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Revising the Philosophical Foundation for Informed Consent Guidelines in International Research on Human Subjects

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REVISING THE PHILOSOPHICAL FOUNDATION FOR INFORMED CONSENT
GUIDELINES IN INTERNATIONAL RESEARCH ON HUMAN SUBJECTS

By

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Revising the Philosophical Foundation for Informed Consent Guidelines in International
Research on Human Subjects

Dissertation directed by Associate Professor David Boonin and Assistant Professor Eric Chwang

Current international guidelines for informed consent in research on human subjects should be revised in order to be more globally applicable. Because many from less developed countries value community to the extent that they would wish to include community in the informed consent process, the foundation and guidelines for informed consent must attend to how community involvement can enhance or impede autonomy. The present provisions for involving community are not specific enough. The reason for this lies in the reliance on the traditional account of respect for autonomy, which overlooks the impact that social structures, or differences in race, class and gender, can have on autonomy. What is needed is a relational account of autonomy that attends to the many ways that social structures affect autonomy. To illustrate how this change would be reflected in policy, I argue for a set of ethical conditions for respecting relational autonomy in research and propose amendments to the current guidelines.

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Chapter 1: Introduction

In 2007, sixty-eight percent of the African population was infected with AIDS.¹ With this disease reaching epidemic proportions in less developed countries, research in these areas is on the rise. Current international guidelines for research on human subjects stress the importance of informed consent, which is meant to ensure that people freely choose whether to participate in a research trial. As many of the current international guidelines for informed consent in research on human subjects spell out, informed consent rests on the principle of respect for autonomy,² the ability to make self-governed choices regarding research participation that reflect one's beliefs and values.

Although some have written on research on human subjects from less developed countries, they have focused on such issues as fair benefit sharing³ and what constitutes adequate and comprehensible information for the purposes of obtaining informed consent.⁴ What is missing is an analysis of whether the current philosophical foundation for informed consent guidelines adequately respects important cultural differences. In providing the philosophical foundation for informed consent in international research on human subjects, the principle of autonomy both justifies the reason for requiring informed consent and guides the way that informed consent should be structured within the research context. Because the philosophical foundation informs the guidelines by

¹ UNAIDS 2007 AIDS Epidemic Update.

² The Belmont Report 1979, Part B:1; CIOMS Ethical Guidelines 2002, Introduction; UNESCO Declaration on Bioethics and Human Rights 2005, Article 5.

³ For example, refer to Conference on Ethical Aspects of Research in Developing Countries 2002 and Arras 2004.

⁴ For example, refer to Ingelfinger 2003 and Mystakidou K, Panagiotou I, Katsaragakis S, Tsilika E, Parpa E. and Sahara, J. 2009.

which researchers determine whether they have ethically obtained subjects' informed consent to participate in research, it is important to examine the possible shortcomings of this foundation.

In the chapters that follow, I argue that the current account of autonomy that is reflected in international informed consent guidelines, an account I refer to as the traditional account, does not adequately address important cultural differences, namely the importance that some cultures place on community to the extent that they would want to include community in their decision-making process. Because community involvement is of the utmost value to many in less developed countries and because the principle of autonomy demands respecting this, it is necessary for informed consent guidelines that are intended to be globally applicable to address community involvement and the ways in which this might enhance or impede subject's autonomy.

Although my focus is on subjects from less developed countries, my arguments also apply to developed countries in which subjects, primarily from certain subcultures within society, place great importance on community. However, due to the urgent need for research in less developed countries in response to various epidemics, I have chosen to focus on less developed countries. Nevertheless, the reader should keep in mind the overall applicability of my arguments.

In order to understand how the current foundation fails to adequately attend to community involvement, I examine what I call the general account of autonomy that underlies the current foundation. Autonomy refers to the ability to make self-governed choices that reflects one's identity, beliefs, and values, and which one believes is in one's

best interest. While all theories of autonomy share minimal conditions for autonomy, they differ in how they define the necessary and sufficient conditions for autonomous choice.

One way of understanding these differences is to look at the particular account of the person that informs the general account of autonomy. Something like this has been done before in political philosophy with regards to the account of human nature that is implicit in accounts of political autonomy, or the ability to make self-governed choices in the political realm.⁵ Although my focus is personal autonomy, or the ability to make self-governed personal choices, I build on the idea of turning to accounts of the person to better understand theories of autonomy.

In doing so, I examine the three accounts of the person that have become popular in the philosophical literature – the abstract individual, the embedded self, and the relational self. I believe that these inform three general accounts of personal autonomy respectively -- accounts that I refer to as the traditional, embedded, and relational accounts. I explain that the traditional account of autonomy currently underlies informed consent guidelines on international research on human subjects. I then explain that this account fails to adequately attend to the ways in which social structures can impede autonomy.

The term, social structures, is commonly used in the social sciences to refer to patterned social arrangements in society, such as people being grouped into economic classes or categorized by race, and the ways in which these arrangements influence the actions of the people who are socialized into this structure.⁶ In referring to the ways that social structures impede autonomy, I am concerned with the ways in which people's

⁵ Jagger 1983; Sandel 1998.

