometimes it may still cause feelings of gratitude which nevertheless lie outside the scope of the law.

The notion of *conditional gift* in this context is based on the understanding of the transformational status of human tissue in research and the personal relationships it exists in. It describes a different dynamic to the one manifest in unconditional interactions: unless balanced *conditions* which impose *limitations* on the uses of tissue in research are agreed and met by the parties, the gifts are not valid. In such case, cooperation and trust perish and the relationship does not exist.

Mutuality**:** mutuality prescribes that the parties are jointly (mutually) bound for the relationship to exist and be enforceable. Joint contributors' obligations are imposed in response to the benefits conferred by others; they are participants to the benefits and rewards that may occur from their shared commitment. Mutuality forms one of the elements of the principle of reciprocity.

Reciprocity: reciprocity requires a return or response as part of an ongoing, cooperative exchange of favours or privileges; it posits that this response must be balanced for cooperation and trust between the parties to exist. A right, claim or

norm is reciprocally justified if one person asks no more of the other than what he or she is willing to give for their relationship to exist. Reciprocity compels a relational, proportional understanding of balance between engaged parties.

Group Empowerment: the concept of group empowerment expands the role and power of groups as proactive partners in research. It focuses not only on what groups are but also on what groups do. It forms the core of claims for better control, transparency, accountability in research, in positive terms for groups. The principle reconfigures group-researcher relationships as collaborative, continuous engagements and relies on reciprocity to preserve their function and character. It provides criteria for evaluation of group contribution in research relationships. Group participants' 'due' is valued proportionately to their overall contribution compared to the contribution of everybody else engaged in the same research relationship.

Group Contribution*:* group contribution is a strong basis for a group's claim to control; it is realised in multiple and cumulative ways in the pursuit of shared goals and common effort, communication of trust, awareness of common history and expectations, formation of networks and creation of group resources that are owned and managed collectively with the view to advance research in particular areas of joint interest. The recognition of group contribution is central to empowerment. Group empowerment prescribes that groups should be protected in mobilising themselves efficiently and that their contribution to the research enterprise is acknowledged is respected. As interest in the creation of contributory processes across different categories of groups willing to get involved in long-term research collaborations is increasing, the possibility to acknowledge group contribution in law can inspire new ways for group mobilisation and influence in research.

Equality**:** equality in this thesis is understood to be proportional and relational, on the basis of giving everyone what they are due. This understanding is derived from

notions warranting the need to "treat the like as like".[713] It can be used as a rational basis for the justification of distribution of resources.

Equity: equity characterises a state of balance derived from keeping to proportional equality according to a particular notion of justice. Equity notions are intimately linked with equality theory and establish that the value of one's benefit should be calculated in proportion to the contribution of everyone else. In this evaluation, the definition of what one is due 'represents' justice.

Justice: principles of justice stipulate equal respect as well as universal and reciprocal justification of norms; in this thesis, justice is understood on the basis of fairness and merit. This understanding of justice allows recognition of group effort while assessing the contribution of groups in research. It highlights the connection between justice as proportional equality and reciprocity in the interpretation of empowerment.

This taxonomy serves both as a reminder of key notions previously introduced and new concepts that help define the scope and function of the principle of group empowerment that I propose in this thesis. So far, I have discussed the inadequacy of current individualistic research protections to capture ethical and legal concerns pertaining to groups, as a major challenge in group research ethics. In the next section, first I discuss an early attempt to develop a new principle for respecting groups, and its limitations; then I propose a new principle which relies on reciprocity and equity. This principle centres on the necessity to maintain an equitable balance between groups' and researchers' contributions in line with the continuous nature of their relationship considered as collaborative, dynamic, and in need of protection.

---

[713] This notion is not new and draws back on an ancient idea, see [Aristotle *Nicomachean Ethics* Book V, Chapter 3 §8] and [Stanford Encyclopaedia of Philosophy on 'Equality']

2. The 'old' principle of 'respect for communities': why not enough?

In the search for better principles to fill the gap that individually-focussed protections create, in the late 1990s, a small team of Canadian bioethics scholars led by professor Weijer proposed an additional ethical principle for research protections to be added to the mainstream US research ethics framework.[714] They called it the principle of "respect for communities" and they dedicated a number of joint publications to its promotion.[715]

Charles Weijer and his colleagues admirably sought to redefine the ethical principles that guide the conduct of research involving human participants (or 'subjects' in the US terminology). By cautioning that the US framework overemphasized individual rights, they raised awareness amongst contemporary ethics, law and anthropology scholars about notions of 'community risks' not previously considered by advocates of early group consent theories.[716]

Their effort to introduce a new principle to the debate was not the first time that scholars sought to introduce additional principles in US frameworks. Much earlier, in 1982, Robert Levine had suggested a principle for "respect for cultures", to recognise "the validity of certain forms of cultural relativism" and "have each culture decide how it should show respect for its own persons".[717] Yet Levine failed to establish why the principle was needed.[718] Interestingly, Weijer and his colleagues concentrated on describing ethical tensions in research with groups. They offered

---

[714] The US Belmont report defined three key ethical principles in the conduct of research involving human 'subjects': respect for persons, beneficence, and justice [US Belmont Report 1979]

[715] [Weijer 1999] [Weijer & Emanuel 2000] [Weijer, Goldsand, Emanuel 1999]

[716] As I discussed earlier, in chapter two [Greely 1997]

[717] [Levine 1982, 16]

[718] Levine was concerned that these frameworks made little or no reference to persons in *relationship* to others or *as members* of communities [Levine 1986, 13] [Weijer 1999, 505]

empirical and hypothetical examples on how genetics research entails 'harm risks' for particular groups.[719] They proposed the idea of a principle of 'respect of communities' as a first step towards affording protections against risks to groups. The principle had three main theses on group rights: separability, moral status and emerging tradition in that a) group interests are *separable* to individual interests (and may even conflict);[720] b) groups are capable of *moral status* and should be awarded such status, so that their interests are taken seriously in moral analysis; and, c) group rights can be justified as *emerging traditions* depending on "just what one thinks ethical principles are" by appeals to tradition and "reflective equilibrium".[721]

Their research centred on questions about what properties groups have, what kinds of political authority, their ways for communicating communally defined needs, with the aim to create important steps towards developing future frameworks to protect groups. They focussed on issues of group harm in ethnic and native groups, participatory research with native groups, and group representation. They considered whether guidelines previously developed specifically for research with native groups could be transplanted to regulating claims of other groups (e.g. Ashkenazi Jewish),

---

[719] Weijer and colleagues used the term 'community' where I use the umbrella term 'group', as I explained in my introductory chapter. As per my chapter 3, their examples of how groups can be harmed while participating in research under the dominant individualistic framework, focussed on cancer genetics research with Ashkenazi Jewish communities, and guidelines for research with aboriginal communities in Australia, and with First Nations communities in Canada.

[720] This also echoed concerns already expressed by Gostin, wondering if individuals could consent to disclosure of information and yet the research study could "violate the right of the collective to privacy". Gostin posited that when one believes that populations have a right to defend their dignity and reputation as much as individuals do, "it is conceivable, even when the information revealed about each member of the group is non-consequential or is not personally identifiable, that the group can be harmed" and 'that the right of populations to have some say in the collection and spread of data that they believe reflect badly on their identity is an important ethical principle' [Gostin 1991, 194]

[721] As opposed to "by appeal to moral theory"; the authors sought to justify those as "principles informing cases – cases informing principles … best described as emerging traditions" [Weijer 1999, 506]

and concluded that further work was needed to highlight group differences.[722] Most of these ideas were influential in work undertaken by scholars such as Morris, Sharp and Foster, who have been developing model protocols for community consultation models.[723]

This work today offers valuable insights into the particularities of group contexts and the need for tailored approaches, as I have highlighted in earlier chapters. They were an honest attempt to catalogue the issues in need for further research, at the time.[724] But something was missing. What their work left wanting was the assertion that groups not only face significant research risks as a whole, but more importantly, that groups have *positive* interests and claims to promote as a collective, in the pursuit of common goals. I find that the 'respect of communities' principle is too passive. These colleagues adopted a language of 'respect' wary of harm – which was a significant trigger for emerging scholarship in group research in the last decade – but they did not acknowledge that groups can have power. Thus, for the purposes of the kinds of group goals and interests that I have been discussing in this thesis, this approach is not proactive enough. I have considered many kinds of group goals throughout this thesis, and I reiterate them in the next section. The key point is that the calls for 'respect for communities' left unaddressed a fundamental tension in the interaction between groups and researchers. Current trends in group research highlight the need for a more proactive and principled approach towards safeguarding group interests. It is this fundamental point that I want to address in this thesis by proposing a new, more robust principle. Let us see how such an approach is possible.

---

[722] *Ibid.*

[723] See also my chapter three on the history of group consent and sister theories.

[724] [Weijer 1999, 510]

3. The new principle of 'group empowerment'

The principle of group empowerment expands the notion of what a group *is*, in order to include not only issues of what group *risks* are – as previous theories do – but fundamentally to address what groups *do*. Throughout this thesis, I have demonstrated a number of instances where the need for a new principle emerges. The inadequacy of consent, the conundrum of group consent theories, the ambiguity of property, the specificity of advocacy, the absence of normative clarity in benefit sharing, the limitations of passive, respect-centred theories above, all point at the need for a novel and principled approach in the regulation of group research. In conformity with the rules of reciprocity and equity, as I discuss hereby, this new principle empowers groups to assert a proactive role in research involvement, conduct and feedback. It does so by bringing the focus of the law on the collaborative nature of their engagement with researchers, especially in large-scale research projects, and by providing criteria to evaluate the contribution and effort that groups bring into this relationship. This conceptual model breaks new ground by actively expanding the notion of research participants – or 'subjects' according to enduring US terms – as *partners* involved in genuinely *collaborative* research relationships.

One key open issue for proponents of group-rights theories in this context is how it is possible to develop *proactive* ways that ensure better group control on the kinds of research conducted with group samples or data, and adequate ways to evaluate and maximise group benefits in research. [725] These concerns increasingly include how to deal with cases where research collaborations go wrong.[726] In response to that need, the principle of group empowerment is explicitly constituted in positive, proactive terms. It manifestly acknowledges the positive qualities of the agents involved,

[725] [Dickenson 2007] [Harry & Kanehe 2006] [McGregor 2007] [Schnarch 2004]
[726][Andrews 2006] [Charo 2006] [McGregor 2007] [Schnarch 2004]

discussed in the following sections. To do otherwise would fail to capture the nature and capacity of many groups in contemporary research. I argue that any other principle would be inadequate to meet the purposes of present day claims for better control, transparency and accountability in group research. I explain further hereby.

First, let us look at the key elements of this principle as encapsulated in the table below:

Table 4. Key elements of group empowerment

A group
An ongoing relationship (between group and researchers)
Good communication
Mutual understanding and respect to group values
Commitment to reciprocity (a collaborative dynamic)
Trust
Negotiation of respective expectations and benefits
Evaluation of contribution
Consideration of the group's previous history in research (and its effects)
Mechanisms for feedback and review of research findings

I contend that these elements are central for achieving empowerment. The degree to which they can be available will influence the balancing and evaluation of 'power' that particular groups may have in their interaction with researchers. In considering their merits further, I would like to remind my reader that I have already discussed in this thesis the meaning and nuances of several 'groups' together with examples of

what prior history means in chapters one and two; types and degrees of group 'communication', 'respect to group values', 'feedback', 'review of findings' and group 'trust' in chapter three; examples of 'negotiation' in chapters two and four (e.g. native claims, patient advocacy agreements); considerations of 'benefits' also in chapter four (benefit sharing); concepts of 'ongoing relationship', 'reciprocity' and 'cooperation' in several parts of chapter two and four, as well as in earlier parts of this chapter.

In order to complete their interpretation and refinement as essential for developing a research model based on group empowerment, I still have to demonstrate what group contribution is. I also need to clarify that the correlation of group contribution with how group research 'benefits' are defined *enhances* empowerment. I undertake to meet these goals in the following sections so as to be able to further examine ways for implementation of the principle of group empowerment via legal mechanisms. In the last part of this chapter, I contend that in so far that legal mechanisms can help balance groups' expectations, interests and rights with those of researchers and funding institutions, they must guarantee opportunities for mutual understanding and agreement about such interests between groups and researchers in the broadest sense. I examine best possible options for such mechanisms and then propose a model of conditional gift as a good empowerment model in the last part of this chapter.

As I have already discussed in the first two parts of this thesis, for several groups, key unaddressed common concerns about their involvement in research include: a) continuous involvement in research design and implementation; b) monitoring the use of samples throughout and after research is done; c) review of dissemination of research findings; d) redress against unauthorised uses of samples; e) respect to cultural values and group history in research.[727] I have stressed that understanding

[727] [Harry & Kanehe 2006]

the effects of research on any given group, is not trivial matter, as these impend on members' views about whether that particular kind of research is acceptable.[728]

Consensus is emerging among scholars and group representatives involved in drafting new research guidelines in Canada, US, also to some extent at EU level,[729] that assessment of research acceptability should be based on a carefully negotiated understanding of diverse needs and values among and with groups, and in the context of power relations within and between groups.[730] Can the same be said for their potential contribution to the research enterprise? In the next section, I discuss the centrality of the notion of group contribution in group empowerment. I want to make clear that centrality does not mean that focussing on contribution is the only way to assess the value of groups in research.[731] This assessment should instead be made by reference to the complex nexus of research dynamics, prior history, value-diversity, respect and mutual understanding of respective interests of parties involved in group research, as well as group health needs, and also unavoidably, market needs. These aspects altogether impact on perceptions about how group members view themselves *in multiple roles at once*, as *sources and resources* of material, as *bearers* of continuous personal interests, and also as *creators* of assets, discussed further hereby.

B. The value of balanced contribution

At the heart of my argument is that empowerment perspectives for reassessing groups, their 'gifts' and their claims actively encourage the promotion of meaningful, reciprocal, group engagement in contemporary human research. I thus propose that

---

[728] [Harry & Kanehe 2006] [McGregor 2007] [Tallbear 2001]

[729] See chapter one.

[730] [Brunger 2003] [CIHR 2007] [Harry & Kanehe 2006] [McGregor 2007]

[731] I discussed the limitations of this narrow approach earlier in chapter 4.

the principle of group empowerment helps address the four fundamental questions posited earlier, as pictured in the tabled below:

Table 5. The value of group empowerment

Group Empowerment	Reinforces *reciprocal* understandings of group engagement in research
	Acknowledges groups' interests in *respectful conduct* of research, with groups as sources of samples, and as custodians of these samples
	Establishes mechanisms to measure source *contributions*
	Enables the *distribution* of research-related benefits to groups, according to mutually agreed conditions

I discussed several aspects of the two first points in previous chapters. In the present section, I am interested to analyse further the two latter points in particular, group contribution and benefit (re)distribution.

1. Group contribution and empowerment

Why is the recognition of group contribution central for empowerment? In evaluating the contribution of groups in research, a first key point is that their value, first of all, comes from the fact that *they are a group*. Their size, but also their biological rarity, or particular geographical, historical, cultural, or health circumstances, their ability or potential as organisational units, all affect their contribution. The realisation that groups have a larger capacity for contribution than individuals as single units is

critical in the formation of current group initiatives, and, in understanding group empowerment in research.

Secondly, particular groups have a better ability to form networks and to create collective resources in view of initiating and advancing research in particular areas of group interest, more than others.[732] For example, as already discussed, in the last two decades, impressive patient initiatives to coordinate and facilitate large-scale advocacy activities are on the increase.[733] These initiatives are dedicated in developing ways to secure group influence in the direction and the use of research, such as the development of therapies, through translational research, and availability of research benefits to their members, e.g. affordable access to diagnostic tests. These activities have become exemplars of group structural organisation, representation and resource-building, and many were discussed in detail earlier, in chapter four.[734]

In most of these cases, group contribution is substantially enhanced by the creation of *group resources* which are owned and managed collectively. These group resources can vary from blood and tissue banks, biorepositories, clinical databases and patient registries, screening facilities, coordinated research clinics data collection and other research infrastructure. They can extend to group member recruitment for clinical trials and regional clinical trial networks, initiation of studies on particular diseases, mentoring or psychosocial adjustment schemes, fund-raising, participation in gene discovery research, e.g. in the development of drug tests and toolkits with favourable licensing terms for commercial investigators.[735] Such resources and

---

[732] As discussed at length in the previous chapter; for key commentators [Anderlik & Rothstein 2004] [Merz 2002] [Rajan 2006] [Terry et al. 2007]

[733] *Ibid.*

[734] E.g. Genetic Alliance Biobank in US; Genetic Interest Group in UK among key others [Kent 2006]

[735] For a comparison of activity between the late 1990s and late 2000s see [Dresser 1999] and [Terry et al. 2007]

activities now form an integral part of how patient group contribution is enriched, with structural re-organisation that enables groups to *participate*, *initiate*, *facilitate* and *accelerate* research.[736] However, such models may not necessarily be appropriate for promoting the interests of other kinds of groups.[737] Nevertheless, it is interesting to note the emergence of recent proposals for developing mechanisms of donor representation and involvement in research conduct, in biobanking projects where the groups are very big and group ties are not necessarily close.[738]

Thus there exist strong reasons why the recognition of group contribution is central to empowerment. It is a fundamental way for some groups to mobilise themselves and build collective resources – as it emerges from patient advocacy cases. Resources *de facto* give power vis-à-vis third parties.[739] This power may be of substantial interest in those areas of law where there is jurisprudential reluctance to acknowledge intellectual property rights, as well as property rights to individuals, as sources of human tissue in research. Interestingly, as discussed previously, in the *Greenberg* case, the Court accepted the plaintiffs' unjust enrichment claim against the University. This to me implies that the Court considered there was something inherently inequitable in the dynamic between the parties, or rather, in the enrichment that the defendants made at the expense of the patient families.[740] It

---

[736] [Terry et al. 2007] mentioning key examples such as PXE International, Genetic Alliance Biobank, CFC International, Alpha 1 Foundation. The authors provide an impressive up-to-date account of how research can be accelerated by advocacy groups in particular, but the work offers ideas for group organisation and mobilisation more broadly.

[737] See large-scale research biobanking projects as an example.

[738] [Winickoff 2007] proposes a donor approval model in the governance of UK Biobank.

[739] For example, commenting on advocacy groups creating their own tissue banks to aid in drug development, at a recent interview in the Wall Street Journal, Sharon Terry, director of PXE International and founding president of the Genetic Alliance Biobank, stated: "[w]e have 33 scientists working under my coordination, largely because I hold the resource, the blood and tissue bank" [Dockser Marcus 2006]. One wonders to what degree other kinds of groups could mobilise themselves in similar ways.

[740] Arguably, this can be understood as an acknowledgment of the failure of implementing reciprocity in the relationship between the parties.

would be fair to anticipate that claims like these are likely to rise, in the context of highly collaborative patient advocacy relationships.[741]

I would like to return to the point of applicability of group mobilisation strategies across different kinds of group categorisations. Not all groups have managed to develop similar methods and organisation structures but interest is emerging in creating comparable processes across different categories of groups willing to get involved in long-term research collaborations.[742] It is important to stress that even if these models may not be applicable to the circumstances of other groups, they inspire new ways for group mobilisation, and further group influence in research.[743] Furthermore, we should not ignore the impact of the fact that group contribution in itself is a genuine outcome of mobilisation processes aimed at building contributions. Such processes can have a fundamental impact on group cohesion, cooperation and trust, both in intra-group as well as in public group relations.[744] Group cohesion becomes both an instrumental and substantive group goal, and helps cultivate trust relationships with third parties. [745]

2. A distinct relationship

The previous points are linked to a fundamental reason why group contribution has significance in terms of empowerment. It is an expression of the *distinct*, *ongoing relationship* that depends on dynamic connections between groups and researchers over time. Aspects of this relationship include that group expectations are considerably different than those of isolated individuals; that group risks and lost

---

[741] [Anderlik & Rothstein 2004] [Oberdorfer 2004]

[742] As mentioned a little earlier, when pointing out that native groups have expressed interest in advocacy strategies.

[743] For example, interest in such processes has been increasing in large-scale biobanking projects.

[744] [Merz 2002] describes the various strategies that the Canavan families used to gather information and stay in communication with more families; see also [Rajan 2006] [Terry et al. 2007]

[745] [Merz 2002] [Terry et al. 2007]

opportunity costs are higher than those of isolated individuals, both in the case of invested time and resources by the group, but also because of possible threats of stigmatisation or adverse discrimination to the group as a whole. Such risks may affect group members in overwhelming ways.[746] In the absence of frameworks for the protection of groups against stigmatisation or adverse discrimination, the latter becomes a highly sensitive issue.[747]

An additional aspect of this *continuous relationship* is the responsibility entrusted to researchers not to act at the expense of possibly vulnerable participants. For some groups vulnerability may exist due to, for example, geographic or cultural isolation, lack of information, training or education. A further aspect of the interaction between groups and researchers is the need to dispel possible associations of new research with uncomfortable historical precedents of group exploitation, and to provide assurances of equitable and respectful collaboration. These aspects all form an important part in balancing and 'counter-weighing' how continuous, personal relationships are forged in group-researcher interactions, and how the overall contribution is viewed by the group.[748]

In sum, the principle of group empowerment prescribes that groups should be protected in mobilising themselves efficiently, that their contribution to the research enterprise is acknowledged and respected. According to the principle, safeguards should be in place to guarantee communication, understanding and negotiation of

---

[746] I discussed this issue in chapter two, see for example [Davis 2004] [Davis 2000] [Zhang et al. 2004]

[747] *Ibid.*

[748] See my discussion-hypothesis on the possible different consequences that the project in Tonga might have had, if the company had, for example, acknowledged their failure to take account of family structures and to consider Tongan values about dignity. [Dickenson 2007, 167-169] offers refreshing insight on how balancing mechanisms might have helped achieve goals which otherwise would be missed!

group expectations in research, as part of an ongoing, collaborative process. These guarantees include tailored consideration of prior group research history, demonstration of respect to group values and norms, mechanisms for group review of research feedback and dissemination, and negotiation of research benefits with groups, in proportion to group contribution, researchers' contribution and, where applicable, market needs. Appropriate accountability mechanisms should be in place, as additional guarantees against exploitation, fraud or any other mishaps that might occur at the expense of groups, as discussed in earlier chapters.

Furthermore, an honest commitment to reciprocity, transparency and cooperation should be ascertained from all respective parties, at the outset of their collaboration onwards. The added value of implementing this new principle is that it creates new avenues to address group claims in better control and research accountability effectively. At the core of this principle is the redefinition of group relationships with researchers and research funding agencies as genuine collaborations on a more equal footing than ever before. This re-evaluation is necessary in order to build trust and maintain balanced partnerships long-term. In assessing best ways to weigh the significance of group contribution and interaction with researchers and research institutions, it is important to consider and apply core ethical values. I discussed earlier that the application of reciprocity rules is central for healthy cooperation and trust-building. In the next section I discuss how these can be applied effectively under the principle of empowerment.