⁶ Abercrombie 2000, 326–327.

membership in an oppressed group in society, such as being a member of an oppressed race, class, gender, sexuality, or disability, affects both the beliefs and autonomy skills they may have and the restraints that they may encounter in society when trying to put their autonomous choices into action. Although there are numerous types of oppressed groups within society, I oftentimes shorten the list to include race, class and gender. This by no means implies that these are the only oppressed groups within society with which we should be concerned.

In addressing social structures, I categorize the ways that social structures impede autonomy into two general categories, internal and external restraints. Internal restraints deal with the ways in which oppressive socialization can impede autonomy, such as when a person has been raised to adopt common societal beliefs about members of her race and uses these beliefs to make choices that further perpetuate her oppression. External restraints deal with restraints that an individual encounters when trying to put her choices into practice in society. These restraints exist out in the world, so to speak. Being unable to exercise one's autonomous choices due to racist practices in society is an example of an external restraint that arises from social structures.

It is important to note that the negative impact of social structures is at play in most, if not all, cases in which people make autonomous choices. Hence, my arguments regarding the ways in which social structures impede autonomy have implications beyond the research context and extend to other contexts in which people make autonomous personal choices, such as decisions regarding medical treatment. This is another thing the reader should keep in mind. In the chapters that follow, I focus on the ways that involving community in the informed consent process in medical research on

human subjects oftentimes magnifies the extent to which social structures impede subjects' autonomy.

In examining the three general accounts of autonomy, the traditional, embedded and relational accounts, I conclude that only relational accounts of autonomy adequately attend to the internal and external restraints to autonomy. Because the current philosophical foundation for informed consent is the traditional account of autonomy, I conclude we should revise the current philosophical foundation to rely on a relational account of autonomy. Once we revise the philosophical foundation, I explain how we also need to revise current informed consent guidelines for research on human subjects to reflect this change.

1.1 Situating My Arguments Within the Literature

Before providing an overview of the chapters, it is helpful for me to clarify where my arguments lie within the current literature. First, I explain how my arguments differ from those within the philosophical literature on respect for autonomy as it relates to informed consent in the medical context. Next, I explain where my work fits with regards to the various areas within philosophy.

1.1.1 How My Arguments Differ From Other Arguments Regarding Autonomy and Informed Consent

It is important to situate my argument within the current literature on informed consent and autonomy in order to clarify what I hope to accomplish. I am not the first to address the principle of respect for autonomy on which current informed consent guidelines rest. Some have objected to the reliance on a singular philosophical foundation for guiding ethical behavior in the medical context. For example, Beauchamp and

Childress have argued that we should combine multiple principles; in addition to the principle of respect for autonomy, we also should rely on the principles of justice, beneficence, and nonmaleficence.⁷ Others have argued that we should continue to rely on the singular philosophical foundation, but we should drastically revise what we mean by autonomy. Joan Tronto argues for revising the current account of autonomy, which she refers to as consent-as-autonomy, to a revised account of autonomy that focuses on the authority that medical professionals have, an account she calls consent-as-authority.⁸ Lastly, some have argued against relying on the principle of autonomy at all. Neil C. Manson and Onora O’Neill argue that we should forgo relying on respect for autonomy as the foundation for informed consent and, instead, think of informed consent as a communicative process that should be guided by various epistemic and ethical norms about communication.⁹

In comparison to these approaches, I have chosen to examine what changes we can make to the current framework of having the principle of autonomy as the philosophical foundation for informed consent guidelines on international research on human subjects. My reason for choosing to slightly revise the current philosophical foundation rather than drastically change it is a modest one. I believe that it is easier to work within a current framework whenever possible rather than attempting to drastically change it. Because my proposed solution entails slight modifications to the current foundation and guidelines as a means of remedying the problems that the current foundation fails to address, I believe my solution is feasible.

⁷ Beauchamp and Childress 2009 (sixth edition).

⁸ Tronto 2009.

⁹ Manson and O’Neil 2007.

1.1.2 Situating My Work in the Philosophical Literature in General

Recall that I mentioned that social structures impede autonomy in two primary ways, what I have referred to as internally and externally. In attending to internal and external restraints, I bridge aspects of political philosophy and philosophical psychology. Traditionally, political philosophy has focused on how social structures result in external restraints that impede a person's ability to exercise his or her choices. For example, political philosophers may be concerned that a woman is unable to exercise choices that reflect her beliefs and values due to unjustly limited options that result from sexist practices within society.

In comparison, philosophical psychology is concerned with how a person internally formulates his or her choices. A philosophical psychologist might be concerned that a person has adopted beliefs that stand in the way of his being able to formulate choices that are self-governed. For example, someone who was abused as a child might mistakenly believe that abuse is acceptable and, consequently, chooses to have abusive relationships.

In examining the extent to which a research subject's choices are self-governed, I believe it is important to look at both internal and external restraints. The ways in which external restraints limit autonomy oftentimes are more apparent. For example, racist practices within society that unjustly limit a person's ability to exercise his choices may be visible. Sometimes, however, a person's autonomy is limited even when there are no apparent external restraints. Consider a case in which a research subject encounters no external restraints to exercising her choices; there are no racist or sexist practices that unjustly limit her options, for example. Despite the lack of external restraints, she may

still encounter internal restraints to making an autonomous choice. She might have been socialized not to be assertive and not to value her own needs as much as others. As a result, she might make choices that reinforce her oppression. As this case illustrates, I believe we have good reason to question the extent to which her choices are self-governed ones.

1.2 Internalized Oppression and Adaptive Preferences

In speaking of internalized oppression, some might be reminded of adaptive preferences. Adaptive preferences, which are also sometimes called deformed desires, refer to preferences that people from oppressed groups formulate as a result of their oppressive socialization. The idea is that, if an individual were removed from the social context in which she is oppressed, she would see how her preferences further oppress her. As a result, she would no longer have these preferences.

The concern is that adaptive preferences are not autonomously chosen and, therefore, impede a person's ability to flourish in society. For example, some have insisted that women's preference to not pursue intellectual careers stems from the deformed desire that results from their being indoctrinated to believing that women are best suited for domestic work.¹⁰ Notably, both internalized oppression and adaptive preferences highlight concerns over the ways in which oppressive socialization can result in internal restraints to one's ability to make self-governed choices.

In the chapters that follow, I have chosen to use the term, "internalized oppression". Simply put, I believe this term more fully captures the harmful effects that arise when one relies on oppressive beliefs in formulating one's choices. However, the

¹⁰ Bartky 1990; Nussbaum 1999.

reader can read this as also referring to adaptive preferences that impede one's ability to make self-governed personal choices.

1.3 Internalized Oppression and Privileged Groups

Prior to proceeding, allow me to make a clarification with regards to internalized oppression. Although people from privileged groups in society might also formulate choices based on mistaken beliefs that arise from their socialization, this does not amount to internalized oppression. Internalized oppression refers to the idea that mistakenly adopted beliefs result in desires and choices that reinforce the position of lesser power that people from oppressed groups have within society.

To illustrate how persons from privileged groups in society who adopt mistaken societal beliefs do not suffer internalized oppression, consider the following two examples. First, consider the parable from the Bible in which the privileged man thanks God for his privilege and for not having been born like those who have less.¹¹ Although the privileged man operates under the mistaken belief that he is a far better person than others, his belief does not detract from his position of power within society.

In the previous example, the person from the privileged group in society does not suffer as a result of his mistaken belief. However, people from privileged groups can adopt mistaken beliefs that result from how they have been socialized as a member of a specific race, class, or gender that do lead to suffering. Yet, this suffering does not amount to decreasing the power they have in society. Consider the second example of a privileged individual who adopts mistaken societal beliefs. A father might adopt the mistaken belief that he should devote his time to working to make money rather than

¹¹ My thanks to Alison Jaggar for this example.

spend time with his children.¹² Although he suffers by having missed out on spending time with his children, his suffering does not decrease his position of power within society.

1.4 Internal Restraints and Ethical Guidelines

Having insisted that we should attend to the internal as well as the external restraints on autonomy, I must clarify a concern that I have with regards to my arguments and the current informed consent guidelines. I insist that we should be concerned with internal restraints on autonomy that can arise if one is a member of an oppressed group within society. Because internalized restraints are difficult to identify, some might wish to err on the side of caution, so to speak, and assume that members of oppressed groups are unable to provide valid consent due to these restraints. This is problematic. Denying those who are already among the more vulnerable in society the right to make choices that pertain to their well-being adds to their oppression.¹³ Instead, we must strike a delicate balance between acknowledging the problem of internal restraints and being careful not to deny those who are at risk of suffering from these restraints the ability to exercise their choices.

In response to this problem, we can glean a lesson from what I believe are the most progressive informed consent guidelines for research on human subjects,¹⁴ the Council for International Organizations of Medical Sciences (CIOMS) *International Ethical*

¹² My thanks to David Boonin for this example.

¹³ For arguments regarding how oppression results in decreased autonomy, refer to McLeod and Sherwin 2000. For arguments regarding how oppressed people continue to make autonomous choices, even in the face of oppression, see Narayan 2001.

¹⁴ To understand why I believe the CIOMS Guidelines are the most progressive, refer to Chapter 9: Current Guidelines.

Guidelines for Biomedical Research Involving Human Subjects.¹⁵ As I explain in Chapter 9, the CIOMS Guidelines are the only guidelines that mention internal restraints that can arise from social structures, although they do not use the term, “internal restraints”. According to Guideline 16, researchers should take special care to promote women’s autonomy in the informed consent process due to concerns over their being socialized to not be assertive, to submit to authority, and to tolerate pain and suffering.¹⁶ The CIOMS Guidelines direct researchers to more carefully attend to promoting women’s autonomy due to the possibility of internal restraints. At the same time, however, they do not assume that women lack the requisite skills for providing valid consent. I build on this approach, in Chapter 10, where I argue for providing subjects from vulnerable populations the option to participate in support groups that can assist them in identifying and remedying the internal restraints that can arise from social structures, while at the same time not presuming that vulnerable people cannot provide valid consent.