3. Evaluating contribution

I noted previously, while considering a supportive environment for group empowerment, that reciprocity, transparency and accountability are essential in fostering trust and cooperation. These qualities enable groups to collaborate with researchers and contribute to commonly agreed research objectives and goals. In pursuing these goals, it becomes necessary to consider a methodology for the evaluation of group contribution. The question is, on what basis the evaluation

should be done? It is worth taking a closer look before agreeing to best options and value considerations.

For example, an evaluation of contribution on the basis of one's mere *need* would mean that they contribute according to their ability what they actually can. If the group is vulnerable economically, politically or culturally, the evaluation of the contribution of both sides would not be sustainable under a reciprocity system. This is because the balance of contributions would be spectacularly unequal.[749] If one party is vulnerable, a stronger system of protection would have to apply on the basis of humanitarian or fiduciary principles.[750] If on the other hand, a group is not vulnerable and has the ability to 'negotiate' as is the case with some kinds of groups at least today, overly protective and paternalistic models would be a cause for concern; they would institutionally entrench the group's lack of power forever![751]

Contributing on the basis of numerical *equality* would mean that one contributes at least as much as everyone else. But as I have discussed, the limited way in which our regulatory system currently treats the contributory ability of groups as opposed to the contributory ability of researchers and research-funding institutions. It does not acknowledge equality, notably in the sphere of intellectual property but also in

[749] See also [Buchanan 1990] and discussion in [Schmidtz 2005]

[750] I discuss the role of fiduciary duty as a model for empowerment in group research further below. As [Walzer 1983] notes, 'need' generates a particular distributive sphere within which it is itself the appropriate distributive principle; other distributive criteria will always be operating alongside of need and it will always be necessary to mark them off from one another. Walzer describes three kinds of distributive principles, free exchange, need and desert as adequate to match the diversity of social goods, asserting that none of them has force across the range of distributions [Walzer 1983, 21]. Similarly, I understand reciprocity to be helpful in establishing better conditions for group-researcher cooperation, especially when groups are not vulnerable.

[751] [Kennedy 1996] and see discussion on the fiduciary model further below.

tangible property.[752] Arguably, such an expectation may not be a realistic one to have overall, given the size of the contribution of funding bodies in existing research projects, the level of their investment, intellectual contribution and labour arguments aside.

I have discussed in various parts of this thesis that the tension for a re-evaluation of power differentials and positioning of groups as autonomous resource bearers, vis-à-vis research funding institutions and their researcher employees is palpable. It calls for novel ways to assess how these relationships can be defined in law as less unequal both in terms of their power and also in terms of their collaborative character. This latter element strengthens the need for recognition of group members' commitment and ongoing interest, and the need to respect and maintain collaborative and beneficial endeavours between groups and researchers.

It is wise to consider an approach between the twin ends of need and equality by turning to the notion of equity. *Equity* represents a balance of proportional equality, linked with ideas about fairness and justice. An evaluation on the basis of equity means that the value of one's benefit can be calculated *in proportion* to the contribution of everyone else.[753] It warrants clarification of such proportions as the necessary elements involved in assessing and balancing group research contributions. I contend that the evaluation of group contribution under equity can be understood as a process with two aspects: i) an institutional recognition of what a group does; and ii) a mechanism on how this collective action is valued in a dynamic and relational context.

---

[752] See extensive discussion in chapter four – For key recent publications on the topic see [Dickenson 2007] and [Rao 2007]

[753] This echoes requirements for reciprocity, stipulating that "returns and reparations should be fitting and proportional" [Becker 1986, 89] with the definition also used by [Kuruk 2003, 430]

I discussed in the previous section the different elements of contribution, such as various communication models, recruitment tactics, resource-building, and opportunities for feedback, as strategies for group mobilisation, resource and morale-building. Mechanisms for evaluation on the other hand are a complex technical problem which transgresses the limits of law scholarship and it merits careful and separate consideration. Calls by scholars and other experts for measuring contributions that could be recognised nationally and globally, acknowledge that international cooperation is needed to develop methods for evaluating such processes. This is seen both as a technical question and as a political problem.[754] For the purposes of this analysis and by building on the variety of claims currently forwarded by groups, I propose that such processes and methods ought to take into account at least the following elements: i) group cohesion; ii) group effort;[755] iii) scarcity of group resource(s); iv) prior history of a group in research; v) health and other benefits expected by the group; vi) contribution of everyone else;[756] vii) market needs.[757]

---

[754] See for example [Tvedt 2006, 201]

[755] This would include, for example, personal time, resources.

[756] For a discussion on the link between symmetry and mutuality, further below.

[757] As I have discussed in chapter two, consideration of – if not dependence on – market needs is inescapable. For example, a group's ability to negotiate levels of royalty fees on products to be developed from research they contribute to, can largely depend on what is profitable in market-terms, in a particular time and place. For an interesting comparison taken from innovation outcomes on traditional knowledge and plant resources, see the level of royalties that the San tribe secured, as part of their benefit sharing agreement with the South African Council for Scientific Industrial Research (S.A.CSIR), for patent royalties from the development of a drug based on the *hoodia cactus*, a local plant with appetite-suppressing royalties. The Council agreed to pay the San 8% of payments by its licensee (Phytopharm), during the clinical development of the drug over the first three years, and 6% of all royalties when the drug is marketed (between 2006 and 2008) [Science in Africa]. According to [O'Connor 2004, 684] [Wynberg 2004, 852], the potential of a slimming drug and cure for obesity in a US market must have sustained high industry interest throughout negotiations with the tribe. Industry motivation for cooperation with groups thus can depend on how desirable particular group samples are, e.g. in terms of particular group resources being scarce, and whether investment in research on them is likely to yield profit. The latter can be difficult to predict. The history and withdrawal of the patent claims on indigenous human cell lines collected from members of the Hagahai, Guyami and Solomon Islands tribes, is a powerful testimony to how the potential for

It goes beyond the scope of this thesis to analyse the particular contexts of each of these areas of action, which include economic considerations. I have discussed some of these elements in previous parts of this thesis, especially the concepts of group cohesion, group effort, prior history, and group benefits. Further interdisciplinary research is required for the study of these concepts while at the same time the law can help by setting limits on what, for example, would be considered exploitative[758] for groups to give away – in line with previous controversies on biopiracy and fraudulent manipulation of groups who participate in research.[759] Such limits would help to create mechanisms for enforcement of standards either at local or national or international levels, depending on the nature of relevant projects. I recommend that it would be wise to pursue these in consultation with particular group representatives and stakeholders, and keep them consistent with reciprocity prerogatives where applicable.[760] Such standards could take account of differences across groups depending on group interests, expectations, research acceptability, prior exploitation, perceived risks or concerns about group survival.

4. Spelling out the benefits

For clarity purposes, it is valuable to consider the notion of benefits and their connection to group contribution. In group empowerment, *contribution is a strong basis for a group's claim to control*, and this itself is a benefit. It is important to retain the distinction between the basis of a group's claim to control and benefits as the consequences of a group's strong claim to control. These could be distinguished

---

profitability – and its absence – affects industry interest in the human context [Bhat 1996] [Lock 1997a] [Whelan 2006]

[758] To use Dickenson's words earlier as in [Dickenson 2004, 113]

[759] See earlier discussion in chapter four of this thesis on the HGDP and Havasupai case studies.

[760] Examples in this direction can be found in the recent review of the CIHR guidelines for research conducted with aboriginal communities in Canada, as a process of extensive consultation and a series of workshops with local representatives of tribes [CIHR 2007]

as 'negotiated benefits' and 'benefits of research'.[761] An example of the latter can be the benefits described in a biobanking project consent form as benefits to be derived from the biobank which justify the 'collective acceptability' of research in that population.[762]

Negotiated benefits are given in exchange for recruitment and for donating the data and materials necessary for the biobank. These latter kinds of benefits are of particular interest in this chapter. They can include research on conditions or issues important to the group and its members, and might result in changes to clinical care or environmental remediation; funding for the group's own biobank and related data collection; access to the biobank by researchers from within the study population; financial compensation or access fees charged by the bank; training in activities related to biobanking and research for local researchers; feedback on research generated information related to clinical care or health planning (feedback); affordable access to tests or treatments arising from the research; health care services that may or may not be related to genetic disease; new local facilities and employment opportunities.[763] They can constitute key reasons for strong group motivation in creating a particular resource, and building a contribution in anticipation of achieving particular benefits, which as just explained, are not limited to health benefits.

It is important to note that both kinds of benefits, as basis for claims and as consequences of claims, are always defined at the level of the *collective*. This is consistent with HUGO recommendations on what constitutes acceptable as well as inappropriate kinds of benefits in group research.[764] In the former case, these

---

[761] [Tansey & Burgess 2005, 37] and see previous discussion in the last part of chapter four.

[762] [Godard, Schmidtke et al. 2003, S88]

[763] [Tansey & Burgess 2005, 37]

[764] I will not repeat the classifications made in chapter four, where I also discuss emerging work on social attitudes reinforcing ideas that benefits are defined at some collective level [HUGO Ethics

recommendations are matched by current trends, for example, by scholars seeking to expand notions of benefits in group research contexts.[765] For example, in the context of large-scale biobanking projects, several authors increasingly comment that "accepting risks to a population in exchange for collective benefits is a political decision, which must be fairly negotiated according to the norms of that population".[766] They regard this 'exchange of benefits' as a way of justifying to the population contributing to the biobank that risks, financial costs, administrative fees and other effects that the biobank may have on the collective, are justified.[767]

The need for reciprocity in the development of these latter discourses is evident or sometimes even explicit. For example, emerging work reveals that researchers question the notion of altruism where no return of any sort is expected by the donor, seeing the act of donation instead as the existence of 'exchange relationships' that form the social basis of a society and where some form of reciprocal benefit is expected.[768] Interestingly, this suggests the need to consider the *forms* of benefit however small or intangible that could be offered, and *explicitly named* to individuals, groups and wider communities rather than focusing on 'educating' participants that they should not expect a benefit.[769]

Committee 2000] [HUGO Ethics Committee 1996] [Haddow et al. 2007] [Hayden 2007] [Hunter 2006] [Pullman & Latus 2003]

[765] [Haddow & Cunningham-Burley 2008] where the authors cite that in research with focus groups for Generation Scotland, "[m]ost (participants) felt that GS should be a public charity and that benefits should be community and publicly-based".

[766] [Tansey & Burgess 2005, 37] [Kaye & Martin 2000] – The expression 'in exchange' here does not relate to the notion of 'negotiated benefits' discussed further above.

[767] [Godard, Schmidtke et al. 2003, S88]

[768] [Sumner 2007]

[769] [Sumner 2007] [Haddow et al. 2007] [Levitt & Weldon 2005]

5. Balancing expectations

In building platforms to recognise group contribution and enable the enforcement of equitable principles for group empowerment, the role of reciprocity needs to be reiterated. The rule of reciprocity warrants a symmetrical approach in balancing group and researchers' expectations.[770] Symmetrical not in a procedural sense of merely returning a benefit in response to another with the value of either benefit bearing no significance – but in direct application of the notion that parties share risks and benefits from research on joint and equitable basis.[771]

Symmetry requires acknowledgment of the contribution of all parties and reciprocation *to the closest degree possible*. Genetic research collaborations require long-term cooperation, realistically possible via mutual recognition of each party's contribution, together with the equitable calculation of their respective contributions. I contend that the recognition of group contribution on symmetrical terms is essential, at least because groups contribute to the research process to a *significantly higher degree* compared to individuals. I argue that the acknowledgement of group contribution will help maintain better relationships between groups and researchers, and enhance group trust against concerns of exploitation.[772] Reciprocity becomes a strategic value-tool in the promotion of empowerment as enhancing a group's ability to gain a better hold to the closest degree possible, over the conduct and possible benefits from research.

At the heart of group empowerment is the idea that power can *change* and that it can *expand* on the basis of the qualities that each party brings into a cooperative

[770] [Becker 1986, 147] [Komter 2005] [Komter 1996]

[771] As it was defined early in this chapter, see also [Becker 1986] [Schmitdz 2005]

[772] [Greely 2001b] [Komter 2005] [Weijer 1999]

relationship.[773] I argue that the evaluation of group 'power' according to the principle of empowerment offers a more precise and balanced approach in pursuing long-term stability and collaboration between groups and researchers. This stability fundamentally depends on transparent, equitable assessment of group contributory expertise and resources, mutual communication, and continuous, respectful understanding of group capabilities and goals.

According to the general criteria for reciprocation considered earlier in this chapter, such understanding should be achieved by taking account of group members' contribution as a whole, their relationship with researcher(s), their intentions for the use of their contribution, as well as the respective expectations of groups, researchers, and funding institutions involved in the research project at hand. Equity considerations complement these criteria well by warranting that their assessment is performed in line with group effort and cohesion, resource scarcity, possible prior involvement in research and group history, group health and other benefits negotiated, *in proportion* to the contribution of everyone else, including market needs.

In order to implement such considerations, it is necessary to consider possible legal mechanisms that offer ways to balance priorities in group research. To conform to the principle of group empowerment, these mechanisms should provide ways to acknowledge and protect group contributions, respect group structures, values and priorities, and define their involvement with researchers in as less unequal terms as possible. Such mechanisms should operate on the basis of considerations of reciprocity and equity. In the next part, I consider three possible models.

---

[773] In researching the possibility of a group empowerment model in genetic research, I looked at law, ethics and advocacy literature that promote notions of group power, e.g. [Merz et al. 2001] [Weijer 1999] [Terry et al. 2007]. I also consulted work by community psychology scholars who examine how social power is developed through community organisation processes and practices, see especially [Florin & Wasserman 1990] [Page & Czuba 1999] [Speer & Hughey 1995]

IV. Group Empowerment Mechanisms (GEMS)

In assessing possible legal models for group empowerment, a number of considerations become paramount. What degrees of protection can such models provide and establish mechanisms to measure group contributions, acknowledge group interests in respectful conduct of research, and enable the distribution of research benefits to groups, according to mutually agreed conditions beneficial to groups? To what extent can these models help reinforce collaborative, reciprocal relationships and facilitate long-term group engagement in research? In this part, I consider three possible models as potential options for empowerment in the form of fiduciary duty, contract and group conditional gift.

A. Fiduciary duty model

1. Is the relationship between groups and researchers a fiduciary relation?

Several attempts have been made to define the nature and content of obligations derived from group-researcher interactions. These vary in scope and intensity and assert different degrees of responsibility. So far, I have discussed some models that define their interaction in limited ways, in the pure altruism model, advocacy, property rights, and the benefit sharing paradigm. I stressed that they focus on limited notions of control, compensatory justice, and the status of transferred samples and data as 'objects'. None of these models pays attention to the nature of the relationship between groups and researchers and in the ways they interact. I argue that in the search for models that can adequately address group interests, it becomes important to examine ways to centre on the nature of this relationship and the dynamics that shape it. First, I consider the theory of fiduciary duty, as a possible avenue of understanding the group research relationship. I envisage this, not as the

only way to view the interaction between researchers and group participants, but as an opportunity to broaden thinking in this context.

A fiduciary relationship is one created under the doctrine of equity.[774] It is usually imposed where there is a *power differential* between the parties that renders one party dependent upon the other. In such circumstances, the fiduciary is under a strict obligation to act loyally, in the best interests of the other party – the beneficiary.[775] Under the existence of a fiduciary duty, a binding code of behaviour is set out to protect the dependant party from harm.

It is not easy to determine whether a particular relationship should be classified as fiduciary. The existence of such as relationship is not determined by a single test, and the boundaries of the category are not clear but the category itself is not closed.[776] Traditionally, it is established that in such a relationship one party places substantial confidence in another in acting on his behalf or in his interest in some respect.[777]

Two situations are generally accepted as establishing a fiduciary relationship; firstly, where the fiduciary undertakes to do something in the interest of the beneficiary, and secondly, where the beneficiary places complete trust and confidence in the fiduciary to act on their behalf and their best interests.[778] At first instance, one might consider that the first situation is not true in research, since the point of research is to create

---

[774] [Martin 2001] [Penner 2004]

[775] [Hoyano 1997, 230]

[776] Some examples are well-established, e.g. solicitors, company directors, pawnbrokers [Martin 2001, 613]

[777] The adjective 'fiduciary' comes from the Latin 'fiducia', which means 'trust', hence the adjective means of or pertaining to a trustee or a trusteeship. For example, a lawyer can commit a breach of the fiduciary duty by stealing his client's money, by entering into a contract with the client without full disclosure, or by sending a client a bill claiming disbursements never made and so forth [Hoyano 1997, 190]

generalisable knowledge, not to tailor it to a particular group seeking protection. But, we could also conceive of the possibility of interpreting fiduciary rules in ways that focus on protecting group interests. For example, if a research funding institution issues research ethics guidelines with particular conditions to be met by researchers in the interest of group participants, it can be argued that an expectation would be created on behalf of the participants that the provisions of the guidelines will in fact be met.

Under such hypothesis, research guidelines could stipulate a duty for researchers and their funding institutions to accept a fiduciary obligation towards participant groups. Such guidelines could be considered to be inherently fiduciary. They would focus on recognising the vulnerability of participants, their reliance on researchers, and the trust and confidence necessitated by the research endeavour.[779] They would be intended to ensure that research is conducted with standards that guarantee respect to participants' interests. As another example, they could require that conflicts of interest are disclosed and that researchers are not allowed to make private profit from the relationship unless any profits are fully disclosed and consent is provided. Requirements like this are characteristic of fiduciary obligations, where a special duty for loyalty towards the vulnerable exists.[780]

2. A moral relation

It has been suggested that equity theory could offer interesting solutions in defining legal interests in human tissue.[781] There are elements of equity theory that can help us rethink the nature of the relationship between groups and researchers, by drawing on the need for *fairness* and *flexibility* which helped establish equitable rights in the

---

[778] [Martin 2001] and see also [Smith 2002]

[779] Compare causes of action in the *Havasupai* and *Greenberg* cases, claiming breach of researchers' fiduciary duty, but unsuccessfully.

[780] [Hoyano 1997] [Pearce & Stevens 2002] [Smith 2002]

first place. Equity theory suggests that people wish neither to under-benefit nor to over-benefit from participating in research; they wish to be fair.[782] According to this thinking, an equitable obligation would be established at the moment when researchers agree to group conditions. A question then arises as to whether this theory can be used as a basis for the development of a new model in group research. It would draw on equitable obligations born out of the special relationship between groups and researchers. For example, this could prescribe that researchers shall use samples in ways that respect group interests.[783]

The development of such a theory would regard the research gift relationship also as a *moral relation*. But, there are important caveats to consider, if one were to rely on the theory of the fiduciary duty as the basis for imposing obligations on researchers in this context. The theory would rely on a special dependency between groups and researchers, stemming from the *vulnerability* of the former. I argue that in such case, a fiduciary model would not deliver satisfactory solutions in achieving group empowerment, except possibly in limited cases where vulnerability indeed exists. I explain why directly below.

While I find the potential use of equity theory extremely helpful in enriching current analysis with ethical reflection on the nature of the relationship between groups and researchers, it has limitations in this context. One could argue that if vulnerability and dependency exist, particularly in isolated and impoverished settings, in that researchers become akin to special advisers, bearers of expert knowledge to the group, then, perhaps, it would be of benefit to consider fiduciary models of protection. That is, if researchers acquire influence over group decision-making, or advice functions directly created from "power-dependency" relationships, then

---

[781] [Hoppe 2006] [Hoppe 2005a] [Hoppe 2005b]

[782] [Martin 2001]

[783] [Birks 2000]

protections of fiduciary law may be required.[784] But such a test is yet to be established. Furthermore, in most cases, group research participants are not being treated or advised by researchers, in ways that would equip the latter with overriding or considerable influence over the former that would render them susceptible to harm.[785]

Moreover, fiduciary models do not offer positive ways to reverse inequities in the future. By focussing on vulnerability, exploitation and violation of special trust, this model offers valuable insights in possible dependency binds, but it does not provide proactive ways to evaluate group efforts and capabilities. It only protects participants as vulnerable parties. This is so because traditionally, equitable duties in the fiduciary relationship are seen as a response to the law's recognition that a relationship involves one party being *unusually vulnerable* to the other party's ability to exercise some power over their interests.[786]

In sum, the fiduciary model does focus on the nature of the relationship between researchers and group participants but it defines the latter in rather passive and vulnerable terms.[787] It relies much more on vulnerability, power imbalance and the need to protect against exploiting a vulnerable party's trust, than on notions of group empowerment, according to which group power changes over time.

I find the contribution of fiduciary theory problematic in this context, while seeking to safeguard interests of groups in contemporary research. Ironically, by focussing on *power imbalance*, the fiduciary approach risks entrenching the imbalance and

[784] [Hoyano 1997, 195]
[785] *Ibid.*
[786] [Jackson 2006, 306]
[787] [Jackson 2006, 306] [Kennedy 1996, 132-136]

ingraining the inequalities it aims to provide solace from.[788] To the extent that such a paternalistic approach might be defensible under the fiduciary model, I would caution scepticism in that such as model might *fix* the group in a *dependent* role in the relationship. I argue that do so would be largely undesirable,[789] except in the case where particular groups are indeed vulnerable, because of particular economic, political, health or other circumstances. I find the fiduciary approach inadequate as it would risk embedding the relationship between researchers and groups in terms of vulnerability and dependence of the latter.

Even when there is recognition of inequality – and to the extent that this could be perceived as lack of resources and equality of opportunity – such acknowledgement does not necessarily lead to recognition of special vulnerability. One might argue that, in the absence of current group protections, groups as research participants have an overall unequal footing compared to researchers, meaning that there is a power-differential in respect of what rights groups can have in law, compared to researchers and funding institutions. This does not render groups dependant on researchers, in the sense of classic characteristics of fiduciary relationships that require loyalty and confidence on the part of the trustee.[790] In support of this, it is worth considering the US example. In US research ethics, while a fiduciary relationship can exist between doctors and patients, this does not necessarily apply between research participants and researchers in non-therapeutic research.[791]

---

[788] *Ibid.*

[789] I find it undesirable because it would deny possibilities for groups themselves to change their power.

[790] [Hoyano 1997, 230]

[791] [Rao 207, 374] commenting on the *Moore* and *Greenberg* cases, explains that the court dismissed the plaintiffs' claim for breach of fiduciary duty, ruling that "there is no automatic fiduciary relationship that attaches when a researcher accepts medical donations". Similarly, in the *Havasupai* case, the Court ruled similarly that a fiduciary relationship did not exist; the judge he dismissed that

For all these reasons, I am not convinced that it would be wise to recommend fiduciary duty model as a possible model of group empowerment, in non-therapeutic group research relationships. It would be a very weak one. It would accept that groups are always dependant on researchers, and would perpetuate notions of groups as vulnerable victims. But I have demonstrated several examples where this is simply not true. By focussing on power imbalance, exploitation of trust and vulnerability, a fiduciary model would not be able to provide guidance on measuring group contributions, and would not enable groups to exert positive control in influencing the research agenda, or monitoring the use of samples throughout research, as many groups claim today.