1.5 Community

Since I refer to community throughout my dissertation, allow me to indicate what I mean by community. Because providing the necessary and sufficient conditions for what constitutes a community would comprise a dissertation in itself, I have opted to provide the reader with an idea of what I mean by community by laying out certain parameters. First, community is not analogous to community leaders. Instead, community must include appropriate representation of its various members. For example, in Chapter 6, I discuss community involvement in the decision-making process as it relates to

¹⁵ CIOMS 2002.

¹⁶ CIOMS 2002, Guideline 16.

research. In doing so, I argue that we should include those who are more directly affected by the research. So as to ensure that oppressed groups within society have a role in the decision-making process, I also argue for including members from oppressed groups based on ethnicity, race, class, gender, sexuality, and disability.

Because much of my discussion regarding community focuses on the ways in which involving community can impede subjects' ability to make self-governed choices regarding research participation, some might focus on the negative aspects of community involvement. It is important to note that community can both enhance and impede autonomy. In my discussion of relational accounts of autonomy, I emphasize the ways in which people's essential characteristics, their identities, beliefs, and values, are constituted to some degree by their relationships to others. This illustrates how community provides an important aspect of people's identity. Community is also the framework in which people develop and get a chance to exercise and refine many of their autonomy skills. Admittedly, much of my focus is on how community impedes autonomy; this is due to the larger context of focusing on revising current informed consent guidelines for international research that are meant to protect human subjects. Nonetheless, I hope that my focus does not cause the reader to lose sight of the benefits of community.

1.6 Autonomy and Informed Consent

Prior to presenting the chapter summaries, it is necessary for me to make a clarification with regards to my overall project. In arguing that we need to revise the account of autonomy that serves as the philosophical foundation for current international guidelines for informed consent in research on human subjects, I examine autonomy and

its relation to informed consent. Although I draw on the relationship between autonomy and informed consent, it is important to note that informed consent and autonomy are not necessarily related. Informed consent refers to making a voluntary and informed decision to participate in research. Autonomy refers to making a choice that is self-governed, meaning that it reflects a person's identity, beliefs, and values as these relate to what is in his best interest. Obligations to obtain subjects' informed consent need not be motivated by respect for autonomy. For example, they could be motivated by legal concerns. However, informed consent is motivated by respect for autonomy in the current guidelines for informed consent in research on human subjects. In this context, the proclaimed reason for requiring that subjects provide voluntary and informed consent to participate in research is to ensure that their decision is autonomous.¹⁷ Consequently, within the context of these guidelines, autonomy has come to normatively frame informed consent requirements. It is this normative relationship that I draw on in arguing that, if we are serious about respecting autonomy, we must make changes to informed consent guidelines.

1.7 Chapter Summaries

Although I draw on the relationship between autonomy and informed consent, it is helpful to think of this dissertation as consisting of two parts. Chapters 2 through 6 deal primarily with autonomy, while Chapters 7 through 10 focus more on informed consent.

In Chapter 2: Autonomy and the Traditional Account, I provide background information for understanding my arguments regarding autonomy. Chapter 2 consists of

¹⁷ The Belmont Report 1979, Part B:1; CIOMS Ethical Guidelines 2002, Introduction; UNESCO Declaration on Bioethics and Human Rights 2005, Article 5.

three parts. I begin the chapter by providing a general definition of autonomy. This gives us the necessary conditions for all theories of autonomy, providing us with a list for better understanding the various general accounts of autonomy that I address in Chapters 2 through 4. I also explain the purpose behind an autonomy theory. This provides us with a measure by which to gauge how well each general account of autonomy fares.

After addressing autonomy in general, I explain my categorization of theories of autonomy into what I call general accounts of personal autonomy. These accounts differ based on the account of the person that informs each. Addressing autonomy theories in this general form helps highlight how accounts of the person inform and sometimes limit autonomy theories.

To illustrate how an account of the person informs a general account of autonomy, I end the chapter by introducing the most common general account of autonomy, the traditional account. Because I believe that there have been many misinterpretations of this account, I focus on the primary tenant underlying the traditional account. It is not until I have introduced the remaining two accounts and have arrived at a set of strong objections to the traditional account (Chapter 3) that I provide a more detailed analysis of the traditional account (Chapter 4). I believe this provides a more concise interpretation of the traditional account.

Having introduced the notion of the traditional account of autonomy, I present the remaining two general accounts in Chapter 3: Embedded and Relational Accounts. Those who espouse an embedded account insist that respect for autonomy is justified by its coherence with community beliefs, values, and practices. I argue that we should reject this account. First, when a person belongs to multiple communities whose values conflict,

it is unclear which community values determine whether to respect individual autonomy. Second, even in cases in which we can identify the community values that deal with respect for autonomy, we should be concerned that community values might trump respect for individual choice. Since research subjects are the ones most directly impacted by medical research, their individual choice must always trump community values when these conflict.

In presenting the relational account, I expand on the reasons for requiring an account of autonomy to attend to the ways in which dependency and differences in race, class, and gender might impede autonomy. I end the chapter with two primary conclusions. First, the relational account is better than the embedded one. Second, the relational account helps us understand why an account of autonomy should acknowledge dependency and attend to differences in race, class, and gender, or what I call social structures.

Building on the second conclusion from Chapter 3, I devote Chapter 4: Traditional Autonomy Theorists Respond to an analysis of how well traditional accounts attend to the problems of dependency and social structures. My method in this chapter is to examine three contemporary theories in the autonomy literature: those by Beauchamp and Childress, by Thomas Hill, and by Gerald Dworkin. I do so with two goals in mind. My first goal is to illustrate how to identify a theory as either traditional or relational. In analyzing these contemporary theories, I conclude that Dworkin's is relational, while Hill's and Beauchamp and Childress' are traditional. This helps the reader better understand the important differences between traditional and relational accounts of autonomy.

My second goal in Chapter 4 is to examine the extent to which traditional accounts of autonomy make conceptual room for attending to the problems of dependency and social structures. I consider a general account of autonomy to leave conceptual room for something if doing so is consistent with the aspects of the account of the person that informs the general account. For example, if the account of the person claims that people's identities, values, and beliefs can be isolated from their social context, then it would be inconsistent for this account to claim that people's social context can affect the way that they internally structure their values and identities.

In examining the accounts by Beauchamp and Childress and by Hill, I explain how traditional accounts attend to the first problem, dependency. However, they fail to attend adequately to the second problem, social structures. I explain that the underlying problem is the traditional autonomy theorists' reliance on the account of the atomistic individual, which prevents them from acknowledging the internal restraints that arise from social structures.

Having explained how traditional accounts of autonomy are unable to adequately attend to the ways in which social structures impede autonomy, I draw the further conclusion that we should reject traditional accounts. Instead, based on my arguments in Chapter 3, where I explained how relational accounts of autonomy attend to these problems, relational accounts are the best general accounts of autonomy.

In Chapter 5: Relational Autonomy in the Context of International Research on Human Subjects, I expand on my arguments from the previous chapter in order to illustrate how a relational account of autonomy is the best account when it comes to international research on human subjects. I present two primary arguments in support of

this conclusion. First, I explain how a relational account of autonomy is more globally applicable by illustrating how it best acknowledges and respects an account of the person that is popular in Africa, where much research is done in response to the AIDS epidemic there. Second, I present examples of how social structures impede autonomy in the context of international research on human subjects. Dependency due to illness, differences in class, differences in gender, and the Western framework of mistakenly assuming that informed consent is a contract between two fairly equally positioned people are all examples of how social structures can impede autonomy in the informed consent process in international research on human subjects. Because only a relational account of autonomy adequately attends to these problems, I conclude that it is the best account in this research context.

Having provided arguments in support of a relational account of autonomy, I devote Chapter 6: Ethical Conditions for Respecting Autonomy to arriving at a minimal set of ethical conditions for best ensuring respect for relational autonomy in the research setting. Because I eventually use these conditions as a framework for structuring amendments to current informed consent guidelines in international research on human subjects, I have intentionally aimed at presenting a set of minimally sufficient conditions. Doing so provides the flexibility for adapting these guidelines to differing cultural contexts.

I begin the chapter by explaining how we might construct an ethical condition directed towards what I pointed out in Chapter 2 is a universal requirement for autonomy: critical reflection of one's beliefs, values, and choices. I then examine ethical conditions that others have recommended that attend to problems with how social structures impede

autonomy. In cases in which others have proposed an ethical condition in other medical contexts, I examine the extent to which the ethical condition might be applicable to the research context. I conclude that providing support systems and having subjects and community participate in various stages of the research process are two ethical conditions that others have suggested that can be useful in addressing problems that arise from differences in race, class, gender, and disability.

I then examine whether any of the three ethical conditions, critical reflection, support, and participation, are singularly sufficient for ensuring subjects' autonomy with regard to providing informed consent. After concluding that none is adequate by itself, I examine whether combining these conditions adequately ensures respect for autonomy in informed consent in research. In doing so, I argue that a combination is still inadequate. We need to add an external monitoring system and a safeguard for prioritizing subjects' choices. Adding these conditions results in a list of five minimally sufficient ethical conditions for best ensuring subjects' autonomous decision-making in research on human subjects: critical reflection, support mechanisms, participation, external monitoring system, and prioritizing subjects' choices. I return to this list in Chapter 10, where I illustrate how these can inform changes to current informed consent guidelines.

Having focused on autonomy in Chapters 2 through 6, I bring in the concept of informed consent and its relation to autonomy in Chapter 7: Informed Consent & Autonomy. In this chapter, I conclude that we have good reason to maintain the connection between autonomy and informed consent once we realize that respect for relational autonomy overcomes the problems that previous attempts to justify informed

consent with the standard, or what I have been calling the traditional, autonomy account encounter.