To the extent that these claims are raised at collective level, I argue that we need new concepts to host these interests. We need to recognise group interests as special interests, for groups to have their contribution acknowledged, not to be exploited for others' gain, to be respected according to group norms, to be involved in continuous relationships that benefit the groups, in ways defined by groups. This is why more conceptual work is needed at a broader level. In considering possible options to achieve a healthy balance in group research relationships and in ways that mutual obligations can be deployed and enforced, I consider another model next, a contract model.

---

count outright, ruling that there was no evidence of acceptance on the part of researchers which would constitute a fiducia [*Tilousi v. Arizona State University* 2005, 5]

B. Contract models

1. The relationship between groups and researchers as a contract: a legal mechanism or a social metaphor?

Can contracts enhance collaborative relationships between groups and researchers, and can they provide means of evaluation and long-term cooperation? There are at least two ways to describe the kinds of responsibilities undertaken by groups and researchers in group research, if their relationship is bound by 'contract'. One way is to consider 'contract' as a formal, binding, legal agreement that warrants the performance of contractual conditions, according to the will and mutual undertaking of obligations for the parties. The other is to consider it as social and moral metaphor that denotes the need for respect of each other's interests. I will consider primarily the former given that two kinds of contractual agreements already exist in the field of group protections; research funding institutions employee contracts, and private agreements between groups and researchers, as in the case of patients groups, with individual researchers.[792]

2. Funding agency research contracts

One way in which contracts are used for group protections, not initialised by groups themselves but by research funding institutions, is in employment contracts between major research institutions and their researchers. In some jurisdictions, national research funding agencies have started to impose conditions for respecting groups, as part of employment contracts with prospective researchers. The commitment to comply with conditions stems from provisions set in research ethics guidelines issued by these funding institutions. In Canada, for example, the Canadian Institutes of Health Research revised their Guidelines for Health Research Involving Aboriginal

[792] See discussion on the PXE agreement in chapter four.

People very recently, in order to establish new research practice standards for research conducted with aboriginal participants.[793]

These standards require researchers to include in their agreements with aboriginal groups full disclosure of *benefits and foreseeable harms* from the proposed research; full disclosure of *sponsors and affiliations* of researchers; fully informed, *written consent* for all subsequent research; an agreement that all tissue and data collection and subsequent research will occur while making efforts to fully *understand the cultural context* of the particular group, as well as the *ramifications* of such research to participant group(s); a provision that groups should be *actively consulted and involved throughout* all phases of the relevant research so that their interests can be actively protected; an agreement to *translate* all provisions of the contract in native languages and to maintain *communications* through interpreters (where research involves aboriginal group participants); a provision to allow the group(s) to *access*, whenever feasible, the *results* of the research; a provision that *due credit* – in the form of authorship, co-authorship, or other appropriate acknowledgment – should be provided to the group, in addition to, or as part of *compensation* arrangements agreed.[794]

Thus in the Canadian model, contractual obligations to protect group interests are part of researchers' employment contracts. In this form, this model institutes somewhat paternalistic protections, as part of research ethics guidelines. It was developed with input by representatives of aboriginal communities, over a long process of dialogue and communication.[795] It is significant in that it promotes respect to cultural contexts and views, and commitment to ongoing and honest

---

[793] See [CIHR Guidelines 2007] prepared by the Ethics Office of the Canadian Institutes of Health Research, in conjunction with its Institute of Aboriginal Peoples' Health, to assist researchers and institutions in carrying out ethical and culturally competent research involving Aboriginal people.

[794] *Ibid.*

[795] *Ibid.*

communication with aboriginal groups. But one wonders why these provisions for group protections form part of contracts between researchers and funding institutions and could not form part of agreements between these institutions and groups themselves instead. Furthermore, it is questionable whether this model provides effective ways to deal with commercial, scientific uses of research material, as well as adequate management of research uses that could be undesirable to groups. The extent to which these guidelines provide ways to evaluate group contributions, and assess promote further groups' potential to develop research resources of their own is unclear.

This model interestingly takes account of cultural, social, economic circumstances of aboriginal groups, and their organisational factors – for example, whether groups have communication networks, and representative structures. But, it does not rely on whether groups have resources; this model relies on notions of compensatory justice, and in simply considering groups as the only resources themselves. Yet, by introducing standards, this model is evidence of current interest in developing protections for groups, even on a self-regulatory basis. These guidelines at least provide useful ideas on what issues major research funding institutions consider of importance to groups. They establish conditions that could be used, for example, to develop minimum legal standards, which perhaps, in the future, could apply to group-researcher interactions directly.

I argue that this model should be complemented by further protections under the principle of group empowerment, in ways that allow groups to take a stance in securing a better role in influencing research and in recapping benefits derived from such research in the future. This is a point to which I will return. But first, I need to discuss another set of cases, where direct contractual interactions between researchers and groups have been achieved.

3. Private group agreements

Private arrangements seek to protect group interests in monitoring the use of group samples and data, subsequent dissemination of research findings, negotiating research-related benefits, licensing royalties from future research, reduced or free access to therapeutic products developed that may be beneficial to group members, agreed via material transfer agreements or memoranda of understanding.[796] These do not provide protections about respect to cultural values and views, or fears against anti-discrimination, but they allow the clarification of parties' expectations and rights *ex ante*, and they are dependant on the private will of the parties.[797]

Practical advantages of these contractual approaches in protecting group interests are that they incorporate elements of free will, mutual responsibility, and legal commitment. The groups can specify what researchers can or cannot do with the transferred tissue samples, data and research outcomes. In the absence of legal recognition of property rights to groups as tissue sources, there is an automatic appeal for groups to consider contracts, in order to negotiate terms with researchers and research institutions, on the commercial and scientific uses of proposed biomedical research, prior to or during the research.[798]

In chapter four, I discussed in detail the rise of genetic patient advocacy in genetics as an important phenomenon in genomic innovation, which draws on a strong tradition of patient advocacy activities since the 1970s.[799] Today patient advocates increasingly seek to negotiate contracts in gene-discovery and drug-related research, and, in market-terms, they build their 'bargaining power' by amassing biological and

[796] [Terry et al. 2007]
[797] [Anderlik & Rothstein 2004] [Oberdorfer 2004]
[798] [Oberdorfer 2004, 389]
[799][Dresser 2001] [Epstein 1995] [Merz et al. 2002] [Novas 2006] [Parthasarathy 2004] [Rajan 2006]

financial resources.[800] With the successful agreement between PXE International representatives and University of Hawaii researchers – which has not been challenged in court – as a prime example, these initiatives rely on private written agreements, usually before researchers gain access to samples, in order to forward group goals.[801]

These are obvious advantages in that contractual negotiations can help avoid disputes that may arise in the absence of an agreement. But significant caveats emerge in groups relying on private means to negotiate and exert substantial control over the terms of research. Contract agreements do not bind third parties, and it is rather uncertain whether they would be deemed enforceable, if challenged in court. For example, in the PXE case, the contract is only binding between the Terrys and the University where the researcher discovered the gene, and if challenged, it could be found void either on the basis of no consideration,[802] or as contrary to public policy. Arti Rao makes exactly the same point in her recent commentary on the *Moore*, *Greenberg*, and *Catalona* cases, that if challenged, these contracts would possibly not be enforceable either because of lack of legal basis (body outside commerce, no financial gain on one's body) or because they may be deemed as curtailing research (and against public interest). [803]

---

[800] *Ibid*. – I discussed that their contribution is not limited to these two factors, but these two aspects are the two main kinds of contribution that scholars tend to highlight.

[801] These agreements are often confidential and it is difficult to check whether the terms agreed are equitable [Bellivier & Noiville 2006]

[802] Key elements to the creation of a contract are *offer and acceptance*, *consideration* and *intention* to create legal relations; each party makes an offer for a bargain, which can include the performance of a condition, and accepts the other's offer [Adams & Brownsword 2000] – It is worth noting in UK context that in Scots contract law, consideration is not required for the formation of a valid contract, unlike in English law [McBryde 2001]

[803] [Rao 2007, 379]

Furthermore, it is not always the case that contractual ability to negotiate *per se* offers real advantage – in particular where the parties are largely unequal in their negotiating capacity or in how clearly defined that are. Contract models do not offer protections against risks of unequal bargains, if one party is in difficulty.[804] This fact could present major obstacles for groups situated in developing countries. Moreover, the fact that contract agreements do not bind third parties is a problem, since transfer of material to third parties would fall under a legal gap. This gap could perhaps be remedied by strategies such as including contractual clauses to limit transfer rights to third parties, or allowing transfers only if third parties agree to the same conditions as the first recipient of group material. Yet, enforcement options are limited, and this can have a chilling effect on possible negotiations.[805]

In view of these considerations, a key question in considering contract models is whether terms and conditions should be left to the parties to define or whether they should be controlled by the law. One may wonder whether it is desirable to use contracts as a better way to achieve group goals, given that contractual formulations can be much more imaginative than current research ethics protections. I contend that it is not, in that the need to address potential imbalance and chilling effects in group-researcher interactions remains unanswered. [806]

This problem does not escape recent commentators. While commenting that the contractual ability of groups depends on groups' position in the market, Arti Rao argues that success in these cases depends on parties' common goals "to share profits

[804] [Rao 2007, 379] and [Tvedt 2006, 192] raise similar points.

[805] See also [Tvedt 2006, 192-193]

[806] On the other hand, contractual agreements can offer new ideas on what groups want and possibly serve as guides in developing new laws; this prompts [Bellivier & Noiville 2006] to charmingly call contracts the "labs of the law" ("*les contrats comme laboratoires de la loi*").

privately".[807] She suggests that patient advocacy activities merely reproduce the property paradigm, and that contract and property are two sides of the same coin. This is so because by taking charge of research activities on a particular gene, patient groups replicate the imbalance that existed originally between them and researchers, which will then be mirrored between them and other groups for whom the gene is important.[808]

I would like to remind my reader that I discussed the nature of advocacy interests and their objectives earlier in chapter four. At this stage, I would only like to stress that, advocacy objectives tend to focus on negotiation control in research in order to secure accessibility and affordability of future products, and not to produce financial gain. This fact reiterates that the pervasive question about control in group research is not ownership *per se*, but rather, control over the *use* of research tissue samples, data, and results, in accordance with group views and needs.

In sum, existing contractual models present problems, have limitations, and do not address broader questions on how to deal with plurality of conflicting views among several groups. These questions have arisen in the US, while seeking to determine best ways to allocate funding for advocacy activities in research on genetic diseases.[809] Yet, the acknowledgment of these limitations helps consider viable alternatives and novel models in the governance of group research. These can range from building central oversight mechanisms and universal standards for contractual research agreements, to proposing novel approaches that challenge current paradigms.

---

[807] [Rao 2007, 379] – comment which echoes further criticisms that such initiatives essentially privatise the redistribution of research resources [Hayden 2007, 744]

[808] [Rao 2007, 379]

[809] [Dresser 1999]

In previous sections I considered fiduciary relationships and legal contracts as two possible avenues for law to view the relationship between groups and researchers, under the principle of empowerment. Whilst both of these approaches broaden thinking about the meaning of empowerment in group research, they both have limitations. In the next section, I propose a novel way for law to view the relationship between groups and researchers, as a new approach which challenges, clarifies and refines current norms. I recommend developing criteria that help evaluate group research 'gifts' as reciprocal, conditional transfers. In doing so, I propose this model to focus regulatory attention on the dynamic nature of group-researcher engagements, and the nature of their contribution in research, as a *sui generis* approach in regulating their interaction.

C. Conditional gift in group research: a new model

1. A reciprocal model of empowerment

A conditional group gift model promotes reciprocal understanding of group-researcher engagement by identifying research gifts not as free, disinterested gifts but rather as *conditional, 'interested'* gifts.[810] This model aims to provide a flexible mechanism which does not deny the possibility of altruistic participation but which also at the same time can accommodate a variety of other intents.

There are two compelling reasons for using the vocabulary of 'gift' in this instance as opposed, for example, to just a 'return' or 'exchange'. First is the need to retain

[810] For example, Komter discusses that "expectations of reciprocity [are] common in most gift giving… the empirical pattern is that of reciprocal gift giving: most gifts appear to be followed by a return gift …those who give many gifts receive many in return, and those who do not give too much also receive the least" [Komter 2005, 28-29]

the normative *value* asserted on gift relationships by certain groups;[811] second is the wish to denote the significance of social and moral *character* of relationships developed and maintained between groups and researchers. The concept of conditional gift cements the ongoing interdependence between the parties involved as a key feature of their *relationship*.[812] The recognition of this dependence is of key importance in understanding that social relations are formed and solidified through acts of giving and returning gifts which become both *markers* and also *marks* of relationships. [813]

This understanding of the reciprocal qualities of giving processes in this context can be developed by *moving away from law* and employing expertise from the social sciences, sociology, psychology and economic anthropology. This is necessary because these disciplines have given systematic attention to questions arising in the study of group claims in research participation. They help us think differently about the nature and role of gifts in contemporary society and shed light on the relationship between gift givers and recipients. They enable better understanding of the role of reciprocity as a mechanism that develops and maintains trust which also nurtures the moral and social parameters of group-researcher relationships.[814] [815]

---

[811] To draw on an example from the aboriginal context, economic anthropologists explain that in native Polynesia, 'gift is animated with the spirit of its original homeland and donor, to whom it strives to return' [Parry 1985, 464]. This attitude characterises many instances of native culture, as it comes in conflict with current articulations of giving for research, as it supports that group gifts will eventually be reclaimed to be returned to the ancestral hearth – see notably the Havasupai claims that the tissue samples used in research they did not consent to, be returned to them to be buried to their land *[Tilousi v. Arizona State University* 2005]

[812] [Bell 1991]

[813] [Appadurai 1986] [Carrier 1995] [Lock 1997a]

[814] [Bell 1991] and [Parry 1985] highlight that this view of gifts exchanges as social relationship establishes a long-term cycle of reciprocal and ultimately balanced exchanges.

In this light, I propose that the parameters of this relationship are defined by:

- the continuity of group expectations
- the significance of group contribution and its value
- strong group interests in researchers having respect to their cultural beliefs and group identity
- the effects of possible previous group history in research that may impede their willingness to participate in research, and
- potential risks for groups becoming stigmatised in the future, as a whole, especially in the absence of legal mechanisms against such abuse

These key factors emphasize the social and moral meanings attached to research participation and its value for groups yet most remain unaddressed by the law.[816] This thesis aims to contribute in developing ways that bridge that gap. The factors named above characterise group expectations and interests born in the group gift relationship: they raise the need for legal and ethical frameworks that recognise its complex nature and strengthen it by means of reciprocity.[817]

In line with the group empowerment principle, such frameworks should acknowledge the role of groups as *partners* in the research process, engaged in collaborative, long-term, mutually beneficial processes with researchers. These collaborations should be protected as genuine engagements that highlight the *mutual investment* and

---

[815] The MRC remarks that "it is part of our understanding of the *nature* of a gift that the making and reception of it confirm a special *relationship* between donor and donee" [MRC 2001 para 2.2] – but they do not proceed further to define the parameters of this engagement which make it special.

[816] To draw an example from sociology, Carrier describes the social nature of objects in that objects derive meaning or identity from the *specific personal relationships* in which they feature; he assesses how transactions bear both general cultural meanings but also particular personal meanings of the relationship in which they are transacted [Carrier 1991, 133]

[817] [Kanellopoulou 2004, 97]

communication of respective interests throughout the research process.[818] Novel models under this principle such as the proposed conditional gift model can focus on the nature and implications of joint commitment between groups and researchers to maintain equitable relationships.

2. Returning favours

For these reasons, the reciprocal group gift is a model for "returning favours", a model of "fair play".[819] *Returning favours* means that group participants and researchers do each other a favour by respecting, listening, understanding and trusting each other, by working towards common goals, cooperating, and, thus, "empowering each other".[820] Some philosophers consider the "duties of reciprocity" to be special as they arise from membership in a cooperative scheme; they contend that these "duties" should be distinguished from contracts because their very nature depends on returning the favour.[821]

Arguably, this is where ideas about contracts as social *metaphors* become pertinent in this context; they highlight collaborative interests in clarifying the terms of group-researcher interactions, and in developing mutually agreed and beneficial conditions. In contrast, I do not accept the use of reciprocity as being a mere metaphor. Reciprocity is conceptually stronger and more advantageous than the contract metaphor in that it calls for shared and balance of returns in group-researcher engagements by reinforcing the collaborative qualities of their interaction.[822]

---

[818] The term 'engagement' is employed precisely because other terms such as 'transaction' or 'exchange' are not communicative and are also possibly associated with a market-based vocabulary.

[819] That is, a model for returning favours better [Schmidtz 2005] and [Segall 2005] – The former describes reciprocity as denoting "partly an act of graciously acknowledging favours" [Schmidtz 2005, 455]

[820] *Ibid.*

[821] [Becker 1986, 73] and [Schmitdz 2005, 455] – The latter adds that duties of reciprocity should be distinguished from contractual obligations because they arise from *implicit* agreements.

[822] *Ibid.*

In addition to these established aspects, it is important to keep in mind emerging notions of reciprocity in human genetic research ethics, however underdeveloped they may currently be. Reciprocity has sometimes been described in the research ethics literature as "a notion of exchange" or as "the recognition of the participation and the contribution of the research participant"[823] by scholars who argue that this notion has now been refined yet they do not explain precisely how. They do not provide guidance on how this "exchange", "participation" and "contribution" are understood or evaluated. In this thesis, I argue that there is an urgent need for defining and establishing reciprocity as a central value in regulating group research.

The above notions of 'participation' and 'contribution' cannot just be assumed. They need to be further refined so as to highlight that viable cooperation between researchers and groups can be achieved if attention is given to the character of their overall social relations. I maintain that, in law, notions of reciprocity should be so refined under the principle of group empowerment. Knoppers and Chadwick draw attention to useful elements in the function of reciprocity in that it *recognises autonomy* and *respects the personal and cultural values* of participants.[824] They add that the principle of reciprocity requires *high levels of communication and transparency*.[825] These four elements of respect for autonomy, appreciation of group cultural values, communication and transparency are key elements of the principle of group empowerment, proposed in this thesis.

I support that the principled use of reciprocity in group research focuses on the nature of the relationship between group participants and researchers, not as a mere exchange, but as a collaborative engagement, sustained by social relations and group

[823] [Knoppers & Chadwick 2005, 75]
[824] [Knoppers & Chadwick 2005, 76]
[825] *Ibid.*

personal and cultural values.[826] This is the crucial reason why I believe that any possible criteria used to refine the parameters of notions of reciprocity should take account of group contributions, their prior history with researchers, their intentions for the use of their contribution, and their comparative expectations in research. Under these criteria, groups and researchers can agree to return conditional research gifts to each other in ways that meet continuing group interests, do not harm groups, and do not impede research.

Here are examples of key group interests that could be included in reciprocal models and evaluated in accordance with empowerment imperatives. These can be basic requirements for interdisciplinary understanding of the relationship between groups and researchers:

- a formal acknowledgment that the research collaboration is a *partnership*
- group *consultation* undertaken sufficiently in advance of the proposed start of research activities and in line with the group's own decision-making processes[827]
- respect to particular group *world views* and practices, and conduct of research in a *culturally sensitive* manner that is relevant, responsive, reciprocal, and which may required researchers' training
- the use of *group knowledge* and expertise in the research process
- recognition of the value of group contribution to the research project
- disclosure of researchers' potential interest in *commercialising* research derived from the use of samples that groups provide
- a formal understanding that research benefits will be shared with the group, in which that research is conducted in the interests of the group, and that it will not disadvantage the group

[826] [Frow 1997] [Mauss 1990]

[827] These were discussed in detail in chapter three of this thesis.

- calculations of *benefits* to be interpreted from the groups' perspective
- group monitoring of the *use* of collected samples and data throughout the research process
- mechanisms for tracking information on *research results* and *feedback* on their possible *uses* to the group
- restrictive provisions on *transfer* of data and biological samples to third parties
- commitment to respect group interests in the *destruction* or *return* of data and biological samples to the group according to group cultural beliefs
- opportunities for groups to participate in the *review* and *dissemination* of results together with considerations of *cultural or historical characteristics* that make a particular group distinct
- *credit* to the group's participation in the dissemination of results, if the group so requires

These are but a few ideas as to the kind of terms that can form part of conditional gift agreements between groups and researchers or funding institutions as part of collaborative, reciprocal research models. At the heart of the conditional group gift model is the urgency to incorporate group claims in research, recognise group significance and group continuous interest in their interaction with researchers. It aims to enable groups to have a *voice* on the use of research material, monitoring of research-related rights and distribution of potential benefits. I maintain that focussing on reciprocity offers a flexible and empowering conceptual framework upon which we can build further mechanisms in measuring group contributions, managing their expectations and returning research benefits to them and to society at large.

V. Conclusions

Revisiting Groups and Group Empowerment Mechanisms

The status of groups in biolaw is the subject of this thesis. This work argues for a more systematic, comprehensive and *relational* understanding of the role and contribution of groups in research. It recommends that rights for groups can be developed as differentiated and complementary to the rights that are traditionally asserted for the protection of individual participants in research. This thesis argues in support of the recognition of group contribution as derived from principles of justice, fairness, and respect for group values, effort and choice. It does so in pursuit of normative principles and practical models which afford better levels of power to groups, to promote trust and enhance cooperation in group-researcher interactions, in better ways than the ones currently available.

Such attempts are not without critics. Recent commentators contend that current processes for building more "relational and dialogical" notions of ethical research participants ('subjects', in US terminology) "fundamentally aim at the recognition of groups as stake-holding contributors to processes of value production".[828] These critics argue that rewarding groups who are best able to make demands "essentially privatises the redistribution of research resources".[829] They contend that current attempts to construct groups, in reality, "cut" the collectives – that is the groups[830] –

[828] [Hayden 2007, 744] and similarly [Reardon 2005, 124]

[829] [Hayden 2007, 744]

[830] While the term 'collectives' is sometimes used by researchers, involved in the study of social and political processes which shape genomic governance, I agree that it can be used interchangeably with my umbrella term of 'groups', as defined in my introductory chapter.

in two ways: they fragment them – or in other words, they carve them up, and they encourage the development of procedures for group gathering and association.[831]

Indeed, increasing attention to group issues focuses on two major areas of concern, discussed at length in several parts of this thesis:

- *effective representation* of group interests and
- (*re)distribution of power* in group research relationships

The use of metaphor in the phrase "cutting the collectives" further above is intriguing. The term does not necessarily mean forging new group entities or identities but also shaping, transforming, moulding, fitting, *tailoring* practices and laws to existing collective claims. More than a decade has passed since the first attempts to create protections for groups were made during the debates on the ethics and politics of the Human Genome Diversity Project.[832] Since then, interdisciplinary scholarship has developed which uses sensitivity and caution in advancing the expertise in this field. This thesis aims to contribute to the development of *equitable* and *effective* processes for the legal recognition and protection of group control rights in research. Many of these groups ("collectives") already exist and some already build their own networks and resources – and sometimes, even their own research codes. Whereas there is a real concern about the legitimacy of constituting some groups as representatives of ethnic entities or recipients of relevant resources (as is arguably the case of HapMap), the main concern in this thesis has been to concentrate on how most groups can be *empowered* in mutual, equitable and culturally appropriate ways throughout their involvement in research.

---

[831] [Hayden 2007, 744]

[832] [Greely 1997] – I discussed criticisms on the legitimacy of their inception and methodologies in chapter two.

In examining what the law has to offer in such processes, I am not concerned to promote the interests of a particular kind of 'fragmented' stakeholder over another, but rather to redress the balance of power in group-researcher relationships. This is linked to questions of trust and accountability and it is needed in order better to ensure such collaborations as *less unequal* and to sustain viable, long-term relationships in large-scale research. In view of this, I discuss how established principles in research ethics in general can, if clarified and enriched, effectively complement novel approaches in the governance of modern-day research. I propose a new principle of group empowerment, with focus on rules of reciprocity, mutuality, equity, and their normative underpinnings, in order to promote more *proportionate* understandings of group research interests and how they can be safeguarded.

Group research is changing, and resources are being redistributed. The law needs to catch up with the social and ethical tensions that increasingly burden research collaborations. It needs to address related inequities by promoting willingness and ability for cooperation, by providing mechanisms that recognise group value and to develop that value, protect group 'character' and promote group 'power' through its strategic use.

I stated in my introduction that the principal aims of my thesis have been to suggest viable solutions to three key problems: i) promote *interdisciplinary understanding of group claims* in research and their significance in law; ii) expose the *inadequacies of current regimes to protect group interests*, in order to assess the availability and viability of rights for groups in research; and iii) propose *a novel approach to group protections* in research. In order to achieve these aims:

i) I developed a new methodology for describing and categorising groups. I proposed a set of *categories* to help organise a better, interdisciplinary understanding of the

nature, scope and urgency of group research-related claims in the broadest sense. These categories broadly divide groups into a) geo-political or national groups, b) disease and patient advocacy groups, c) aboriginal and cultural groups, d) ethnic/racial groups, e) family-based groups, f) humanity at large as a group. In proposing this new process, I acknowledged the limits of law in creating rigid classifications within what is a sensitive and diverse context.[833] This analysis was instrumental in clarifying the role and interests of particular groups, to better understand their goals and generate a critical discussion of core issues for model group protections.

ii) I pursued a critical assessment of possible criteria for the development of protections paired by novel analysis of *current legal mechanisms* available for the protection of group interests in research. After analysing the reasons why consent as a first and last step to protecting emerging interests, is not sufficient, I examined models of property, advocacy and benefit sharing as possible ways to address the dilemmas of *disempowerment* inherent in current research participation frameworks. It became apparent that the present guidance on the management of human biological samples for research is beleaguered by ambiguities and inconsistencies which only serve to entrench inequalities within the discipline.

iii) Through this analysis, it further became apparent that urgent clarification of prevailing normative notions about gifts in research is needed. In the quest for building protections for groups in research, I presented a thorough, critical account of current regulatory paradoxes in the area of tissue research and proposed a new definition of *gifts as relationships* in group research. This new approach seeks to define group gifts as conditional and reciprocal, at the same time constitutive of, and dependant on, continuous *engagements* with researchers. In these engagements, cooperation and trust are vital. I recommended that for cooperation and trust to be

[833] Please refer to chapter two.

sustained, new methodologies need to be developed in order to establish *reciprocity* as a requirement for achieving *balance* in group-researcher interactions.

In developing ways to implement reciprocity in group research protections, I propose a new research ethics principle of '*Group Empowerment'* which captures the need for law to acknowledge the role and contribution of groups in research and offers novel conceptual ways to reshape group research relationships in law. Group empowerment requires *reciprocity* of overall group-researcher contribution; it frames the dynamic interface between groups and researchers as a rich site of sensitive social relations and ongoing cooperation. And importantly, it allows a new understanding of groups in multiple roles at once, as providers of research material, bearers of continuous personal interests, creators and managers of valuable assets, and recipients of research-related benefits themselves.

In pursuing this conceptual analysis, it was necessary to go beyond the law, and to borrow from the scholarship of sociology, anthropology, psychology, economics and ethics. This exercise contributed valuable comparative insights and empirical findings about to the impact of reciprocity on current social practices which directly benefited my investigation of the law's capacity to substantiate claims for reciprocity, evident in recent group initiatives. By relying on existing notions of power balance and its interpretation in research ethics and medical law scholarship, I then considered possible legal models of group empowerment.

A comparison of these models reveals a number of differences, limitations and qualities in terms of empowerment, further depicted in the following table and commentary:

Table 6. Comparison of group empowerment mechanisms (GEMS)

Group Empowerment Criteria	**Legal Models**		
	Fiduciary Duty	***Contract***	***Conditional Group Gift***
Acknowledgement of contribution	*Yes*	*Yes*	*Yes*
Reciprocal engagement	*No*	*Will of the parties*	*Yes*
Negotiation of conditions	*No*	*Will of the parties*	*Yes*
Respect for group values & beliefs	*No*	*Will of the parties*	*Yes*
Normative principle	*Yes*	*Will of the parties*	*Yes*
Legally available	*No*	*Yes*	*Proposed*
Enforceable	*No*	*Uncertain*	*Proposed*
Empowerment	***Weak***	***Uncertain***	**YES**

Thus far, the courts have not accepted a ***fiduciary duty*** in the context of non-therapeutic research. I maintain that, in the event that they did, it would represent, at best, a weak group empowerment model. The fiduciary model takes account of differences in the contributory capacity of groups and researchers, but it relies on vulnerability, and it s primary aim is to protect passive participants. Thus, it does not acknowledge group power not does it pursue the interests of the groups themselves. It may be useful as a complementary protective model for vulnerable participants who are unable to mobilise themselves. In such cases it should be complemented by benefit-sharing or other solidarity-based arrangements by which to promote capacity building, education, and health benefits to the group.

Contracts can be considered as models of 'self-help' empowerment, as this thesis discusses in detail in chapter four on the development of patient advocacy contractual agreements; they seem to work in some cases. It is uncertain whether they would be enforced by courts in case of conflict. They have also been criticised as replicating the same exclusive effects as property models do. According to the novel analysis that has been pursued in this thesis, contract models are not the best way to protect groups' interests long term.

Group conditional gift models *are* an adequate and novel way to implement the proposed principle of group empowerment. They reinforce collaborative elements in group-researcher relationships. They offer flexible ways by which to promote cooperation and to evaluate group contribution in research. Calls for reciprocity and flexibility are currently being made in several areas of group research albeit with some degree of ambiguity as to how these could be developed further – such as in the context of public consultations for biobanking projects and more recent attempts to develop native agreements in the DNA loan approach, as discussed in chapters two and four of this thesis.

By proposing the use of *conditional* gift models in group research, this thesis seeks to clarify legal ambiguities raised in these often sensitive and complex contexts, and also draw attention to novel elements necessary for further the implementation of reciprocal models in group research. This thesis highlights the value of such reciprocal models as two-fold, in that not only they invite a new, socially-informed approach in defining collaborative and ongoing group-researcher engagement but also they help devise equitable means to evaluate group significance in research. They offer novel opportunities to reconfigure *how research relationships are constructed in law*. They highlight the value of groups both as intrinsic and instrumental. They call for careful reflection on group needs, resources, motives, expectations, as well as other ethical or social constraints that may apply in particular

cases. They create new opportunities through which to assert and agree claims that are contingent upon and proportionate to the value of benefits received, according to fair principles.

Under the principle of empowerment, these new legal models require that the relationship between researchers and participant groups is defined as *collaborative*, *conditional* and *special* – the latter not denoting vulnerability but rather balancing power and mutual commitment. This thesis puts forward that the clarification and protection of group-researcher relationships in law can help spell out responsibilities assigned to both sides. It can have significant practical consequences and create new possibilities for developing mutually agreed conditions and limitations with groups.

If wronged, these terms could be enforced according to various established legal routes, including equity and estoppel, the latter gaining increased importance in private law.[834] In the event of disagreement, such routes would provide a wide range of legal and equitable remedies by which to enforce group members' rights in research *as a group* – for example, they could enforce restraints on researchers passing on samples to third party laboratories or restricting group members' access to testing through exclusive licensing (of research developed with the assistance of the

[834] As discussed earlier, equity was designed originally to redress situations in which the strict application of the common law has been found to be lacking in fairness. Estoppel is as an equitable doctrine that creates legal obligations, if a party has given another an assurance and the other has relied on the assurance to their detriment. Estoppel is increasingly used to create obligations during pre-contractual negotiations; it is based on the approach that an exchange of promises rather than an exchange in valuable assets is the correct basis for undertaking mutual responsibilities. This doctrine applies rules on both the legitimacy of promises made, but also on the consequences of breach, e.g. withdrawal rights irrespective of reason, and equitable remedies to redress, e.g. causes of action giving rise to unjust enrichment or to tortuous liability for affront [Adams & Brownsword 2000, 74] [Atiyah 1986]

group). They could also enforce evaluation of group effort and contribution in the research process.[835]

On the whole, this thesis calls for clear guidelines, normative principles and meaningful protections in for group claims and interests. The proposed principle of group empowerment establishes reciprocity as central in achieving the elusive balance in group-research interaction. It warrants respect for group values, expectations and proactive initiatives that forward group goals. It is put forward as a novel way to help satisfy emerging trends and group claims over better levels of power and control in the research enterprise. This new model is the first to ascertain the significance of reciprocity as a core value for collaborative group-researcher engagement and also the first to present practical ways by which to apply the rules of reciprocity in genomic research. It is also an evaluative tool for assessing the merits of the various legal approaches to regulating group involvement in research.

This work expands recent debates on the protection of group interests in research by turning the law's gaze towards the *collaborative* aspects of relationships between group participants and researchers. It proposes a new approach which establishes reciprocity firmly within the principles of justice and fairness as being "fundamental to the very concept of justice".[836] To the extent that justice helps rather than hinders the achievement of common goals and ideals, it is to be hoped that this new approach will help promote group willingness to join and sustain long-term collaborations in modern research, seen as essential to the future health of humanity._

---

[835] The injunction claim for breach of fiduciary duty in [*Greenberg v. Miami Children Hospital* 2004] has created a promising legal route for considering group claims in this direction [Oberdorfer 2004]

[836] [Becker 1986, 74] [Schmidtz 2005, 454]

Bibliography

Abbott, A., 'Genetic patent singles out Jewish women' 2005 *Nature* Vol. 436, No. 7047, 12

Aboriginal Health Research Ethics Committee of South Australia, *Ethical Considerations for Health Related Research Involving Aboriginal Peoples*, Australia, 1998

Act on a Health Sector Database, Icelandic Parliament, 123rd session, 1998-99, available at http://government.is/interpro/htr/htr.nsf/pages/gagngr-log-ensk

Adams, J.N., Brownsword, R., *Understanding Contract Law*, Sweet & Maxwell, 2000

Addis, A., 'Individualism, communitarianism, and the rights of ethnic minorities' 1992 *Notre Dame L. Rev.* Vol. 67, p. 615

Amani, B., Coombe, R.J., 'The Human Genome Diversity Project: the politics of patents at the intersection of race, religion, and research ethics' 2005 *Law & Policy* Vol. 27, No. 1, pp. 152-188

American Indian and Alaska Native Genetics Research Policy Formulation Meeting, Summary Meeting Report, 2001

American Indian Law Center, *Model Tribal Research Code*, American Indian Law Center, Albuquerque, 1994

Anderlik, M.R., Rothstein, M.A, 'Canavan decision favors researchers over families' 2004 *J. L. Med. & Ethics* Vol. 31, p. 450

Andreasen, N.C., 'The Amish: A Naturalistic Laboratory for Epidemiologic and Genetic Research', 1983 *American Journal of Psychiatry*, Vol. 140, No. 1, pp. 75-76

Andrews, L., 'Who owns your body? A patient's perspective on Washington University v. Catalona' 2006 *J Law Med Ethics* Vol. 34, pp. 398-414

Andrews, L.A., 'Havasupai Tribe Sues Genetic Researchers' 2004 *LabReport (Law and Bioethics Report)* Vol. 4, No. 2, pp. 10 -11

Andrews, L., *Future Perfect: Confronting Decisions about Genetics*, Columbia University Press, 2001

Angastiniotis, M., Kyriakidou, S., Hadjiminas, M. 'How thalassaemia was controlled in Cyprus' 1986 *World Health Forum* Vol. 7, pp. 221-245

Annas, G.J., 'Rules for research on human genetic variation - lessons from Iceland' 2000 New England Journal of Medicine Vol. 342, No. 24, pp. 1830-1833

Annas, G., Grodin, M., *The Nazi Doctors and the Nuremberg Code - Human Rights in Human Experimentation*, OUP, 1992

'Apology for Study Done in Tuskegee' 1997, available at http://clinton4.nara.gov/textonly/New/Remarks/Fri/19970516-898.html

Appadurai, A., 'Introduction: commodities and the politics of value' in Appadurai, A., (ed) *The Social Life of Things: Commodities in Cultural Perspective*, Cambridge University Press, 1986, pp. 3-63

Arbour, L. Cook, D., 'DNA on loan: issues to consider when carrying out genetic research with aboriginal families and communities' 2006 *Community Genetics* Vol. 9 No. 3, pp. 153-160

Aristotle, *Nicomachean Ethics* translated by Irwin, T. (ed), Hackett Publishing Company, Inc., 1999

Armstrong, D., 'NitroMed halts marketing of drug', 16th January 2008, *The Wall Street Journal*, p. D8, available at

http://online.wsj.com/article/SB120044147052292697.html?mod=rss_Health

Arnason, V., 'Coding and consent: moral challenges of the database project in Iceland' 2004 *Bioethics* Vol. 18, No. 1, pp. 27-49

Arnason, E., Sigurgislason, H., Benedikz, E., 'Genetic homogeneity of Icelanders: fact or fiction?' 2000 *Nat Genet* Vol. 25, pp. 373 – 374

Arrow, K.J., 'Gifts and exchanges' 1972 *Philosophy and Public Affairs* Vol. 1 No. 4, pp. 343-362

Article 29 Data Protection Working Party, *Working Document on Genetic Data*, 12178/03/EN WP 91, adopted on 17 March 2004, p. 4

'Ashkenazi signals are timely' 1997 *Nature* Vol. 389, p. 315

Atiyah, P.S., 'Consideration: A Restatement' in *Essays on Contract*, 1986, Oxford University Press

Austin, M.A., Crouch, J., DiGiacomo, A., 'Applying international guidelines on ethical, legal and social issues to new international genebanks' 2005 *Jurimetrics J.* Vol. 45, p. 116

Austin, M., Harding, S., McElroy, C., 'Genebanks: a comparison of eight proposed international genetic databases', 2003 *Community Genet* Vol.6, p.37 [2003a]

Austin, M.A., et al., 'Monitoring ethical, legal and social issues in developing population genetic databases', 2003 *Genetics Med.* Vol. 5, p. 451 [2003b]

Australia National Health and Medical Research Council, *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research*, Australia, 1991, Publication No. E13

Australian Law Reform Commission (ALRC), *Essentially Yours: The Protection of Human Genetic Information in Australia*, 2003

Aziz, M., *The Regulation of Medical Research Involving Human Subjects – A Comparative Study*, PhD Thesis, University of Edinburgh, 1997

Baker, R., 'Transcultural medical ethics and human rights' in Tröhler, U., Reiter-Theil, S., Herych, E., (eds), *Ethics Codes in Medicine - Foundations and achievements of codification since 1947*, Ashgate, 1998

Ballantyne, Z. Nelki, D., 'Managing IP for the greater good' *Managing Intellectual Property*, 1 May 2007, available at www.managingip.com

Bamshad, M.,' Genetic influences on health: does race matter?' 2005 *J. Am. Med Assoc.* Vol. 294, pp. 937-946

Barr, M., '"I'm not really read up on genetics": biobanks and the social context of informed consent' 2006 *BioSocieties* Vol. 1, pp. 252-262

Baslar, K., *The Concept of the Common Heritage of Mankind in International Law*, Brill, Martinus Nijhoff Publishers, 1997

Bayertz, K., 'Begriff und Problem der Solidarität' in Bayertz, K., (ed.) *Solidarität – Begriff und Problem*, Suhrkamp, 1998

BBC News 'Concern over DNA database access' 17th September 2007, available at http://news.bbc.co.uk/1/hi/health/6995307.stm

Beauchamp, T.L., Childress, J.F., *Principles of Biomedical Ethics* 2001, Oxford University Press

Becker, L.C., *Reciprocity*, Routledge & Kegan Paul, 1986

Bell, D., 'Modes of exchange: gift and commodity' 1991 *Journal of Socio-Economics* Vol. 20, No. 2, pp. 155-167

Bellivier, F., Noiville, C., *Contrats et Vivant – Le Droit de la Circulation des Ressources Biologiques*, L.G.D.J., 2006

Berg, K., 'The ethics of benefit sharing' 2001 *Clin. Genet.* Vol. 59, pp. 240-243

Bernier, L., Durrell, K.L., Gold, R.E., *W.H.O. Literature Review on Access to Genetic Technologies and Services: View from Developing Countries*, McGill Centre for Intellectual Property Policy, 2004

Beskow, L.M., et al, 'Informed consent for population-based genetic research' 2001 *JAMA* Vol. 286, pp. 2315-2321

Beyleveld, D., Brownsword, R., 'My body, my parts, my property?' 2004 *Health Care Analysis* Vol. 8, pp. 87-99

Bhat, A., 'The National Institutes of Health and the Papua New Guinea cell line' 1996 *Cultural Survival Quarterly* Vol. 20, No. 2, available online at http://www.culturalsurvival.org/publications/csq/index.cfm?id=20.2

Bibbins-Domingo, K., Fernandez, A., 'BiDil for heart failure in black patients: implications of the U.S. Food and Drug Administration approval' 2007 *Annals of Internal Medicine*, Vol. 146, No. 1, pp. 52-56

Birenbaum Carmeli, D., 'Prevalence of Jews as subjects in genetic research: Figures, explanation, and potential implications' 2004 *American Journal of Medical Genetics Part A*, Vol. 130A, No. 1, pp. 76-83

Birks, P., 'The content of fiduciary obligation' 2000 *Isr. L. Rev.* Vol. 34, pp. 3-38

Björkman, B., Hansson, S.O., 'Bodily rights and property rights' 2006 *JME* Vol. 32, No. 5, pp. 209-214

Blum, L., 'Altruism' in Becker, L.C. & Becker C.B. (eds), *Encyclopedia of Ethics*, Routledge, 2001

Blum, L., 'Review: [Untitled] Reciprocity' 1988 *Political Theory* Vol. 16, No. 1, pp. 143-148

BMA (British Medical Association) *Confidentiality and Disclosure of Health Information* 1999

Boulier, W., 'Sperm, spleens and other valuables: the need to recognize property rights in human body parts' 1995 *Hofstra L. Rev.* Vol. 23, p. 693

Bovenberg, J.A., *Property Rights in Blood, Genes & Data: Naturally Yours?* Martinus Nijhoff Publishers, 2006

Bovenberg, J.A., 'Inalienably yours? The new case for an inalienable property right in human biological material: empowerment of sample donors or a recipe for a tragic Anti-Commons?' 2004 *SCRIPT-ed* Vol. 1, No. 4, available online at http://www.law.ed.ac.uk/ahrc/script-ed/issue4/bovenberg.asp

Bowekaty, M.B., 'Perspectives on research in American Indian communities' 2002 *Jurimetrics J.* vol. 42, p. 145

Bowekaty, M,B., Davis, D.S., 'Cultural issues in genetic research with American Indian and Alaskan Native people' 2003 *IRB: Ethics and Human Research* Vol. 25, No. 4, pp. 12-15

Boyd, K.M., Higgs, R., Pinching, A.J., *The New Dictionary of Medical Ethics*, BMJ Publishing Group, 1997

Brice, P., 'First phase of UK Biobank recruitment begins' *PHG Newsletter*, March 2006, available at

www.phgu.org.uk/newsletter?newsletter_year=2006&newsletter_month=03#story_2303

Brodwin, P, 'Genetic knowledge and collective identity' 2005 *Culture, Psychiatry & Medicine* Vol. 29, No. 2, pp. 139-143

Brodwin, P., 'Genetics, identity and anthropology of essentialism' 2002 *Anthropological Quarterly* Vol. 75, No. 2, pp. 323-330

Brown, M., 'Can culture be copyrighted?' 1998 *Current Anthropology* Vol. 39, No. 2, pp. 193-222

Brown, N., 'Hope against hype – accountability in biopasts, presents, and futures' 2003 *Sci Stud* Vol. 16, No. 2, pp. 3-21

Brugge, D., Missaghian, M., 'Protecting the Navajo People through tribal regulation of research', 2006 *Science and Engineering Ethics* Vol. 12, No. 3, pp. 491-507

Brunger, F., 'Problematizing the notion of "community" in research ethics' in Knoppers, B.M., (ed.), *Populations and Genetics: Legal and Socio-Ethical Perspectives*, Brill Academic Publishers, 2003, pp. 245-255

Brunger, F., Burgess, M., 'A cultural understanding of research ethics governance' 2005 *Health Law Review* Vol. 13, Nos. 2-3, pp. 69-74

Brunger, F., Cox, S, 'Ethics and genetics: The need for transparency' in Miller, F., et al (eds), *The Gender of Genetic Futures: The Canadian Biotechnology Strategy, Women and Health*, National Network on Environments and Women's Health Working Paper Series 2000, pp. 1-5

Brysk, A., *From Tribal Village to Global Village: Indian Rights and International Relations in Latin America*, Stanford University Press 2000

Buchanan, A., 'Justice as reciprocity versus subject-centered justice' 1990 *Philosophy and Public Affairs* Vol. 19, No. 3, pp. 227-252

Burgermeister J., 'Estonia genome project lives on' *The Scientist*, 28th April 2004, Vol. 5, No.1

Burgess, M. M., Brunger, F., 'Negotiating collective acceptability of health research', in McDonald, M., *The Governance of Health Research Involving Human Subjects (HRIHS)*, Law Commission of Canada, 2000, pp. 117-151

Burhansstipanov, L., Bemis, T.L., Dignan, M., 'Native American recommendations for genetic research to be culturally respectful' 2002 *Jurimetrics J.* Vol. 42, pp. 149-157

Burrows, 'We do this at common law but that in equity' 2002 *Oxford Journal of Legal Studies* Vol. 22, No. 1, pp. 1-16

Burton, B., 'Opposition stalls genetic profiling plan for Tonga' 2002, available at www.commondreams.org/headlines02/0218-02.htm [Burton 2002a]

Burton, B., 'Proposed genetic database on Tongans opposed', 2002 *BMJ* Vol. 324, p. 443 [Burton 2002b]