I begin Chapter 7 by providing a brief history of informed consent in the medical context, explaining how informed consent has come to rest on the principle of respect for autonomy within the context of research on human subjects. Although I do not intend to provide a thorough defense of this relationship, I strengthen my arguments regarding the benefits of relying on a relational account of autonomy in the context of informed consent guidelines for research on human subjects by addressing what I believe are two of the strongest objections against relying on the principle of autonomy to justify informed consent.

The first objection I address is by Neil C. Manson and Onora O’Neill, who insist that relying on autonomy to justify informed consent justifies too much in some regards and too little in others.¹⁸ I explain how their objections rest on a mistaken assumption about what it means for the principle of autonomy to justify informed consent. The second objection I examine is by Joan Tronto.¹⁹ She argues that the reliance on the principle of autonomy as justifying informed consent results in our structuring informed consent so that it overlooks the ways that social injustices and disparate power impede a person’s ability to make a self-governed decision about medical care or research participation. I explain how revising our account of autonomy to reflect a relational account remedies these problems.

To further illustrate the benefits of relying on relational autonomy, I devote Chapter 8: Addressing Alternative Solutions to analyzing the feasibility of other possible

¹⁸ Manson and O’Neil 2007.

¹⁹ Tronto 2009.

solutions to structuring informed consent so that it is still aimed at ensuring that people make self-governed choices regarding medical treatment and research participation but does not rely on the traditional principle of autonomy to accomplish this. My purpose of this chapter is not to examine all of the arguments for possible alternative accounts of informed consent that are aimed at ensuring that subjects make autonomous choices. Instead, my aim is to strengthen my conclusion that we should rely on a relational autonomy account to inform how we structure informed consent. To do so, I examine two of the more recently proposed alternative accounts of how to structure informed consent, those by Manson and O'Neill (2007) and by Tronto (2009).²⁰ Due to insurmountable problems that I believe each account encounters and due to the fact that a relational informed consent account overcomes these problems, I conclude that relying on a relational autonomy account to guide us in how we structure the informed consent process provides a better solution.

I devote Chapter 9: Current Informed Consent Guidelines to an analysis of the current informed consent guidelines for international research on human subjects. I examine these guidelines to determine on which general account of autonomy each relies. In doing so, I conclude that none of the current international guidelines for informed consent in research on human subjects adequately attends to the problems arising from social structures. I explain how this illustrates the failure of current guidelines to adequately respect a relational account of autonomy.

²⁰ Because I only address two proposals, I am not implying that my arguments lead to the conclusion that relational autonomy is the only feasible solution for providing a philosophical foundation that aptly justifies and informs how we think of informed consent.

Because I am concerned with how current policy guides researchers' conduct in obtaining informed consent, I address guidelines that carry some force, whether this is as the master document that guides other guidelines (i.e., *Declaration of Helsinki*) or as an enforceable guideline (i.e., *Federal Code of Regulations*). With this in mind, I address the following guidelines: *Declaration of Helsinki*; *Belmont Report*; the Council for International Organizations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*; the United States Department of Health and Human Services (HHS) *Code of Federal Regulations*; and the United Nations Educational, Scientific and Cultural Organization (UNESCO) *Universal Declaration on Bioethics and Human Rights*. In examining these guidelines, I insist that many rely on a traditional account of autonomy. However, the more progressive ones rely on a relational account. As I explain, even the most progressive document, the CIOMS Ethical Guidelines, requires revisions in order to better ensure subjects' autonomous decision-making in the research context.

In Chapter 10: Revisions to Informed Consent Guidelines, I propose amendments to the current guidelines for better ensuring respect for relational autonomy as it relates to informed consent in research on human subjects. Drawing on the set of ethical conditions I arrived at in Chapter 6, I explain how these can be translated into specific guidelines. To illustrate, I map these changes onto the most progressive guidelines, the CIOMS Guidelines, to show how we can improve these guidelines to better attend to cross-cultural differences regarding community value and the problems that can arise from differences in race, class, gender, and disability, especially when we include community in informed consent.

Chapter 2: Autonomy & the Traditional Autonomy Account

In this chapter, I provide background information for understanding the general accounts of autonomy. There are three parts to this chapter. In the first part, I introduce the notion of autonomy. I provide a general definition of autonomy, including laying out the necessary conditions for all accounts of autonomy. I then clarify the purpose of a theory of autonomy. This will help the reader better understand how the general accounts of autonomy fit the more general definition of theories of autonomy.

In the second part, I explain my categorization of theories of autonomy into what I call general accounts. As I explain, I categorize theories of autonomy into general accounts based on the account of the person that informs them.

In the final part of the chapter, I illustrate how accounts of the person inform general accounts of autonomy by briefly explaining the general account of autonomy that is most common in the philosophical literature, what I am calling the traditional account. This sets the stage for presenting the remaining two general accounts, the embedded and relational accounts, which rest on accounts of the person that were responses to the atomistic account of the person. I address these two accounts in the next chapter.

2.1 Distinctions

Before presenting a general definition of autonomy, it is important for me to attend to a few distinctions in the autonomy literature. In the first two subsections, I explain two types of distinctions that come into play in my discussion of autonomy: the distinction between moral and personal autonomy and the distinction between political and personal autonomy. In the third subsection, I briefly attend to a distinction that has become popular in the autonomy literature but which is not directly related to my focus,

the distinction between procedural and substantive theories of autonomy. I do so because of the popularity of this distinction and to provide the reader with a general idea of where my proposed solutions fall within this distinction.