Busby, H., 'Blood donation for genetic research: what can we learn from donors' narratives?' in Tutton, R., Corrigan, O. (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, Routledge 2004, pp. 39-56

Callahan, D., 'Individual good and common good – A utilitarian approach to bioethics' 2003 *Perspectives in Biology and Medicine* Vol. 46, No. 4, pp. 496-507

Callon, M., Rabeharisoa, V., 'Growing engagement of emergent concerned groups in political and economic life: lessons from the French association of neuromuscular disease patients' 2008 *Science, Technology Human Values* Vol. 33, No. 2, pp. 230-261

Cambon-Thomsen, A., 'The social and ethical issues of post-genomic human biobanks' 2004 *Nat Rev Genet* Vol. 5, pp. 866-873

Canada Royal Commission on Aboriginal Peoples, 'Ethical guidelines for research' in *Integrated Research Plan,* Appendix B, Ottawa, 1993

Canadian Institutes for Health Research, *CIHR Guidelines for Health Research Involving Aboriginal People*, May 2007

Canavan Foundation, Joint press release, 29th September 2003, available at http://www.canavanfoundation.org/news/09-03_miami.php

Cao, A., Rosatelli, M.C., Monni, G., Alanello, R., 'Screening for thalassemia: a model of success' 2002 *Obstetrics and Gynecology Clinics of North* America Vol. 29, pp. 305-328

Cardinal, G., Deschênes, M., 'Surveying the population biobankers' in Knoppers, B.M., (ed.), *Populations and Genetics: Legal and Socio-Ethical Perspectives*, Martinus Nijhoff Publishers, 2003, pp. 37-94

Carrier, J.G., *Gifts and Commodities – Exchange and Western Capitalism since 1700*, Routledge, 1995

Carrier, J., 'Gifts, commodities, and social relations: a Maussian view of exchange' 1991 *Sociological Forum* Vol. 6, No. 1, pp. 119-136

Carson, R.A., 'The paradigm shift in health care and the patient-physician relationship from an American perspective' in Tröhler, U., Reiter-Theil, S., Herych, E., (eds), *Ethics Codes in Medicine - Foundations and achievements of codification since 1947*, Ashgate, 1998

Carsten, J., *After Kinship*, Cambridge University Press, 2003

CARTaGENE website at www.cartagene.qc.ca/

Catalona, W.J., 'Ownership and use of tissue specimens for research' 2005 *JAMA*, Vol. 293, No. 11, 1325

Cavalli-Sforza et al., 'Call for a worldwide survey of human genetic diversity: a vanishing opportunity for the Human Genome Project' 1991 *Genomics* Vol. 11, p. 490

Chadwick, R., Berg, K., Solidarity and equity: new ethical frameworks for genetic databases' 2001 *Nat Rev Genet* Vol. 2, pp. 318-321

Chadwick, R., 'The Icelandic database - do modern times need modern sagas?' 1999 *BMJ* Vol. 319, pp. 441–444

Chadwick, R., ten Have, H., Husted, J., Levitt, M., McGleenan, T., Shickle, D., Wiesing, U. 'Genetic screening and ethics: European perspectives' 1998 *Journal of Medicine and Philosophy*, Vol. 23, No. 3, pp. 255-273

Chadwick, R., Levitt, M., Shickle, D., *The Right to Know and the Right Not to Know*, Dartmouth, 1997

Chalmers, D., Nicol, D., 'Commercialisation of biotechnology: public trust and research' 2004 *International Journal of Biotechnology*, Vol. 6, No. 2/3, pp. 116-133

Charo, R.A., 'Body of research – Ownership and use of human tissue' 2006 *NEJM* Vol. 355, No. 15, pp. 1517-1519

CHRB (Convention on Human Rights and Biomedicine), Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, CETS No.: 164, 1997

CHRB (Convention on Human Rights and Biomedicine) *Explanatory Report*, Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, CETS No.: 164, 1997

CIOMS (Council for International Organizations of Medical Sciences), *International Guidelines for Ethical Review of Epidemiological Studies* 1991

CIOMS (Council for International Organizations of Medical Sciences), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* 1993

Clayton, E.W., 'Implications for existing law/regulations' 2005-2006 *La. L. Rev.* Vol. 66, pp. 125-130

Clayton, E.W., 'The complex relationship of genetics, groups, and health: what it means for public health' 2002 *J.L. Med. & Ethics* Vol. 30, p.290

Collins, F.S., 'The case for a US prospective cohort study of genes and environment' 2004 *Nature* Vol. 429, pp. 475-477

Collom, L., 'Judge tosses tribe's case on technicality' *The Arizona Republic*, 4 May 2007, available at http://www.abor.asu.edu/

Committee on Human Genetic Diversity, Commission on Life Sciences, National Research Council, *Evaluating Human Genetic Diversity*, National Academy Press, 1997

Convention on the Elimination of All Forms of Racial Discrimination 1965

Corbie-Smith, G, et al., 'Attitudes and beliefs of African-Americans toward participation in medical research' 1999 *J Gen Intern Med* Vol. 14, pp. 537-546

Council of Europe, *Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data* 1981

Council of Europe, *Recommendation on the Protection of Medical Data* (1997, No. R (97) 5)

Council of Europe, *Recommendation on Regulations for Automated Medical Databanks* 1981, No. R (81) 1)

Couzin, J., 'New mapping project splits community' 2002 *Science* Vol. 296, pp. 1391-1392

Cragg, Ross, Dawson, *Public Perceptions of the Collection of Human Biological Samples*, 2000, London, Wellcome Trust/MRC, available at www.wellcome.ac.uk

Cunningham, H. 'Colonial encounters in post-colonial contexts: patenting indigenous DNA and the Human Genome Diversity Project' 1998 *Critique of Anthropology* Vol. 18, pp. 205-233

Cutter, A.M., Wilson, S., Chadwick, R., 'Balancing powers: examining models of biobank governance' 2004 *JIBL* Vol.1, pp. 187-192

Cystic Fibrosis Foundation (US) website at www.cff.org

Daar. A.S., Singer, P.A., 'Pharmacogenetics and geographical ancestry: implications for drug development and global health' 2005 *Nature Reviews Genetics* Vol. 6, pp. 241-246

Daes, E.I., *Protection of the Heritage of Indigenous Peoples*, UN Commission on Human Rights (UNCHR), Sub-Commission on Prevention of Discrimination and Protection for Minorities, Annex 12, UN Document E/CN.4/Sub.2/1995/26, 21st June 1995

Dalpé, R., Bouchard, L., Houle, A.J., Bédard, L., 'Watching the race to find the breast cancer genes' 2003 *Science Technology Human Values* Vol. 28, No. 2, pp. 187-216

Dalton, R., 'When tribes go to war', 2004 *Nature* Vol.430, pp. 500-502

Davies, S.C. et al., 'Screening for sickle cell disease and thalassaemia – a systematic review with supplementary research' 2000 *Health Technol Assess* Vol. 4, No. 3

Davis, D.S., 'Genetic research & communal narratives' 2004 *Hasting Center Report* Vol. 34, No. 4, pp. 40-49

Davis, D.S., 'Groups, communities, and contested identities in genetic research' 2000 *The Hastings Center Report* Vol. 30, No. 6, pp. 38-45

Declaration of Indigenous Peoples of the Western Hemisphere Regarding the Human Genome Diversity Project' 1996 *Cultural Survival Quarterly* Vol. 20, available at www.indians.org/welker/genome.htm

Deech, R., 'Family law and genetics' in Brownsword, R., Cornish, W.R., Llewelyn, M., (eds), *Law and Human Genetics: Regulating a Revolution*, Hart Publishing, 1998

Delgado, R., Leskovac, H., 'Informed consent in human experimentation: bridging the gap between ethical thought and current practice', 1986 *UCLA L Rev* Vol. 34, p.67

Deloukas, P., Bentley. D., 'The HapMap project and its application to genetic studies of drug response' 2004, *Pharmacogenomics J*. Vol. 4, No. 2, pp. 88-90

Department of Health (UK), *Our Inheritance, Our Future – Realising the Potential of Genetics in the NHS*, 2003

Dickenson, D.L., *Property in the Body: Feminist Perspectives*, Cambridge University Press 2007

Dickenson, D.L., 'The Lady vanishes: what's missing from the stem cell debate' 2006 *Bioethical Inquiry* Vol. 3, pp. 43-54

Dickenson, D. 'Human tissue and global ethics', *Genomics Society and Policy* 2005, Vol. 1, No.1, pp.41-53

Dickenson, D.L., 'Consent, commodification and benefit sharing' 2004 *Developing World Bioethics* Vol. 4, No. 2, pp. 109-124

Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with regards to the Processing of Personal Data and on the Free Movement of Such Data, OJ (*Official Journal of the European Communities)* L281, 23.11.1995, p.31, available from http://europa.eu.int/comm/internal_market/en/media/dataprot/index.htm

'Discrimination fears over breast cancer test' *BioNews*, 23 May 2005, available at www.bionews.org.uk/new.lasso?storyid=2577

Dixon-Woods, M., Cavers, D., Jackson, C.J., Young, B., Forster, J., Heney, D., Pritchard-Jones, K., 'Tissue samples as "gifts" for research: a qualitative study of families and professionals' 2008 *Medical Law International* Vol. 9, No. 2, pp. 131-150

Dockser Marcus, A., 'Patients with rare diseases work to jump-start research' 2006 *Wall Street Journal*, July 11th, available online at

www.acceleratedcure.org/news/bcp/20060711-wsj.php

Dolgin, J.L., 'Ideologies of discrimination: personhood and the "genetic group" ' 2001 *Stud. Hist. Phil. Biol. & Biomed. Sci.* Vol. 32, No.4, pp.705-721

Dolgin, J.D., 'Choice, tradition and the new genetics: the fragmentation of the ideology of the family' 2000 *Conn. L. Rev.* Vol. 32, pp. 523-566

Douglas, M., 'Foreword' in Mauss, M., *The Gift: The Form and Reason for Exchange in Archaic Societies'*, Routledge, 1990, pp. vii-xviii

Dove, M.R., 'Indigenous peoples and environmental politics' 2006 *Annu. Rev. Anthropol.* Vol. 35, pp. 191-208

Dresser, R., *When Science Offers Salvation: Patient Advocacy and Research Ethics*, Oxford University Press, 2001

Dresser, R., 'Public advocacy and allocation of federal funds in biomedical research' 1999 *The Milbank Quarterly* Vol. 77, No. 2, pp. 257-274

Ducor, P., 'Coauthorship and coinventorship' 2000 *Science*, Vol. 289, No. 5481, pp. 873-875

Duster, T., 'Lessons from history: why race and ethnicity: have played a major role in biomedical research' 2006 *Journal of Law Medicine & Ethics* Vol. 34, No.4, pp. 487-496

Duster, T., *Backdoor to Eugenics*, Routledge, 2003, pp. 87-89 [2003a]

Duster, T., 'Buried alive: the concept of race in science' in Goodman, A.H., Heath, D., Lindee, M.S., (eds) *Genetic Nature / Culture – Anthropology and Science beyond the Two-Culture Divide*, University of California Press, 2003, pp. 267-269 [2003b]

Dutfield, G., *Intellectual Property Rights and Development*, UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, 2003

Dutfield, G., Leverve, F., *Bioprospecting and Intellectual Property Protection*, IPR-Helpdesk, European Commission, DG Enterprise, 2003

Dutfield, G., Posey, D., *Beyond Intellectual Property – Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, 1996

Edelson, P.J., 'Workshop on the brca1 breast cancer gene in the Jewish population: the Tay-Sachs disease screening program in the U.S. as a model for the control of genetic disease: an historical view' 1997 *Health Matrix* Vol. 7, pp. 125-133

Edwards. S., Strathern, M., 'Including our own' in Carsten, J., (ed) *Cultures of Relatedness – New Approaches to the Study of Kinship*, Cambridge University Press, 2000, pp. 149-165

Einsiedel, E., *Whose Genes, Whose Safe, How Safe? Publics' and Professionals' Views of Biobanks*, 2003

Eisenberg, R., 'Reaching through the genome' in Kieff, S., (ed) *Perspectives on Properties of the Human Genome Project*, Elsevier Academic Press, 2003, pp. 213-230

Ekberg, M., 'The old eugenics and the new genetics compared' 2007 *Social History of Medicine* Vol. 20, No. 3, pp. 581-593

Elger, B.s., Caplan, A.L., 'Consent and anonymization in research involving biobanks' 2006 *EMBO reports* Vol. 7, No. 7, pp. 661-666

Ellison, G.T., Jones, I.R., 'Social identities and the "new genetics": scientific and social consequences' 2002 *Critical Public Health* Vol. 12, No. 3, pp. 265-282

Emery, A.H.E., Miller, J.R., *Registers for the Detection and Prevention of Genetic Disease*, Symposia Specialists, 1976

EPO (European Patent Office) press release, 'Patent on "Breast Cancer Gene 2"', in amended form after public hearing, 29 June 2005, available at http://www.european-patent-office.org/news/pressrel/2005_06_29_e.htm

Epstein, S., 'Bodily differences and collective identities: the politics of gender and race in biomedical research in the United States' 2004 *Body & Society* Vol. 10, Nos. 2-3, pp. 183-203

Epstein, S., 'The construction of lay expertise: AIDS activism and the forging of credibility in the reform of clinical trials' 1995 *Science, Technology Human Values* Vol. 20, No. 4, pp. 408-437

Erickson, A.K., 'Ethnicity puts clinical trials to the rest' 2003 *Nature Medicine* Vol. 9, p. 983

Eriksson, K.E., Gudmundsdóttir, M.L., Korts, K., Weldon. S., 'A sociological perspective: perceptions of privacy and trust in institutions managing and regulating genetic databases' in Häyry, M., Chadwick, R., Árnason, V., Árnason, G., *The Ethics and Governance of Human Genetic Databases: European Perspectives – European Perspectives*, Cambridge University Press, 2007, pp. 45-71

Eriksson, S. 'Informed consent and biobanks', in Hansson, M.G., (ed), *The Use of Human Biobanks – Ethical, Social, Economical and Legal Aspects*, 2001

ESHG (European Society of Human Genetics) press release, 'Geneticists opposed singling out Jewish women in European breast cancer patent, 15th June 2005, available online at http://www.eshg.org/PressReleaseESHG15-06-2005.pdf

Estonian Genome Project website at www.geenivaramu.ee/

Estonian Genome Project Foundation, 'The Estonian Genome Project' publication, available at www.geenivaramu.ee/mp3/trykisENG.pdf

Estonian Human Genes Research Act, 13 December 2000, RT I 2000, 104, 685, available at http://www.legaltext.ee/text/en/X50010.htm

ETC Group Communiqué, 'The new genomics agenda - a political ppilogue to the book of life: update on pharmaceutical multinationals and the human genome', Issue 72, 2001

European Convention on Human Rights 1950

Eversole, R., McNeish, J.A., Cimadamore, D., *Indigenous Peoples and Poverty – An International Perspective*, CROP International Studies in Poverty Research, Zeb Books, 2005

Faden, R.R., Beauchamp, T.C., *A History and Theory of Informed Consent*, OUP, 1986

Featherstone, K., Atkinson, P., Bharadwaj, A., Clarke, A., *Risky Relations: Family, Kinship and the New Genetics*, Berg Publishers, 2006

Ferguson, J., 'Cultural exchange: new developments in the anthropology of commodities' 1988 *Cultural Anthropology* Vol. 3, No. 4, pp. 488-513

Field, L.W., 'Dynamic tensions in indigenous sovereignty and representation: a sampler' 2003 *Americal Ethnologist* Vol. 3, No.3, pp. 447-453

Finkler, K., 'Family, kinship, memory and temporality in the age of the new genetics' 2005 *Social Science & Medicine* Vol. 61, pp.1059-1071

Finkler, K., Skrzynia, C., Evans, J.P., 'The new genetics and its consequences for family, kinship, medicine and medical genetics' 2003 *Social Science & Medicine* Vol. 57, pp. 403-412

Fischer, M.J., 'In the science zone' 2004 *Anthropology Today* Vol. 17, No. 4, pp. 9-14

Fisher, P.A., Ball, T.J., 'Tribal participatory research: mechanisms of a collaborative model' 2003 *American Journal of Community Psychology* Vol. 32, Nos. 3-4, pp. 207-216

Fleischer, M., 'Patent Thyself', The American Lawyer (online version), June 21st, 2001, available at http://www.americanlawyer.com/newcontents06.html

Fletcher, A.L., 'Field of genes: science and identity in the Estonian Genome Project' 2004 *New Genetics and Society* Vol. 23, No.1, pp. 3-14

Florin, P., Wandersman, A, 'An introduction to citizen participation, voluntary organizations, and community development: insights for empowerment through research' 1990 American Journal of Community Psychology Vol. 18, No.1, pp. 41-54

Fortun, M., 'Towards genomic solidarity: lessons from Iceland and Estonia' *Open Democracy*, 10th July 2003, available at www.opendemocracy.net

Foster, M.W., 'Genetics and social identity after the HapMap' 2005 *Nature Reviews Genetics* Vol. 6, p. 1

Foster, M.W., Sharp, R.R., 'Genetic research and culturally specific risks' 2000 *TIG* Vol. 16, No. 2, pp. 93-95

Foster, M., 'The Human Genome Diversity Project and the patenting of life: indigenous peoples cry out' 1999 *Canterbury Law Review* Vol. 7, pp. 343-370

Foster, M.W., 'Communal discourse as a supplement to informed consent in genetic research' 1997 *Nat. Genet.* Vol. 17, pp. 277-279

Foucault, M., (interview) 'Polemics, politics and problematizations' in Rabinow , P., (ed.), *Ethics: Subjectivity and Truth: Essential Works of Michel Foucault: Vol. 1*, The New Press, 1997, pp. 111-119

Fraboni, M., Lenzerini, F., 'Indigenous peoples' rights, biogenetic resources and traditional knowledge: the case of the Sateré-Mawé people' in Francioni, F., Scovazzi, T., *Biotechnology and International Law*, Hart Publishing 2006, pp. 341-365

Frank, L., 'Storm brews over gene bank of Estonian population' 1999 *Science* Vol. 286, pp. 1262-1263

Franklin, S., 'Biologization revisited: kinship theory in the context of the new biologies' in Franklin, S., McKinnon, S., (eds) *Relative Values – Reconfiguring Kinship Studies*, Duke University Press, 2001, pp. 302-325

Franklin, S., McKinnon, S., 'Relative values: reconfiguring kinship studies' in Franklin, S., McKinnon, S., (eds) *Relative Values – Reconfiguring Kinship Studies*, Duke University Press, 2001, pp. 1-28

Freeman, W.L., 'The role of community in research with stored tissue samples' in Weir, R.F., (ed), *Stored Tissue Samples – Ethical, Legal and Public Policy Implications*, University of Iowa Press, 1998, pp. 267-301

Friedlaender, J., 'Genes, people, and property: furore erupts over genetic research on indigenous groups' 1996 *Cultural Survival Quarterly* Vol. 20, No. 2, available online at http://www.culturalsurvival.org/publications/csq/index.cfm?id=20.2

Frow, J., *Time and Commodity Culture: Essays in Cultural Theory and Postmodernity*, Oxford University Press, 1997

Gannett, L., 'Group categories in pharmacogenetics research' 2005 *Philosophy of Science* Vol. 72, pp. 1232-1247

Gannett, L., 'Making populations: bounding genes in space and in time' 2003 *Philosophy of* Science Vol. 70, No. 5, pp. 989-1001

Gannett, L., 'Racism and human genome diversity research: The ethical limits of "population thinking"' 2001 *Philosophy of Science* Vol. 68, No.3, Supplement: Proceedings of the 2000 Biennial Meeting of the Philosophy of Science Association, Part I: Contributed Papers (September), pp. S479-S492

Generation Scotland website at www.generationscotland.org/

Genetic Alliance website http://www.geneticalliance.org/

GeneWatch Memorandum about UK Biobank, UK House of Lords Select Committee on Science and Technology, *Third Report*, *Appendices to the Minutes of Evidence*, *Appendix 2*, 2002, available at http://www.publications.parliament.uk/pa/cm200203/cmselect/cmsctech/132/132ap03.htm

'Genome Project Ends Cooperation with Current Financier', 27 December 2004, available at http://www.geenivaramu.ee/index.php?lang=eng&show=uudised&id=172

Gertz, R., 'Withdrawing from participating in a biobank – a comparative study' 2008 *European Journal of Health Law* Vol. 15, No. 4, pp. 381-389

Gertz, 'An analysis of the Icelandic Supreme Court judgement on the Health Sector Database Act' 2004 *SCRIPT-ed* Vol. 1, No. 2, available at www.law.ed.ac.uk/ahrb/script-ed/issue2/iceland.asp [2004a]

Gertz. R., 'Is it 'me' or 'we'? Genetic relations and the meaning of 'personal data' under the Data Protection Directive' 2004 *European Journal of Health Law* Vol. 11, No.3, p. 231 [2004b]

Ghosh, P., 'Biobank now opening for business' *BBC News*, 15 March 2006, available at http://news.bbc.co.uk/1/hi/health/4805504.stm

Ghosh, P., 'Will Biobank pay off?' *BBC News,* 24 September 2003, available at http://news.bbc.co.uk/1/hi/health/3134622.stm

Gibbon, S., *Breast Cancer Genes and the Gendering of Knowledge*, Palgrave Macmillan, 2007

Gibbons, S.M.C., 'Governance of population genetic databases: a comparative analysis of legal regulation in Estonia, Iceland, Sweden and the UK' in Häyry, M., Chadwick, R., Árnason, V., Árnason, G., *The Ethics and Governance of Human Genetic Databases: European Perspectives – European Perspectives*, Cambridge University Press, 2007, pp. 132-139

Gillett, G., McKergow, F., 'Genes, ownership, and indigenous reality' 2007 *Social Science & Medicine* Vol. 65, No. 10, pp. 2093-2104

Gitter D. 'Resolving the open source paradox in biotechnology: a proposal for a revised open source policy for publicly funded genomic databases' 2007 *Houston Law Review* Vol. 43, No. 7, pp. 1-69

Gitter, D.M., 'Ownership of human tissue: a proposal for federal recognition of human research participants' property rights in their biological material' 2004 *Wash & Lee L. Rev.* Vol. 61, pp. 257-345

GMC (General Medical Council) *Confidentiality: Protecting and Providing Information*, 2000

GMC (General Medical Council) *Good Practice in Research*, 2002

Godard, B., Marshall, J., Laberge, C., 'Community engagement in genetic research: results of the first public consultation for the Quebec CARTaGENE Project' 2007 *Community Genet* Vol. 10, pp. 147-158

Godard, B., Marshall, J., Laberge, C., Knoppers, B.M., 'Strategies for consulting with the community: the cases of four large-scale genetic databases' 2004 *Sci Eng Ethics* Vol. 10, No.3, pp. 457-77

Godard, B., et al. 'Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits – a professional perspective' 2003 *European Journal of Human Genetics* Vol. 11, Suppl. 2, pp. S88-S122

Godard, B., et al. 'Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits – a professional perspective' EUROGAPP project 1999-2000, European Society of Human Genetics Public and Professional Policy Committee, 2002

Goodman, A.H., 'Seeing culture in biology' in Ellison, G.T., Goodman, A.H., (eds) *The Nature of Difference – Science, Society and Human Biology*, CRC Press, 2006, pp. 225-241

Gorner, P., 'Parents suing over patenting of genetic test', *The Chicago Tribune*, 19th November 2000, available at

http://home.iprimus.com.au/dna_info/dna/JA_DNA_ChiTrib_20001119a.html

Gostin, L., 'Ethical principles for the conduct of human subject research: population-based research and ethics' *Journal of Law, Medicine and Ethics,* 1991, Vol.19, pp. 191-201

Gottlieb, K., 'Human biological samples and the laws of property: the trust as a model for biological repositories', in Weir. R.F., (ed), *Stored Tissue Samples – Ethical, Legal, and Public Policy Implications*, University of Iowa Press, 1998

Gouldner, A., 'The norm of reciprocity' 1960 *American Sociological Review* Vol. 25, No. 2, pp. 161-178

Graves, J.L. Jr., 'What we know and what we don't know: human genetic variation and the social construction of race', US SSRC (Social Sciences Research Council) web forum 'Is Race "Real"?', 25 April 2005, available at http://raceandgenomics.ssrc.org/Graves/

Greely, H.T., DNA Fingerprinting and Civil Liberties Project Workshop Presentation, American Society of Law, Medicine and Ethics, Workshop 3, May 2005

Greely, H.T., 'Human genome diversity: what about the other human genome project?' 2001 *Nature Reviews Genetics*, Vol. 2, pp. 222-227 [Greely 2001a]

Greely, H.T., 'Human genomics research - New challenges for research ethics' *Perspectives in Biology and Medicine*, 2001, Vol.44, No.2, pp. 221-229 [Greely 2001b]

Greely, H.T., 'Informed consent and other ethical issues in human population genetics' 2001 *Annu. Rev. Genet.* Vol. 35, p. 785 [Greely 2001c]

Greely, H.T., 'Iceland's plan for genomics research: facts and implications', 2000 *Jurimetrics J.* Vol. 40, pp.153–191

Greely, H.T., 'The control of genetic research: involving the "groups between"', 1997 *Houston Law Review*, Vol. 33, p. 1397

Greene, S., 'Indigenous people incorporated?' 2004 *Current Anthropology* Vol. 45, No. 2, pp. 211-237

Greenhough, B., 'Situated knowledges and the spaces of consent' 2007 *Geoforum* Vol. 38, pp. 1140–1151

Gregory, C.A., *Gifts and Commodities*, Academic Press, 1982

Gregory, R.J., 'Tribes and tribal: origin, use, and future of the concept, 2003 *Stud. Tribes Tribals* Vol. 1, No. 1, pp. 1-5

Guenther, M., Kenrick, J., Kuper, A., Plaice, E., Thuen, T., Wolfe, P., Zips, W., Barnard, A., 'Discussion: the concept of indigeneity' 2006 *Social Anthropology* Vol. 14, No.1, pp. 17-32

Guerrero, M.A.J., 'Global genocide and biocolonialism – On the effect of the Human Genome Diversity Project on targeted indigenous peoples/ecocultures as "isolates of historic interest"' in Aldama, A.J., *Violence and the Body – Race, Gender, and the State*, Indiana University Press, 2003, pp. 171-188

Hacking, I., 'Genetics, biosocial groups & the future of identity' 2006 *Daedalus* Fall, pp. 81-95

Haddow, G., 'Because you're worth it? The taking and selling of transplantable organs' 2006 *Journal of Medical Ethics*, Vol. 32, pp. 324-328

Haddow, G., Cunningham-Burley, S., 'Tokens of trust or token trust: the case of population genetic data collections" in Greene, A., Bronwlie, J., Howson, A., (eds) *Trust, Health and Illness*, Routledge 2008

Haddow, G., Cunningham-Burley, S., Bruce, A., Parry, S., 'Generation Scotland: consulting publics and specialists at an early stage in a genetic database's development' 2008 *Critical Public Health* Vol. 18, No. 2, pp. 139-149

Haddow, G., Cunningham-Burley, S., Bruce, A., Parry, S., *Generation Scotland, Preliminary Consultation Exercise 2003-04, Public and Stakeholder Views from Focus Groups and Interviews*, Innogen Working Paper No. 20, 2004, available at www.innogen.ac.uk/Publications/20-Generation-Scotland

Haddow, G., Laurie, G, Cunningham-Burley, S., Hunter, K., 'Tackling community concerns about commercialisation and genetic research: a modest interdisciplinary proposal, 2007 *Social Science & Medicine* Vol. 64, pp. 272-282

Hadgood, R., Shickle, D., Kent, A., '*Consultation with Primary Care Health Professionals on Issues Relating to the Recruitment of Patients to A DNA Collection Study'* 2001

Hadjiminas, M. 'The Cyprus experience – screening to combat a serious genetic disease' in Council of Europe, *Ethics and Human Genetics*, Proceedings: 2nd Symposium of the Council of Europe on Bioethics, Strasbourg, 1994, pp. 26-48

Haimes, E., Whong-Barr, M., 'Levels and styles of participation in genetic databases: a case study from the North Cumbria Community Genetics Project' in Tutton, R., Corrigan, O. (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, Routledge 2004, pp. 57-77

Haksar, V., 'Collective rights and the value of groups' 1998 *Inquiry* Vol. 41, No. 1, pp. 21-43

Hamilton, C., 'The Human Genome Diversity Project and the new biological imperialism' 2001 *Santa Clara Law Review* Vol. 41, No. 2, pp. 619-640

Hardcastle, R., *Law and the Human Body: Property Rights, Ownership and Control*, 2007, Hart Publishing

Hardin, R., 'Altruism and Mutual Advantage' 1993 *Social Service Review*, Vol. 67, No. 3, pp. 358-373

Harmon, S.H., 'Solidarity – A (new) ethic for global health policy', 2006 *Health Care Analysis* Vol. 14, pp. 215-236

Harrison, C.H., 'Neither Moore not the market: alternative models for compensating contributors of human tissue' 2002 *Am. J.L. & Med.* Vol. 28, p. 77

Harris, J.W., *Property and Justice*, Clarendon Press, 1996

Harry, D., Kanehe, L.M., 'Asserting tribal sovereignty over cultural property: moving towards protection of genetic material and indigenous knowledge' 2006 *Seattle Journal of Social Science* Vol. 5, pp. 27-54

Harry, D., 'The Human Genome Diversity Project and its implications for indigenous peoples' 2005, Indigenous Peoples Council for Biocolonialism (IPCB) Information About Intellectual Property Rights Briefing Paper No.6, available at www.ipcb.org/publications/briefing_papers/files/hgdp.html

Hart, S., Sobraske, K.A., *Investigative Findings: ASU/Havasupai Investigation*, 2003 (personal copy on file with the author)

Hausman, D., 'Protecting groups from genetic research' 2008 *Bioethics* Vol. 22, No.3, pp. 157-165

'Havasupai suits involving blood research moved', *The Arizona Daily Star*, 5 May 2005, available at www.azstarnet.com/dailystar/allheadlines/73660.php

Hayashi, N. et al., 'Reciprocity, trust and the sense of control' 1999 *Rationality and Society* Vol. 11, No. 1, pp. 27-46

Hayden, C., 'Taking as giving: bioscience, exchange and the politics of benefit-sharing' 2007 *Social Studies of Science* Vol. 37, No.5, pp. 729-758

Healy, K., *Last Best Gifts: Altruism and the Market for Human Blood and Organs*, University of Chicago Press, 2006

Healy, K., 'Altruism as an organizational problem: the case of organ procurement' 2004 *American Sociological Review*, Vol. 69, pp. 387-404

Hecht, F., Cadien, J.D., 'Tay-Sachs disease and other fatal metabolic disorders' in Wald, N.J., (ed.), *Antenatal and Neonatal Screening*, Oxford University Press, 2000

Hedgecoe, A., Martin, P., 'The drugs don't work: expectations and the shaping of pharmacogenetics' 2003 *Soc. Studies of Science* Vol. 33, pp. 327-364

Heller, M., Eisenberg, R.S., 'Can patents deter innovation? The anticommons in biomedical research' 1998 *Science* Vol. 280, pp. 698-701

HGC (Human Genetics Commission), *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, 2002

HGC (Human Genetics Commission), *Public Attitudes to Human Genetic Information – People's Panel Quantitative Study*, 2001

HGC (Human Genetics Commission), *Whose Hands On Your Genes?* November 2000

HGDP (Human Genome Diversity Project) Workshop, *Human Genome Diversity Workshop*, Stanford, 1992

HGP (Human Genome Project) website at www.genome.gov

Hicks, R., 'Pseudoxanthoma elasticum (PXE)' available at
http://www.bbc.co.uk/health/conditions/pxe1.shtml

Hinds, D.A., et al., 'Whole-genome patterns of common DNA variation in three human populations' *Science* 2005 Vol. 307, pp. 1072-1079

Hoedemaekers, R., ten Have, H., 'Geneticization: the Cyprus paradigm' 1998 *Journal of Medicine and Philosophy*, Vol. 23, No.3, pp. 274-287

Holm, S., 'The role of informed consent in genetic experimentation' in *A Companion to Genethics*, Blackwell, 2002

Honoré, A.M., 'Ownership', in Guest, A.G., (ed.), *Oxford Essays in Jurisprudence*, Oxford University Press, 1961, pp. 108-1200

Hope, J., 'Open source licensing' in Krattiger, A., Mahoney, R.T., Nelsen, L. (eds) *Intellectual Property Management in Health and Agricultural Innovation: a Handbook of Best Practices*, MIHR and PIPRA, 2007, pp. 107-118

Hoppe, N., 'Equity is the key: from trusts to trading, or, old solutions to new problems' in PropEur Property Rights and Human Tissue Workshop II Report, *Commodification and Trust*, 2006

Hoppe, N., 'Assignment of rights in human tissue and the conditional gift concept' in PropEur Property Rights and Human Tissue Workshop I Report, *Donation/Gift and Conditional Gift Models of Regulation in Intellectual Property Rights*, 2005 [2005a]

Hoppe, N., 'Bodycheque: assignment of rights in human tissue' in 2005 *Journal of Academic Legal Studies*, Vol. 1, pp. 14-16 [2005b]

Hoyano, L., 'The flight to the fiduciary heaven' in Birks, P., (ed) *Privacy and Loyalty*, Oxford, Clarendon Press, 1997, pp. 169-248

Hsieh, A., 'A nation's genes for a cure to cancer: evolving ethical, social and legal issues regarding population genetic databases' 2004 *Colum. J.L. & Soc. Probs.* Vol. 37, No. 3, pp. 359-412

HUGO (Human Genome Organisation) Ethics Committee, *Statement on Pharmacogenomics (PGx): Solidarity, Equity and Governance*, 2007

HUGO (Human Genome Organisation) Ethics Committee, *Statement on Benefit Sharing*, 2000

Human Genome Special Issue, *Nature* Feb. 15, 2001

Human Genome Special Issue, *Science* 16 February 2001, Vol. 291, Issue 5507

Human Tissue (Scotland) Act 2006

Human Tissue Act (HT Act) 2004

HTA (Human Tissue Authority) website at www.hta.gov.uk/about_hta/human_tissue_act.cfm

Hunter, K.G., 'DNA as taxable property – The elephant in the room or a red herring?' 2006 *European Journal of Health Law*, Vol. 13, No. 3, pp. 263-275

IHMC (International HapMap Consortium), 'A haplotype map of the human genome' 2005 *Nature* Vol. 27, No. 437, pp. 1299-3

IHMC (International HapMap Consortium), 'Integrating ethics and science in the International HapMap Project', 2004 *Nature Reviews Genetics*¸ Vol. 5, pp. 467-475

IHMC (International HapMap Consortium), 'The International HapMap Project' 2003, *Nature*, Vol. 18, No. 426, p. 789

IPCB (Indigenous Peoples Council on Biocolonialism), *Indigenous Peoples, Genes and Genetics* 2000

International Covenant on Economic, Social and Cultural Rights 1966

International HapMap Project website www.hapmap.org/

Jackson, E., *Medical Law – Text, Cases and Materials*, Oxford University Press, 2006

Jaffey, P., *Private Law and Property Claims*, Hart Publishing, 2007

Johnston, C., Kaye, J., 'Does the UK Biobank have a legal obligation to feedback individual findings to participants?' 2004 *Medical Law Review* Vol. 12, pp. 239-267

Johnston, D.M., 'Native rights as collective rights: a question for group self-preservation' 1989 *Can. J. L. & Jurisprudence* Vol. 2, No. 1, pp. 19-34

Jones, J.H., Reverby S.M., (eds), *Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study*, University of North Carolina Press, 2000

Jones, J.H., *Bad Blood: The Tuskagee Syphilis Experiment*, The Free Press, 1992

Juengst, E.T., 'What "community review" can do', *Journal of Law, Medicine and Ethics* 2000, Vol. 28, p. 52

Juengst, E.T., 'Groups as gatekeepers to genomic research: conceptually confusing, morally hazardous and practically useless' 1998 *Kennedy Institute of Ethics Journal* Vol. 8, No. 2, pp. 183-200 [Juengst 1998a]

Juengst, E.T., 'Group identity and human diversity: keeping biology straight from culture' 1998 *Am. J. Hum. Genet.* Vol. 63, pp. 673–677 [Juengst 1998b]

Kahn, J.D., 'How a drug becomes "ethnic": law, commerce and the production of racial categories in medicine' 2004 *Yale J Health Policy Law Ethics* Vol. 4, pp. 1-46

Kahn, J., Sankar, P., 'BiDil: race medicine or race marketing?' 2005 *Health Affairs* Vol. 5, pp. 455-463

Kahn, P., 'Genetic diversity project tries again', 1994, *Science* Vol. 266, p. 720

Kahn, S.M., 'Multiple meanings of Jewish genes' 2005 *Culture, Medicine & Psychiatry* Vol. 29, pp. 179-192

Kahnawake Schools Diabetes Prevention Project, *Code of Research Ethics,* Kahnawake Territory, Mohawk Nation, Canada, 1996

Kambu, A., 'Lessons from omissions in biomedical research: the Hagahai patent case of Papua New Guinea' presented at Joint UNESCO-UNU Bioethics Roundtable, 15th-16th February, Yokohama, 2007

Kanellopoulou, N.K. (forthcoming), 'Advocacy groups as research organisations: novel approaches in research governance' in Tait, J., Lyall, C. (eds), *Limits of Governance*, Ashgate, 2009

Kanellopoulou, N.K., 'Gift or duty? A normative discussion for participation in human genetic databases research' in Árnason, G., Nordal, S., Árnason, V. (eds), *Blood and Data – Ethical, Legal and Social Aspects of Human Genetic Databases,* University of Iceland Press, 2004, pp. 95-99

Katz, R.A., 'The re-gift of life: can charity law prevent for-profit firms from exploiting donated tissue and nonprofit tissue banks?' 2006 *DePaul L. Rev.* Vol. 55, No. 3, pp. 943-1015

Kaye, J., 'Abandoning informed consent: the case of genetic research in population collections' in Tutton, R., Corrigan, O. (eds), *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA*, Routledge, 2004

Kaye, J. 'Genetic research on the UK population - Do new principles need to be developed?' *Trends in Molecular Medicine* 2001, Vol.7, No.11, pp. 528-530

Kaye, J., Helgason H.H., Nomper A., Sild, T., Wendel, L., 'Population genetic databases: a comparative analysis of the law in Iceland, Sweden, Estonia and the UK' *Trames* 2004, Vol. 8, No.1/2, pp. 15-33

Kaye, J., Johnston, C., 'Does the UK Biobank have a legal obligation to feedback individual findings to participants?' 2004 *Medical Law Review* Vol. 12, No. 3, pp. 239-267

Kaye, J., Martin, P., 'Safeguards for research using large scale DNA collections' 2000 *BMJ* Vol. 321, p. 1146

Kegley, J.A.K., 'Challenges to informed consent' 2004 *EMBO reports* Vol. 5, No. 9, 832-836

Kennedy, I., 'The fiduciary relationship and its application to doctors and patients' in Birks, P., (ed), *Wrongs and Remedies in the Twenty-First Century*, Clarendon Press, 1996

Kent, A., 'Genomics and modes of democratic dialogue: an analysis of two projects' in Knoppers, B.M. (ed), *Genomics and Public Health: Legal and Socio-ethical Perspectives*, Martinus Nijhoff, 2006

Kent, A., 'Patients and IP – Should we care?' 2006 *SCRIPT-ed* Vol. 3, No. 4, pp. 260-264

Keown, J., 'The gift of blood in Europe: an ethical defence of EC directive 89/381' 1997 *Journal of Medical Ethics* Vol. 23, pp. 96-100

Kerr, A., Cunningham-Burley, S., Amos, A., 'Eugenics and the new genetics in Britain: examining contemporary professionals'accounts' 1998 *Science Technology Human Values* Vol. 23, pp. 175-199

Kevles, D.J., *In the Name of Eugenics: Genetics and the Uses of Human Heredity*, Harvard University Press, 1995

Kiefer, M., 'Ruling revives lawsuits over blood research on Havasupai' 29 November 2008, available at www.azcentral.com

Kinderlerer, J., Longley, D., 'Human genetics: the new panacea?' in Brownsword, R., Cornish, W.R., Llewelyn, M., (eds), *Law and Human Genetics: Regulating a Revolution*, Hart Publishing, 1998

Kirsch, S., 'Property limits: debates on the body, nature and culture' in Hirsch, E., Strathern, M., (eds) *Transactions and Creations: Property Debates and the Stimulus of Melanesia*, Berghahn Books, 2004, pp. 21-39

Knoppers, B.M., *Populations and Genetics: Legal and Socio-Ethical Perspectives*, Brill Academic Publishers, 2003

Knoppers, B.M., 'From medical ethics to genethics', *The Lancet Perspectives* December 2000, 356, Supplement 1, s38 [Knoppers 2000a]

Knoppers, B.M., 'Genetic benefit sharing' editorial, 2000 *Science* Vol. 290, No. 5489, p. 49 (6 October) [2000b]

Knoppers, B.M., 'Population genetics and benefit sharing' 2000 *Community Genetics* Vol. 3, pp. 212-214 [2000c]

Knoppers, B.M., 'Status, sale and patenting of human genetic material: an international survey' 1999 *Nature Genetics* Vol. 22, pp. 23-26

Knoppers, B.M., 'Human genetic material: commodity or gift?' in Weir. R.F. (ed), *Stored Tissue Samples – Ethical, Legal, And Public Policy Implications*, University of Iowa Press, 1998

Knoppers, B.M., Chadwick, R., 'Human genetic research: emerging trends in ethics' 2005 *Nat Rev Genet* Vol. 6, pp. 75-79

Knoppers, B.M., Hirtle, M., Glass, K.C., 'Commercialisation of genetic research and public policy' 1999 *Science* Vol. 286, pp. 2277-78

Koik, A., 'The Estonian Genome Project: a hot media item' 7 July 2003, available at www.opendemocracy.net/theme_9-genes/article_1335.jsp

Kollock, P., 'The anatomy of cooperation' 1998 *Annu. Rev. Sociol.* Vol. 24, pp. 183-214

Komter, A.E., *Social Solidarity and the Gift*, Cambridge University Press, 2005

Komter, A.E. (ed), *The Gift – An Interdisciplinary Perspective*, Amsterdam University Press, 1996

Kopytoff, I., 'The cultural biography of things: commoditization as a process' in Appadurai, A., (ed) *The Social Life of Things: Commodities in Cultural Perspective*, Cambridge University Press, 1986

Korts, K., Estonia' in Häyry, M., Chadwick, R., Árnason, V., Árnason, G., *The Ethics and Governance of Human Genetic Databases: European Perspectives – European Perspectives*, Cambridge University Press, 2007, pp.47-52

Korts, K., 'Becoming masters of our genes: public acceptance of the Estonian Genome Project' in Árnason, G., Nordal, S., Árnason, V., (eds), *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*, University of Iceland Press & Centre for Ethics, 2004, pp. 187-192

Krimsky, S., 'The profit of scientific discovery and its normative implications' 1999 *Chi.-Kent. L. Rev.* Vol. 75, pp. 15-40

Krull, J.A., 'Family ties' available at www.miami.edu/ummedicine-magazine/Spring2004/fstory4.html

Kuppuswamy, C., *The International Legal Governance of the Human Genome*, PhD Thesis, University of Sheffield, 2007 (personal copy, on file with the author)

Kuruk, P., 'Bridging the gap between traditional knowledge and intellectual property rights - Is reciprocity an answer?' 2003 *Journal of World Intellectual Property* 2003, Vol. 6, No. 5, pp. 429-446

Lacy, P.A., '*Gene patenting: universal heritage vs. reward for human effort*' 1998, *Or. L. Rev.* Vol. 77, p. 783

Laken, S.J., et al., 'Familial colorectal cancer in Ashkenazim due to a hypermutable tract in APC', 1997, *Nature Genetics* Vol. 17, pp. 79–83

Laurie, G.T., 'Privacy and property? Multi-level strategies for protecting personal interests in genetic material' in Knoppers, B.M., Scriver, C., (eds) *Genomics, Health and Society – Emerging Issues for Public Policy*, Policy Research Initiative, 2004, pp. 83-98

Laurie, G.T., 'DNA theft': new crime in the UK', 2003 *Nature Rev Genet* Vol. 4, p. 584 (2003)

Laurie, G.T., *Genetic Privacy: a Challenge to Medico-Legal Norms*, Cambridge University Press, 2002

Laurie, G.T., Gibson, J., *Generation Scotland: Legal and Ethical Aspects*, 2003

Laurie, G.T., Hunter, K.G., 'Benefit-sharing and public trust in genetic research' in Árnason, G., Nordal, S., Árnason, V. (eds), *Blood and Data – Ethical, Legal and Social Aspects of Humna Genetic Databases*, University of Iceland Press, 2004, pp. 323-331

'Lawsuit over Havasupai blood moved to state court', 5 May 2005, available at www.indianz.com/News/2005/007997.asp

Lehrman, S., 'Jewish leaders seek genetic guidelines' 1997 *Nature* Vol. 389, p. 322

Lemke, T., 'Genetic testing, eugenics and risk' 2002 *Critical Public Health* Vol. 12, pp. 283-290

Levine, R. J., 'Informed consent: some challenges to the universal validity of the western model' in Beauchamp, T.C., Walters, L., (eds), *Contemporary Issues in Bioethics*, Brooks/Cole Publishing, 1999

Levine, R.J., *Ethics and Regulation of Clinical Research*, Urban & Schwarzenberg, 1986