2.1.1 Personal vs. Moral Autonomy

Philosophers draw a distinction between moral and personal autonomy.¹ Moral autonomy refers to one's ability to formulate and follow the objective moral law. For example, treating others with respect is objectively morally good; regardless of the time and place, all people deserve a minimal level of respect. One who has moral autonomy both recognizes and follows this moral law.

Personal or individual autonomy deals with an individual's ability to make self-governed choices regarding how to act and live her life that will add to her overall well-being. As Joseph Raz explains, "The ideal of personal autonomy is the vision of people controlling, to some degree, their own destiny, fashioning it through successive decisions throughout their lives."² An example of personal autonomy is the career choice that a person makes.

Some of the choices that an individual makes that deal with living what she believes is a good life are also moral choices. For example, one might think that treating others with respect is part of a good life. Yet, not all personal choices relate to the objective moral law. An individual's decision to participate in a research trial is a personal choice that deals with personal autonomy but not moral autonomy. Since I am

¹ Christman 2009, 1-3.

² Raz 1986, 369.

concerned with research subjects' choices regarding research participation, my focus is on personal and not moral autonomy.

2.1.2 Personal vs. Political Autonomy

Another distinction that comes into play in my discussion of autonomy is between political and personal autonomy. Because I draw lessons from political philosophy, it is important for me to clarify that my overall concern is with personal and not political autonomy. Political autonomy deals with the extent to which people are able to make self-governed decisions in the political sphere. For example, those who have political autonomy are able to participate in constructing political policies and in providing social criticism.³ In contrast, recall that personal autonomy deals with choices that a person makes with regards to his personal life.

Notably, limitations to people's political autonomy can bear on their personal autonomy. For example, a couple might wish to have a family but may be unable to do so due to current laws that bar homosexuals from adopting children. Although political and personal autonomy may be causally interrelated, we can distinguish between the two. As I have mentioned, my focus is on personal autonomy as it relates to a person's choices regarding research participation.⁴

³ *Ibid*, 3.

⁴ The reader should not confuse my focus on international informed consent guidelines as indicating that I am also concerned with political philosophy. I do not attend to the question of whether and to what extent such guidelines are justified, which is a question for political philosophy. Instead, my arguments are situated within the already existent structure of having these guidelines in place.

2.1.3 Substantive vs. Procedural Theories of Autonomy

A distinction that has become popular in the autonomy literature is between procedural and substantive theories.⁵ Procedural autonomy theorists focus on the process of critical reflection that a person uses in making her choices rather than on the content of her choices. For example, Harry Frankfurt presents a procedural autonomy theory in “Freedom of the Will and the Concept of a Person”.⁶ He insists that autonomy consists of aligning one’s first-order desires, the desires from which one makes a particular choice, with one’s second-order desires, or those desires that reflect one’s true self or the desires with which one identifies. Suppose, for example, that an individual identifies herself as a health-conscious individual; she has the second-order desire to be healthy. To ensure that her choices are self-governed or stem from her true self, she would critically reflect on them to make sure that they aligned with her second-order desire to be health-conscious. In doing so, she would choose to eat a healthy diet and exercise regularly.

In addition to focusing on the critical reflection process, substantive autonomy theorists argue that we also must consider the content of a person’s choices to determine whether her choices are autonomous. Some argue for restraints on the content of people’s choices, which is called strong substantive autonomy. Susan Wolf presents a strong substantive autonomy theory. She insists that the content of autonomous choices must reflect that the chooser is able to distinguish right from wrong.⁷ A son who merely mimics the choices that his tyrannous father makes and has not been raised to realize that these are wrong does not choose autonomously.

⁵ Chrisman 2009, 5; Mackenzie and Stoljar 2000, 12-21.

⁶ Frankfurt 1971.

⁷ Wolf 1987.

Substantive autonomy theories also can take the form of weak substantive accounts. Those who espouse weak substantive autonomy theories argue for restrictions to the process that are meant to narrow the possible content of people's choices. Many weak substantive autonomy theories take the form of insisting that the content of a person's choices must reflect certain capacities in order to be considered autonomous. For example, Trudy Govier argues that a person's choices must reflect self-worth.⁸

A discussion of whether a procedural or substantive approach to autonomy is best is beyond the scope of this dissertation. Nonetheless, because this distinction has gained popularity in the autonomy literature, it is worth pointing out that my arguments amount to weak substantive autonomy. Recall that, in addition to focusing on the process of critical reflection, weak substantive autonomy theories also focus on the capacities that a person has that affect the content of her choices. In Chapter 10, I present specific amendments to current informed consent guidelines for international research on human subjects that focus on the critical reflection process by providing questions that subjects, community members and researchers should ask themselves to better ensure critical reflection. In addition to focusing on the critical reflection process, I also focus on the relationship between capacities and the content of people's choices. As will become apparent in my discussion of oppressive socialization in Chapter 3, I am concerned with the ways in which a person is socialized as a member of an oppressed race, class, gender, etc. that can impede autonomy. I point out that oppressive socialization can result in decreased autonomy capacities, such as self-worth, and can result in people making choices that further perpetuate their oppression, which I refer to as internalized

⁸ Govier 1993.

oppression. In Chapter 10, I present amendments to current informed consent guidelines that are intended to address these problems. For example, I insist that subjects should be offered the opportunity to participate in support groups that are directed towards identifying internalized oppressive beliefs and towards further developing requisite autonomy skills, such as self-worth and self-assertion.