Levine, R.J., 'Validity of consent procedures in technologically developing countries' in Bankowski, Z. Howard-Jones, N. (eds), *Human Experimentation and Medical Ethics: Proceedings of the XV CIOMS Round Table Conference*, Council for International Organisations of Medical Sciences, 1982, pp. 16-30

Levitt, M., 'Public consultation in bioethics: what's the point of asking the public when they have neither scientific nor ethical expertise?' 2003 *Health Care Analysis* Vol. 11, No. 1, pp. 15-25

Levitt, M., Weldon, S., 'A well placed trust? Public perceptions of the governance of DNA databases' 2005 *Critical Public Health* Vol. 15, No. 4, pp. 311-321

Lewis, M.J., Peterson, S.K., 'Perceptions of genetic testing for cancer predisposition among Ashkenazi Jewish women' 2007 *Community Genet* Vol. 10, pp. 72-81

Lewis R., 'Founder populations fuel gene discovery' 2001 *The Scientist* Vol. 15 (8)

Liddell, K., 'Did the watchdog bark, bite or whimper? The UK report on the use of personal information' 2003 *European Journal of Health Law* Vol. 9, No. 3, pp. 243-256

Lt. Harry, M.A., 'The deep seabed: the common heritage of mankind or arena for unilateral exploitation?' 1992 *Naval L. Rev.* Vol. 40, pp. 207-208

Lillehammer, H., 'From genes to eugenics' 2001 *Stud. Hist. Phil. Biol. & Biomed. Sci.* Vol. 32, No. 4, pp. 589-600

Liloqula, R., 'Value of life: saving genes versus saving indigenous peoples' 1996 *Cultural Survival Quarterly* Vol. 20, available at http://209.200.101.189/publications/csq/index.cfm

Lock, M., 'Communities constituted through the new genetics: actions and reactions – commentary on the theme of biotechnology and community' in Miller, F., et al (eds), *The Gender of Genetic Futures: The Canadian Biotechnology Strategy, Women and Health*, National Network on Environments and Women's Health Working Paper Series 2000, pp. 1-6

Lock, M., 'Genetic diversity and the politics of difference', 1999, *Chi.-Kent L. Rev.* Vol. 75, p. 83

Lock, M., 'The alienation of body tissue and the politics of immortalised cell lines' 1997 *Body Society* Vol. 7, Nos. 2-3, pp. 63-91 [Lock 1997a]

Lock, M., 'Decentering the natural body: making differences matter' 1997 *Configurations* Vol. 5, No. 2, pp. 267-292 [Lock 1997b]

Lowrance, W., *Learning from Experience: Privacy and the Secondary Use of Data in Health Research*, Nuffield Trust, 2002

Lowrance, W., 'The promise of human genetic databases' 2001 *BMJ* Vol. 322, p. 1009

Lyall, C., Tait, J. *New Modes of Governance: Developing an Integrated Policy Approach to Science, Technology, Risk and the Environment*, Ashgate, 2005

M'Charek, A., *The Human Genome Diversity Project: an Ethnography of Scientific Practice*, Cambridge University Press, 2005

Mabrey, V., 'Genetic disorders hit Amish hard', *CBS News*, 8 June 2005, available at www.cbsnews.com/stories/2005/06/08/60II/main700519.shtml

Macaulay, A.C., et al., 'Participatory research maximises community and lay involvement', 1999 *British Medical Journal* Vol. 319, pp. 774-778

Macaulay, A.C. *et al.* Participatory research with native community of Kahnawake creates innovative code of research ethics', 1998 *Can. J. Public Health* Vol. 89, pp. 105-108

Macer, D., 'Ethical considerations in the HapMap project: an insider's personal view' 2003 *Eubios Journal of Asian and International Bioethics* Vol. 13, pp. 125-127, available at http://www2.unescobkk.org/eubios/EJ134/ej134a.htm

Macer, D., Kent, A., 'Community engagement in genetic research' HUGO (Human Genome Organisation) General Meeting 2004, Summary of Workshop 11, available at http://hgm2004.hgu.mrc.ac.uk/Programme/Workshops/summary_ws11.html

Maddocks, I., 'Ethics in aboriginal research: a model for minorities or for all?' 1992 *Med. J. Aust.* Vol. 157, pp. 553-555

Maheshwari, V., 'Estonia touts its genetic credentials' *Financial Times* 31 October 2000

Mahoney, J.D., 'The market for human tissue' 2000 *Virginia Law Review* Vol. 86, No.2, pp. 163-223

Major Events in the U.S. Human Genome Project and Related Projects, available at www.ornl.gov/sci/techresources/Human_Genome/project/timeline.shtml

Malinowski, M.J., 'Choosing the genetic make-up of children: our eugenics past-present and future?' 2003 *Conn. L. Rev.* Vol. 36, pp. 125-224

Malinowski, M.J., 'Law, policy, and market implications of genetic profiling in drug development' 2002 *Hous. J. Health L. & Pol'y* Vol. 2, pp. 31-63

Malinowski, M.J., O'Rourke, M., 'A false start? The impact of federal policy on the genotechnology industry' 1996 *Yale J. on Reg.* Vol. 3, p. 163

Mann, J.M., et als, *Health and Human Rights: a Reader*, Routledge, 1999

Mannverndt website at www.mannvernd.is/

Marks, J., 'Your body, my property: the problem of colonial genetics in a postcolonial world' in Meskell, L., Pels, P., (eds), *Embedding Ethics*, Berg 2005, pp. 29-45

Marshall, E., 'European patents - BRCA2 claim faces new challenge' 2005 *Science* Vol. 308, No.5730, p. 1851

Marshall, E., 'Patient advocate named co-inventor on patent for the PXE disease gene' 2004 *Science* Vol. 305, p. 1226

Martin, J.E., *Hanbury & Martin Modern Equity*, Sweet & Maxwell, 2001

Martin, P., Kaye, J., *The Use of Biological Sample Collection and Personal Medical Information in Human Genetics Research*, Wellcome Trust, 1999

Mason, A., 'The place of equity and equitable remedies in the contemporary common law world' 1994 *LQR* Vol. 110, p. 238

Mason, J.K., Laurie. G.T., *Law and Medical Ethics*, Oxford University Press, 2006

Mason, J.K., Laurie. G.T., 'Consent of property? Dealing with the body and its parts in the shadow of Bristol and Alder Hey' 2001 *Modern Law Review* Vol. 64, pp. 710-729

Mataatua Declaration of Cultural and Intellectual Property Rights of Indigenous Peoples, June 1993, available at http://www.wipo.int/tk/en/folklore/creative_heritage/indigenous/link0002.html

Matthews, P. 'The man of property' 1995 *Med L. Rev.* Vol. 3, p. 251

Mauss, M., *The Gift – The Form and Reason for Exchange in Archaic Societies*, Routledge, 1990

Mautner, T. (ed), *The Penguin Dictionary of Philosophy*, Penguin Books, 2000

Mayrhofer, M., 'Patient organizations as the (unusual) suspects' in Gottweis, H., Petersen, A, (eds), *Biobanks Governance in Comparative Perspective*, Routledge, 2008, pp. 71-87

Mbeoji, I., 'Talking past each other: genetic testing and indigenous populations' in *ActionBioscience*, September 2007, available at

http://www.actionbioscience.org/genomic/mgbeoji.html

McBryde, W.W., *The Law of Contract in Scotland*, W. Green, 2001

McCain 'Does race have a place in biotechnology research?' 2005 *Biotechnology Healthcare*, pp. 54-72

McGrath, D., 'Ethical concerns at the DNA bank' *Wired*, 6 May 2002, available at www.wired.com/news/medtech/0,1286,52176,00.html

McGregor, J.L., 'Population genomics and research ethics with socially identifiable groups' 2007 *Journal of Law, Medicine and Ethics* Vol. 35, No.3, pp. 356-370

McHale, J.V., 'Regulating genetic databases: some legal and ethical issues' 2004 *Medical Law Review* Vol. 12, No. 1, pp. 70-96

McKusick, V.A., 'Ellis-van Creveld syndrome and the Amish' 2000 *Nature Genetics* Vol. 24, pp. 203 - 204

McManus, R., 'Once declared meaningless, race still influences' at www.nih.gov/news/NIH-Record/06_12_2001/story03.htm

Mead, A.T.P., 'Genealogy, sacredness and the commodities market' 1996 *Cultural Survival Quarterly* Vol. 20, available at http://209.200.101.189/publications/csq/index.cfm

Mead, A., 'The Convention on Biological Diversity: Are human genes biological resources?' in Thomas, N., (ed), *New Zealand Environmental Law Reporter*, 1995, University of Auckland, pp. 127-132

Medical Research Council of Canada, Natural Sciences Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Ottawa, 1998

Menzies School of Health Research, *Health Research Guidelines: Aboriginal Communities in the Northern Territory*, Darwin, Australia, 1989

Merriam-Webster Online Dictionary at www.merriam-webster.com/dictionary

Merz, J.F., 'Discoveries: Are there limits on what may be patented?' in Magnus, D., Caplan, A., McGee, G., (eds), *Who Owns Life?* Prometheus Books, 2002, pp. 99-116

Merz, J.F., Magnus D., Cho, M.K., Caplan, A.L., 'Protecting subjects' interests in genetics research', *Am J Hum Genet.* 2002 Vol. 70, No. 4, pp. 965–971

Merz, J., McGee, G.E., Sankar,P. '"Iceland Inc"? On the ethics of commercial population genetics' 2004 *Social Science and Medicine* Vol. 58, No. 4, pp. 1201-1209

Miller, S. A., 'Blood narrative: indigenous identity in American Indian and Maori literary and activist texts' 2005 *Studies in American Indian Literatures* Vol.17, No. 3, pp. 128-132

Mitchell, G.R., Happe, K., 'Defining the subject of consent in DNA research' 2001 *Journal of Medical Humanities* Vol. 22, No. 1, pp. 41-53

Mitnick, E.J., 'Constitutive rights' 2000 *Oxford Journal of Legal Studies* Vol. 20 No.2, pp. 185-204

Modell, B., Petrou, M., 'Thalassaemia screening: ethics and practice' in Cruikshank, J.K., Beevers, D.G., (eds.) *Ethnic Factors in Health and Disease*, Wright, Butterworth & Co. Publ., 1989

MRC (Medical Research Council) Working Group on Human Tissue and Biological Samples, *Human Tissue and Biological Samples for Use in Research*, 2001

MRC (Medical Research Council), *Personal Information in Medical Research*, 2000 [MRC 2000a]

MRC (Medical Research Council), *Public Perceptions of the Collection of Human Biological Samples*, 2000 [MRC 2000b]

Munzer, S., *A Theory of Property*, Cambridge University Press, 1990

Murray, H., 'Gifts of the body and the needs of strangers' 1987 *Hastings Center Report* Vol. 17, No. 2, pp. 30-38

Nash, C., 'Genetic kinship' 2004 *Cultural Studies* Vol. 18, No. 1, pp. 1-33

Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3001, 1990

Nelkin, D., 'On the social nature of genetic information' in Kevles, D.J., Hood, L., (eds) *The Code of Codes: Human and Social Issues in the Human Genome Project*, Harvard University Press, 1992

Nelkin, D., Andrews, L.B., 'The body, economic power and social control' 1999 *Chi.- Kent. L. Rev.* Vol. 75, p.3

Newton, J., Garner, S., *Disease Registers in England*, Institute of Health Sciences, Oxford, 2002

NHGRI (National Human Genome Research Institute) website entry on 'All about the Human Genome Project (HGP)' available at http://www.genome.gov/10001772

NHS (National Health Service) Executive, Department of Health (UK), *Standing Medical Advisory Committee Working Party Report on Sickle Cell, Thalassaemia and Other Haemoglobinopathies*, London, 1999

NHS (National Health Service) Sickle Cell & Thalassaemia Screening Programme, available at www.kcl-phs.org.uk/haemscreening/

Nichols-Hill, A., 'One man's trash is another man's treasure, bioprospecting: protecting the rights and interests of human donors of genetic material' 2002 *J. Health Care L. & Pol'y* Vol. 5, p. 259

Nicol, D., 'Public trust, intellectual property and human genetic databanks: the need to take benefit sharing seriously' 2004 *JIBL* Vol. 3, No. 1, pp. 89-103

Nightingale, P., Martin, P., 'The myth of the biotech revolution' 2004 *Trends in Biotechnology* Vol. 22, No. 11, pp. 564-569

NIH (National Institutes of Health) website HapMap page, available at http://www.genome.gov/page.cfm?pageID=10001688

NARC (North American Regional Committee of the Human Genome Diversity Project), 'Proposed Model Ethical Protocol for collecting DNA samples' 1997 *Hous. L. Rev.* Vol. 33, pp. 1431- 1473

Norton, I.M., Manson, S.M., 'Research in American Indian and Alaska Native communities: navigating the cultural universe of values and process' 1996, *Journal of Consulting and Clinical Psychology*, Vol. 64, No. 5, pp. 856-860

Novas, C., 'The political economy of hope: patients' organizations, science and biovalue' 2006 *BioSocieties* Vol. 1, pp. 289-305

Nowak, R., 'Gene sale' *New Scientist*, 24th November 2000

Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues*, 1995

Nuremberg Code 1947, taken from *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Vol. II, Nuremberg, Germany, October 1946 - April 1949, available at

http://www.bioethicscourse.info/onlinetextsite/Nuremberg%20Code.doc

O'Connor, B., 'Protecting traditional knowledge – An overview of a developing area of intellectual property law' 2003 *Journal of World Intellectual Property* Vol. 6, No. 5, pp. 677-698

O'Fallon, L.R., Dearry, A., 'Community-based participatory research as a tool to advance environmental health sciences' 2002 *Environmental Health Perspectives* Vol. 110, Supplement 2, pp. 155-159

O'Neill, O., *Autonomy and Trust in Bioethics,* Cambridge University Press, 2002

O'Neill, O., 'Informed consent and genetic information' 2001 *Studies in the History and Philosophy of Biological and Biomedical Sciences* Vol. 32, pp. 689-74

O'Neill, O., 'Insurance and genetics: the current state of play', in Brownsword, R., Cornish, W.R., Llewelyn, M., (eds), *Law and Human Genetics: Regulating a Revolution,* Hart Publishing, 1998, pp. 124-131

Oberdorfer, K.L.J., 'The lessons of Greenberg: informed consent and the protection of tissue sources' research interests, 2004, *Geo. L.J.* Vol. 93, pp. 365-394

Oberman, M., 'When the truth is not enough: tissue donation, altruism, and the market', 2006 *DePaul L. Rev*. Vol. 55, No. 3, pp. 903-942

Orlando, M., 'Moore revisited: state-sponsored biotechnological research and the taking clause' 2001 *Whittier L Rev* Vol. 23, p. 437

Ossorio, P.N., 'The human genome as common heritage: common sense or legal nonsense?' 2007 *Journal of Law Medicine and Ethics* Vol. 35, No. 3, pp. 425-439

Ossorio, P.N., 'Race, genetic variation and the Haplotype Mapping Project' 2005-2006 *La. L. Rev*. Vol. 66, pp. 131-144

Osteen, M., 'Introduction: Questions of the Gift' in Osteen, M., (ed), The Question of the Gift: Essays Across Disciplines, Routledge, 2002

Outram, S.M., Ellison G.T., 'The truth will out: scientific pragmatism and the geneticization of race and ethnicity' in Ellison, G.T., Goodman, A.H., (eds) *The Nature of Difference – Science, Society and Human Biology,* CRC Press, 2006, pp. 157-180

Page, N., Czuba, C.E., 'Empowerment: what is it?' 1999 *Journal of Extension* Vol. 37, No. 5

Pálsson, G. *Anthropology and the New Genetics*, Cambridge University Press, 2007

Pálsson, G., Hardadóttir, K.E., 'For whom the bell tolls - debates about biomedicine' 2003 *Current Anthropology* Vol. 43 (2), p. 271

Pálsson, G., Helgason, A., 'Blondes, lost and found: representations of genes, identity, and history', 2003 *Developing World Bioethics* Vol. 3, No. 2, pp. 159-69

Pálsson, G., 'The life of family trees and the Book of Icelanders', 2002 *Med Anthropol*. Vol. 21, No. 3- 4, pp. 337-367

Pálsson, G., Rabinow, P., 'The Iceland controversy: reflections on the transnational market of civic virtue' in Ong, A., Collier, S., (eds) *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems*, Blackwell Publishers, 2004, pp. 3-21

Pálsson, G., Rabinow, P., 'The Icelandic genome debate' *Trends in Biotechnology* 2001, Vol.19, No. 5, pp. 166-171

Pálsson, G., Rabinow, P., 'Iceland: the case of a national human genome project', 1999 *Anthropology Today* Vol. 15, No. 5, pp. 14-18

Pärl, Ŏ., 'Estonia's gene database – a "crazy idea" becomes a reality' 2003 *Biotech Estonia* pp. 8-11

Parliamentary Office of Science and Technology (POST), 'The UK Biobank' *Postnote* No. 180, July 2002, available from www.parliament.uk/post/home.htm

Parry, B., *Trading the Genome: Investigating the Commodification of Bio-Information*, Columbia University Press, 2004

Parry, J., 'The gift, the Indian gift and the 'Indian gift'' 1985 *Man* (N.S.), Vol. 21, pp. 453-473

Parthasarathy, S., *Building Genetic Medicine – Breast Cancer, Technology and the Comparative Politics of Health Care*, MIT Press, 2007

Parthasarathy, S., 'Regulating risk: defining genetic privacy in the United States and Britain' 2004 *Science, Technology Human Values* Vol. 29, No. 3, pp. 332-352

Pearce, R.A., Stevens, J., *The Law of Trusts and Equitable Obligations*, Butterworths, 2002

Penner, J.E., *The Law of Trusts*, Oxford University Press, 2004

People Science and Policy Ltd., *UK Biobank: A Consultation with Nurses in General Practice and Research*, 2003

People Science & Policy Ltd, *BioBank UK: A Question of Trust: A Consultation Exploring and Addressing Questions of Public Trust*, 2002

Petersen, A., 'Biobanks: challenges for ethics' 2005 *Critical Public Health* Vol. 15, No. 4, pp. 303-310

Philipkoski, K., 'Genetics Scandal Inflames Iceland', 20 March 2000, available at http://www.wirednews.com/news/politics/0,1283,35024,00.html

Pierik, R., 'Conceptualizing cultural groups and cultural difference: the social mechanism approach' 2004 *Ethnicities* Vol. 4, No. 4, p. 528

Plomer, A., *The Law and Ethics of Medical Research: International Bioethics and Human Rights*, Routledge Cavendish, 2005

Posey, D.A., Dutfield, G., *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*, Ottawa: International Development Research Centre, 1996, available online at http://www.idrc.ca/openebooks/799-x/

Pottage, A., 'The Inscription of life in law: genes, patents and bio-politics', in Brownsword, R., Cornish, W.R., Llewelyn, M., (eds), *Law and Human Genetics: Regulating a Revolution*, Hart Publishing, 1998

Potts, J., 'At least give the natives glass beads: an examination of the bargain made between Iceland and deCODE genetics with implications for global bioprospecting' 2002 *Va. J.L. & Tech.* Vol. 7, p.8

Prainsack B., 'The rise of genetic couplehood? Comparative view of premarital genetic testing' 2006 *BioSocieties* Vol. 1, pp. 17-36

Press, N., Burke, W., Durfy, S., 'How are Jewish women different from all other women?' *Journal of Law and Medicine* 1998, Vol. 7, No.1, p. 1-17

PropEur (Property Regulation in European Science, Ethics and Law), *Final Project Conference Report*, Birmingham, September 2006

Pullman, D., Latus, A., *Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador - A Report for the Newfoundland and Labrador Department of Health and Community Services*, January 2003

Pullman, D., Latus, A., 'DNA Databases: a benefit-sharing model', 2002 *L' Observatoire de la Génétique* No. 6

PXE (Pseudoxanthoma Elasticum) International website www.pxe.org

Quane, H., 'The rights of indigenous peoples and the development process' 2005 *Human Rights Quarterly* Vol. 27, No. 2, pp. 652-682

Rabinow, P., *Essays on the Anthropology of Reason*, Princeton University Press, 1996

Rabeharisoa, V., Callon, M., 'Patients and scientists: French Muscular Dystrophy. Research' in Jasanoff, S., (ed), *States of Knowledge – The Co-production of Science and Socila Order*, Routledge 2004, pp. 142-160

Rachels, J., *The Elements of Moral Philosophy*, McGraw-Hill, 1999

Rachels, J., *Can Ethics Provide Answers? And Other Essays in Moral Philosophy*, Rowman & Littlefield Publishers, 1997

Rainer, K., Riivo, A.,'The Estonian Genome Project and economic development' 2004 *Trames* Issue Vol. 8, No.1-2, pp. 241-253

Rajan, K.S, *Biocapital – The Construction of Postgenomic Life*, Duke University Press, 2006

Rao, A., 'Genes and spleens: property, contract, or privacy rights in the human body?' 2007 *Journal of Law, Medicine and Ethics* Vol. 35, No. 3, pp. 371-382

Rao, A., 'Property, privacy, and the human body' 2000 *B.U.L. Rev.* Vol. 80, p. 433

Ratto, M., Beaulieu, A., 'Banking on the Human Genome Project' 2007 *CRSA/RCSA* Vol. 44, No. 2, pp. 175-200

Reardon, J., 'Democratic mis-haps: the problem of democratization in a time of biopolitics' 2007 *Biosocieties* Vol. 2, pp. 239-256

Reardon, J., *Race to the Finish – Identity and Governance in an Age of Genomics*, Princeton University Press, 2005

Reardon, J., 'Decoding Race and Human Difference in a Genomic Age' 2004 *Differences* Vol. 15, No. 3, p. 38

Reardon, J., 'The Human Genome Diversity Project: a case study in coproduction' 2001 *Soc. Stud. Sci.* Vol. 31, p. 357

Reed, M.I., 'Organization, trust and control: a realist analysis' 2001 *Organization Studies* Vol. 22, No. 2, pp. 201-228

Regan, P., 'Preserving privacy' 2000 *Issues in Science and Technology* Vol. 16, No. 4, online issue

Reiser, S.J., 'Misconduct and the development of ethics in the biological sciences' 1994 *Cambridge Quarterly of Healthcare Ethics* Vol. 3, p. 499

Resnik, D.B., 'Are DNA patents bad for medicine?' 2003 *Health Policy* Vol. 65, No. 2, pp. 181-97

Reverby, S. (ed), *Tuskegee's Truths – Rethinking the Tuskegee Syphilis Study*, The University of North Carolina Press, 2000

Richards, C.S., Ward, P.A., Roa, B.B., Friedman, L.C., Boyd, A.A., Kuenzli, G., Dunn, J.K., Plon, S.E., 'Screening for 185de1AG in the Ashkenazim', *American Journal of Human Genetics* 1998, Vol. 60, No. 5, pp. 1085-1098

Richards, M., 'It runs in the family: lay knowledge about inheritance' in Clarke, A., Parsons, E., (eds), *Culture, Kinship and Genes: Towards Cross-Cultural Genetics*, Palgrave, Macmillan, 1997, pp. 175 - 194

Richards, M., 'Families, kinship and genetics' in Marteau, T., Richards, M., (eds.), *The Troubled Helix: Social and Psychological Implications of the New Genetics*, Cambridge University Press, 1996

Riley, A., '"Straight stealing": towards an indigenous system of cultural property protection' 2005 *Wash. L. Rev.* Vol. 80, pp. 69-164

Rischn, N., Buchardn, E., Zivn, E., Tangn, H., 'Categorization of humans in biomedical research: genes, race and disease', *Genome Biol* 2002, Vol. 3, pp. 1-12

Rohter, L., 'In the Amazon, giving blood but getting nothing' 20th June 2007, The New York Times

Rose, N., *The Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century*, Princeton University Press, 2006

Rose, N., Novas, C., 'Biological citizenship', in Ong, A., Collier, S., (eds) *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems*, Blackwell Publishers, 2004, pp. 3-21

Rothstein, M.A., Griffin Epps, P., 'Ethical and legal implications of pharmacogenomics' 2001 *Nature Rev Genet* vol. 2, pp. 228-231

Rotimi, C., et al., 'Community engagement and informed consent in the International HapMap Project' 2007 *Community Genet* Vol. 10, pp. 186-198

Rouse, R., 'Tonga joins list of laboratory communities' 2001 *Nat Med*. Vol. 7, No. 1, p.8

Rubin, P., 'Court ruling on Havasupai blood case good news for tiny tribe' 15 December 2008, available at http://blogs.phoenixnewtimes.com

Salter, B., Jones, M., 'Biobanks and bioethics: the politics of legitimation' 2005 *Journal of European Public Policy* Vol. 12, No. 4, pp. 710-732, also available at

http://www.york.ac.uk/res/iht/projects/l218252005/SalterBiobanksAndBioethicsPaper.pdf

Schanche Hodge, F., et al., 'Recruitment of American Indians and Alaska Natives into clinical trials', 2000, *Annals of Epidemiology* Vol. 10, S41

Schmidt, C.W., 'Spheres of influence' 2001 *Environmental Health Perspectives* Vol. 109, No.5, pp. A 216-A219

Schmidtz, D., 'What we deserve, and how we reciprocate' 2005 *The Journal of Ethics* Vol. 9, pp. 435-464

Schnarch, B., 'Ownership, control, access, and possession (OCAP) or self-determination applied to research – A critical analysis of contemporary First-Nations research and some options for First Nations communities' 2004 *Journal of Aboriginal Health* Vol. 1, No.1, pp. 80-95

Schrag, B., 'Research with groups: group rights, group consent, and collaborative research - Commentary on protecting the Navajo People through tribal regulation of research' 2006 *Science and Engineering Ethics* Vol. 12, pp. 511-521

Schroeder, D., 'Benefit sharing: it's time for a definition' 2007 *J Med Ethics* Vol. 33, pp. 205-209

Schuklenk, U., Kleinsmidt, A.,'North–South benefit sharing arrangements in bioprospecting and genetic research: a critical ethical and legal analysis' 2006 *Developing World Bioethics* Vol. 6, No. 3, pp. 122-134

Schwartz, B., 'The social psychology of the gift' 1967 *American Journal of Sociology* Vol. 73, No. 1, pp. 1-11

Science Encyclopedia, The History of Ideas, Vol. 1, entry on 'altruism' available at http://science.jrank.org/pages/7481/Altruism.html

Science in Africa, 'Marginalised San win royalties from diet drug' available online at www.scienceinafrica.co.za/2003/may/san.htm

'Scientists attacked for "patenting" pacific tribe' 1995 *Science* Vol. 270, p. 1112

Segall, S., 'Unconditional welfare benefits and the principle of reciprocity' 2005 *Politics, Philosophy Economics* Vol. 4, pp. 331-354

Senituli, L., 'The gene hunters' 2002, available at http://newint.org/features/2002/09/01/genetic-information/

Senituli, L., Boyes, M., 'Whose DNA? Tonga and Iceland, biotech, ownership and consent' Australasian Bioethics Association Annual Conference paper, Adelaide, 2002

Sharp, R.R., Foster, M.W., 'Grappling with groups: protecting collective interests in biomedical research' 2007 *Journal of Medicine and Philosophy* Vol. 32, No. 4, pp. 321-337

Sharp, R.R., Foster, M.W., 'An analysis of research guidelines on the collection and use of human biological materials from American Indian and Alaskan native communities' 2002 *Jurimetrics J.* Vol. 42, p. 165

Sharp, R.R., Foster, M.W., 'Involving study populations in the review of genetic research", 2000, J. L. Med. & Ethics Vol. 28, p. 41

Shaw, R., 'The notion of the gift in the donation of body tissues' 2008 *Sociological Research Online* Vol. 13, No. 8, available online at http://www.socresonline.org.uk/13/6/4.html

Sheremeta, L., Knoppers, B.M., 'Beyond the rhetoric: population genetics and benefit-sharing' in book series by International Library of Environmental, Agricultural and Food Ethics, *Accessing and Sharing the Benefits of the Genomics Revolution*, Vol. 11, Springer, 2007, pp. 157-182

Sheremeta, L., Knoppers, B.M., 'Beyond the rhetoric: population genetics and benefit-sharing' 2003 *Health Law Journal* Vol. 11, pp. 89-117

Schmidt, C.W., 'Spheres of influence – Indi-gene-ous conflicts' 2001 *Environmental Health Perspectives* Vol. 109, No. 5, pp. A216-219

Simm, K., *Benefit Sharing: an Inquiry into Justification*, Tartu University Press, 2005, PhD Thesis, Tartu University (personal copy – on file with the author) [Simm 2005a]

Simm, K., 'Benefit-sharing: an inquiry regarding the meaning and limits of the concept in human genetic research' 2005 *Genomics, Society and Policy* Vol.1, No.2, pp.29–40 [Simm 2005b]

Simpson, B., 'Imagined genetic communities; ethnicity and essentialism in the twenty-first century' 2000 *Anthropology Today* Vol. 16, No.3, pp. 3-6

Singeo, L., 'The patentability of the Native Hawaiian Genome' 2007 *American Journal of Law & Medicine* Vol. 33, No. 1, pp. 119-139

Skene, L., 'Theft of DNA' 2003, working paper available at www.ccels.cf.ac.uk/archives/publications/2003/skenepaper.pdf

Sleebom-Faulkner, M., 'How to define a population: cultural politics and population genetics in the People's Republic of China and the Republic of China' 2006 *BioSocieties* Vol. 1, pp. 399-419

'Slimmed down breast cancer gene patent upheld' *BioNews*, 30 June 2005, available at www.bionews.org.uk/new.lasso?storyid=2635

Smaglik, P., 'Tissue donors use their influence in deal over gene patent terms" 2000, *Nature*, Vol. 407, No. 6806, p. 821

Smith, D., 'Human biobanks: for whom the benefit tolls?' 2008 *Genomics Network* No. 7, pp. 17-19

Smith, D.G., 'The critical resource theory of fiduciary duty' 2002 *Vanderbilt L Rev* Vol. 55, pp. 1399-1497

Smith, P., 'Duties of group membership: justice as reciprocity and liberal democratic institutions' in Sistare, C, May, L., Francis, L., *Groups and Group Rights*, University Press of Kansas, 2001, pp. 172-182

Sober, E., Wilson D.S., *Unto Others: The Evolution and Psychology of Unselfish Behavior*, Harvard University Press, 1998

Soo-Jin Lee, S., 'Racializing drug design: implications of pharmacogenomics for health disparities' *Am J Publ Health* 2005, Vol.95, No. 12, pp. 2133-2138

Sorenson, D., 'Havasupai suit over research tossed' *The Arizona Daily Star*, 4 May 2007, available at http://www.abor.asu.edu/

Speer, P.W., Hughey, J., 'Community organizing: An ecological route to empowerment and power' 1995 *American Journal of Community Psychology*, Vol. 23, No. 5, pp. 729-748

Spier, R., 'Genes in Court' 2001 *Science and Engineering Ethics*, Vol. 7, No. 1, pp. 3-6

Stanford Encyclopaedia of Philosophy entry on 'Biological Altruism' available at http://plato.stanford.edu/entries/altruism-biological/

Stanford Encyclopaedia of Philosophy on 'Equality' available at http://plato.stanford.edu/entries/equality

Steans, J., 'Negotiating the politics of difference in the project of feminist solidarity' 2007 *Review of International Studies* Vol. 33, pp. 729-743

Steinvorth, U., 'Kann Solidarität erzwingbar sein?' in Bayertz, K., (ed.) *Solidarität – Begriff und Problem*, Suhrkamp, 1998

Stern, W., 'Consideration and gift' 1965 *The International and Comparative Law Quarterly*, Vol. 14, No. 2, pp. 675-684

Stewart, A., 'Funding for Quebec CARTaGENE project' *PHG Foundation Newsletter*, 8 June 2007, available at www.phgfoundation.org/news/3417/

Stockdale, A., Terry, S.F., 'Advocacy groups and the new genetics' in Alper, J.S. et al., *The Double-Edged Helix: Social Implications of Genetics in a Diverse Society*, The John Hopkins University Press, 2002, pp. 80-101

Stolberg, S.G., 'Jewish concern grows as scientists deepen studies of Ashkenazi genes' *New York Times*, April 22, 1998

Strathern, M., 'Partners and consumers: making relations visible' 1992 *New Literary History* Vol. 22, No. 3, pp. 581-601

Strathern, M., *Reproducing the Future: Anthropology, Kinship and the New Reproductive Technologies*, Macnhester University Press, 1982

Strauss, R.P., 'The role of Community Advisory Boards: involving communities in the informed consent process' 2001 *American Journal of Public Health* Vol. 91, No. 12, pp. 1938-1943

Streetly, A., 'A national screening policy for sickle cell disease and thalassaemia major for the United Kingdom', 2000 *BMJ* Vol. 320, pp.1353-1354

Struewing, J.P., et al., 'The risk of cancer associated with specific mutations of BRCA1 and BRCA2 among Ashkenazi Jews'1997 *N. Engl. J. Med.*, Vol. 336, No. 20, pp. 1401-1408

Sturges, M.L., 'Who should hold property rights to the human genome? An application of the common heritage of humankind' 1997 *Am. U. Int'l L. Rev* Vol. 13, pp. 219-261

Sumner, J., 'Previous research on public attitudes to biobanks and related ethics and governance issues' 2007, available online at http://www.egcukbiobank.org.uk/meetingsandreports/

Sutrop, M., Simm, K., 'The Estonian healthcare system and the genetic database project' 2004 *Cambridge Quarterly of Healthcare Ethics"* Vol. 13, No. 3, pp. 254-262

Tallbear, K., *Native American DNA: Narratives of Origin and Race*, PhD Thesis, University of California Santa Cruz, 2005 (personal copy, on file with the author)

TallBear, K., 'The tribal specific approach to genetic research and technology' International Institute for Indigenous Resource Management, Conference Paper, 2001

Tammpuu, P., 'Public discourses on human genetic databases' in Häyry, M., Chadwick, R., Árnason, V., Árnason, G., *The Ethics and Governance of Human Genetic Databases: European Perspectives – European Perspectives*, Cambridge University Press, 2007, pp. 73-87

Tammpuu, P, 'Making genes commonly meaningful: implications of national self-images on human genetic databases' in Árnason, G., Nordal, S., Árnason, V., (eds), *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*, University of Iceland Press & Centre for Ethics, 2004, pp. 161-165

Tansey, J, Burgess, J.M., *The Foundations, Applications and Ethical Dimensions of Biobanks'*, CAE Working Paper Series, Paper No. DEG 005, 2005

Tasmuth, T., 'The Estonian gene bank project – an overt business plan', 29 May 2003, available at www.openDemocracy.net

Taussig, K.S., 'Ambiguous mutations: breast cancer genetics and the quest for meaningful molecular medicine' 2007 *BioSocieties* Vol. 2, No. 4, pp. 456-459

Taylor, M., 'Why current regulatory frameworks cannot be relied upon to protect privacy in biobanks?' 2007/2008 *L' Observatoire de la Génétique* Vol. 35

Taylor, M., 'Does Data Protection Directive 95/46/EC adequately protect people from the risks to fundamental rights and freedoms posed by the acquisition and use of personal genetic data? A UK perspective', Transcript, Brocher Foundation Symposium, 'Value and Risks of Genetic Data Collections', November 2005 (on file with the author)

Tenenbaum, E.S., 'A world park in Antarctica: the common heritage of mankind', 1990 *VA. Envtl. L.J.* Vol. 10, p. 112

Tenfelde, K., 'Arbeiterschaft, Solidarität und Arbeiterbeqengung', Kommentar zum Beitrag von Karl H. Metz, in Bayertz, K., (ed.) *Solidarität – Begriff und Problem,* Suhrkamp, 1998

Terry, S., et al., 'Advocacy groups as research organizations: the PXE International example' 2007 *Nat Rev Genet* Vol. 8, pp. 157-164

Terry, P.F., 'PXE International: Harnessing intellectual property law for benefit-sharing' in Knoppers, B.M., (ed), *Populations and Genetics: Legal and Socio-Ethical Perspectives*, Martinus Nijhoff Publishers, 2003, pp. 377-393

Thacker, E., *The Global Genome – Biotechnology, Politics, and Culture*, MIT Press, 2005

Titmuss, R.M., *The Gift Relationship: From Human Blood to Social Policy*, George Allen & Unwin Ltd, 1970

'Tribal suit over blood samples dismissed' 4 May 2007, available at http://news.findlaw.com/ap/o/632/05-04-2007/8cb3000ed5c43c8e.html

Trivers, R.L., 'The evolution of reciprocal altruism' 1971 *Quarterly Review of* Biology, Vol. 46, pp. 35-57

Tsosie, R., 'Cultural challenges to biotechnology: Native American genetic resources and the concept of cultural harm' 2007 *Journal of Law, Medicine and Ethics* Vol. 35, No. 3, pp. 396-411

Tutton, R., 'Constructing participation in genetic databases: citizenship, governance, and ambivalence' 2007 *Science Technology Human Values* Vol. 32, No. 2, pp. 172-195

Tutton, R., 'Person, property and gift: exploring languages of tissue donation' in Tutton, R., Corrigan, O. (eds), *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA*, Routledge, 2004, pp. 19-38

Tutton, R., Corrigan, O., 'Introduction – Public participation in genetic databases' in Tutton, R., Corrigan, O. (eds), *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA*, Routledge, 2004, pp. 1-18

Tvedt, M. W., 'Elements for legislation in user countries to meet the fair and equitable benefit-sharing commitment' 2006 *the Journal of World Intellectual Property* Vol. 9, No. 2, pp. 189-212

Twyman, R., 'Biobanks: the long game' *Wellcome Science* No. 5, February 2007, pp. 12-13

UK Biobank EGF (*Ethics and Governance Framework*) *comment Version 3.0*, October 2007

UK Biobank EGF (*Ethics and Governance Framework*) *comment Version 1*, 24th September 2003

UK Biobank (IP & Access) *Policy on Intellectual Property and Access*, May 2007

UK Biobank public consultations, available at www.ukbiobank.ac.uk/ethics/consultations.php

UK Biobank website at www.ukbiobank.ac.uk

UK Cystic Fibrosis Trust website at www.cftrust.org.uk/

UK *Data Protection Act* 1998

UK House of Lords Select Committee on Science and Technology, Fourth Report, *Report on Human Genetic Databases: Challenges and Opportunities*, 2001, available at http://www.publications.parliament.uk/pa/ld200001/ldselect/ldsctech/57/5701.htm

UK *Human Rights Act* 1998

UK Information Commissioner, *Guidance on Use and Disclosure of Health Data*, May 2002

Underkuffler, L.S., 'Human genetic studies: the case for group rights' 2007 *J.L. Med. & Ethics*, Vol. 35, No.3, pp. 383-395

Underkuffler, L.S., 'Human genetic studies: the case for group rights' 2006 Duke Law School Working Paper Series, No. 56

UNESCO (United Nations Educational Scientific and Cultural Organization) IBC International Bioethics Committee, *International Declaration on Human Genetic Data* 2003

UNESCO (United Nations Educational Scientific and Cultural Organization), *Race and Science: The Race Question in Modern Science*, Columbia University Press, New York, 1961

UNESCO (United Nations Educational Scientific and Cultural Organization), *Universal Declaration on the Human Genome and Human Rights* 1997

United Nations *Universal Declaration on Human Rights* 1948

US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*¸ 1979, available from the US Office of Human Subjects Research website at http://ohsr.od.nih.gov/guidelines/belmont.html

'US drops patent claim to Hagahai cell line' 1996 *Nature* Vol. 384, p. 500

'US patent on tribesman's blood raises ethical questions – Can a government claim rights over parts of your body?' 20th April 1996, available at http://coombs.anu.edu.au./SpecialProj/PNG/htmls/AP.html

USA Today, 'Group can sue over gene researcher's patent on testing' 6th May 2003, available at http://www.usatoday.com/tech/news/techpolicy/2003-06-05-dna-miami_x.htm

Wadman, M., 'Is race enough?' 2005 *Nature* Vol. 435, pp. 1108

Waldby, C., Mitchell, R., *Tissue Economies – Blood, Organs and Cell Lines in Late Capitalism*, Duke University Press, 2006

Wall, S., 'Collective rights and individual autonomy' 2007 *Ethics* Vol. 117, No. 2, pp. 234-264

Walzer, M., *Spheres of Justice – A Defence of Pluralism and Equality*, Blackwell, 1983

Warne, D., 'Genetics research in American Indian communities: sociocultural considerations and participatory research' 2005 *Jurimetrics J.* Vol. 45, p. 191

Watkins, R.E., 'Negotiating rights and difference – Liberalism, cosmopolitanism and democracy' 2006 *Political Theory*, Vol. 34, No. 5, pp. 628-633

Webster, A., Brown, N., Douglas C., Lewis, G., 'Public attitudes to third party access and benefit sharing: their application to UK Biobank', 2008

Weijer, C., 'Benefit-sharing and other protections for communities in genetic research' 2000 *Clin. Genet.* Vol. 58, pp. 367-368

Weijer, C., 'Protecting communities in research: philosophical and pragmatic challenges' 1999 *Cambridge Quarterly of Healthcare Ethics* Vol. 8, pp. 501-513

Weijer, C., Emanuel, E.J., 'Protecting communities in biomedical research' 2000 *Science*, Vol. 289, pp. 1142-1144

Weijer, C., Goldsand, G., Emanuel, E.J., 'Protecting communities in research: current guidelines and limits of extrapolation' 1999 *Nat Genet* Vol. 23, p. 275

Weijer, C., 'Protecting communities in research: philosophical and pragmatic challenges' 1999 *Cambridge Quarterly of Healthcare Ethics* Vol. 8, pp. 501-513

Wellcome Trust, *Report on the Workshop on Human Biological Sample Collections*, November 1999

Wendler, D., Emanuel. E., 'The debate over research on stored biological samples – What do sources think?' 2002 *Arch Intern Med.* Vol. 162, pp. 1457-1462

Whelan, M.L., 'What, if any, are the ethical obligations of the U.S. Patent Office? A closer look at the biological sampling of indigenous groups' 2006 *Duke Law & Technology Review*, iBrief, No. 14

White. R.M., 'Unraveling the Tuskegee study of untreated syphilis' 2000 *Arch. Intern. Med.* Vol. 160, pp. 585-598

Whitt, L.A., 'Value-bifurcation in bioscience: the rhetoric of research justification' 1999 *Perspectives on Science* Vol. 7, No. 4, pp. 413-446

Whitt, L.A., 'Indigenous peoples, intellectual property & the new imperial science' 1998 *Oklahoma City University Law Review* Vol. 23, pp. 211-259

Whitty, N.R., 'Rights of personality, property rights and the human body in Scots law' 2005 *Edin LR* Vol. 9, No. 2, pp. 194-237

Williams, S., 'A case study of ethical issues in genetic research: the Sally Hemmings-Thomas Jefferson Story" in Turner, T. (ed), *Biological Anthropology and Ethics: From Repatriation to Genetic Identity*, State University of New York Press, 2005, pp. 185-208

Winickoff, D.E., *From Benefit Sharing to Power Sharing: Partnership Governance in Population Genomics Research*, JSP/CSLS Working Papers, University of California, Berkeley, 2008, available at http://repositories.cdlib.org/csls/fwp/68

Winickoff, D.E., 'Partnership in UK Biobank: a third way for genomic property?' 2007 *Journal of Law, Medicine and Ethics* Vol. 35, No. 3, pp. 440-456

Winickoff, D.E., 'Genome and nation – Iceland's Health Sector Database and its legacy' 2006 *Innovations* Vol. 1, No.2, pp. 80-105

Winickoff, D.E., Neumann, L., 'Towards a social contract model for genomics: property and the public in the 'biotrust' model' 2005 *Genomics, Society and Policy*, Vol. 1, No., 3, pp. 8-21

Winickoff, D.E., 'Governing population genomics: law, bioethics and biopolitics in three case studies' 2003 *Jurimetrics* Vol. 43, pp. 187-228 [Winickoff 2003a]

Winickoff, D.E., Winickoff, R.N., 'The charitable trust as a model for genomic biobanks' 2003 *NEJM* Vol. 349, No. 12, pp. 1180-1184 [Winickoff 2003b]

World Health Organization (WHO), *Declaration on the Promotion of Patients' Rights* 1994

World Health Organization (WHO) European Partnership on Patients' Rights and Citizens' Empowerment, *Genetic Databases: Assessing the Benefits and the Impact on Human & Patient Rights*, 2000

World Health Organization (WHO), *International Guidelines on Ethical Issues in Medical Genetics and Genetic Services*, 1997

World Health Organization (WHO) Human Genetic Programme: *Proposed Guidelines on Ethical Issues in Medical Genetics and Genetic Services*, Geneva 1997

World Medical Association *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 1964, revised in 2000

Wynberg, R., 'Rhetoric, realism and benefit sharing: use of traditional knowledge of *hoodia* species in the development of an appetite suppressant' 2004 *Journal of World Intellectual Property* Vol. 7, No. 6, pp. 851-876

Xanthaki, A., *Indigenous Rights and United Nations Standards: Self-Determination, Culture and Land*, Cambridge University Press, 2007

Zeuner, D et al, Antenatal and neonatal haemoglobinopathy screening in the UK: review and economic analysis, 1999 *Health Technol Assess* Vol. 3, No. 11

Zhang, B., Dearing, L., Amos, J., 'DNA-based carrier screening in the Ashkenazi Jewish population' 2004 *Expert Review of Molecular Diagnostics* Vol. 4, No. 3, pp. 377-392

Zion, J.W., 'Traditional Indian law, the intellectual property regime, and the protection of indigenous genetic materials', International Institute for Indigenous Resources Management Roundtable, Denver, Colorado, Conference Paper, 4th-5th June 2001