2.2 General Definition of Autonomy

Having clarified that my focus is on personal autonomy and not moral or political autonomy, one might wonder what is meant by personal autonomy. In general, personal autonomy refers to self-rule or a person's ability to formulate and exercise choices that reflect her values and beliefs. Thomas L. Beauchamp and James F. Childress point out that there are two necessary conditions for personal autonomy: (1) agency, or the capacity for intentional action; and (2) liberty, or independence from controlling influences.⁹ I would add that theorists also agree on a third necessary condition, critical reflection, or the need for an individual to critically reflect on his choices to determine whether they reflect his values and beliefs or whether they result from something else, such as manipulation or coercion. Although theorists agree that these three conditions are necessary, they disagree regarding whether they are sufficient. Some argue for additional conditions. In addition, theorists differ in the way that each defines the three necessary conditions.¹⁰

⁹ Beauchamp and Childress 2009 (sixth edition), 100.

¹⁰ Most (if not all) theories on autonomy concede that perfect autonomy is an unrealistic expectation. Instead, a more realistic account of autonomy grants that autonomy occurs along a spectrum.

In my explanation of each general account of personal autonomy, I will explain how each interprets these three necessary conditions for autonomy. My reason for doing so is two-fold. First, it illustrates how the general accounts of personal autonomy fall within the current parameters of discussions of autonomy. Second, how each account addresses these conditions illustrates important differences between them.

In explaining how each account interprets the three necessary conditions for autonomy, I focus on how each addresses the second necessary condition of autonomy, controlling influences. Specifically, I am concerned with what each account considers to be controlling influences by others. Thus, in presenting each of the general accounts, I explain how each would generally interpret this condition for autonomy.

As will become apparent in my discussion of the three general accounts in this and the following two chapters, some of the differences in how theorists specify the conditions for autonomy depend on what they believe about agents or those who are capable of making autonomous choices. These beliefs are reflected in accounts of the person. Accounts of the person provide descriptive facts about those who have personhood, the necessary and sufficient capacities for moral agency. These descriptive facts, in turn, inform ideas about how people can and should formulate and exercise their self-governed or autonomous choices. For example, one might believe that people are capable of isolating their interests, beliefs, identities, and values from social context, or their relations to others. One might also believe that others' influences taint people's ability to formulate self-governed choices. Based on these ideas about the person, it follows that one of the requisites for autonomy will be that people must isolate their identities, beliefs and values from others' influences when making autonomous choices.

2.3 The Purpose of a Theory of Autonomy

It is helpful to explain the purpose of a theory of autonomy, as this provides a measure against which to judge the general accounts of autonomy in the proceeding chapters.¹¹ Simply put, a theory of autonomy spells out the necessary and sufficient conditions for determining whether someone has acted freely, or in accordance with a self-chosen or self-governed plan.¹²

In defining autonomy, some theorists focus on the necessary and sufficient conditions, or capacities, that an individual must have in order to be autonomous. However, focusing on the autonomous person overlooks instances in which those who have the requisite self-governing capacities for acting autonomously fail to do so.¹³ For example, an individual who does not bother to read a consent form prior to signing it may have the capacity to act autonomously but does not exercise this capacity.¹⁴

Moreover, focusing on the autonomous person fails to identify cases in which those who generally lack the necessary and sufficient conditions to be considered as an autonomous person are able to make some self-governed decisions. For example, prisoners constitute a population that is not autonomous due to their physical

¹¹ In this chapter, I am concerned with addressing theories of autonomy in general. As will become apparent in my discussion of the principle of autonomy as it relates to informed consent in Chapter 7, the purpose of a theory of autonomy can take on a more specified role when it is used to provide the philosophical foundation for informed consent guidelines. As the philosophical foundation for informed consent guidelines, the principle of autonomy both justifies our reasons for requiring informed consent and guides us in how we structure informed consent.

¹² Beauchamp and Childress (sixth edition) 2009, 99.

¹³ For example, see Beauchamp and Childress 2009, 100. For arguments regarding how those who are oppressed can make autonomous decisions, see Narayan 2001.

¹⁴ Beauchamp and Childress 2009, 100.

confinement. Nonetheless, they are able to make autonomous or self-governed choices, such as deciding whether to participate in medical research. Similarly, people who suffer from dementia fail to consistently exhibit the mental capabilities required for autonomy. Despite their dementia, however, many are able to make self-governed decisions some of the time, such as deciding what foods they wish to eat or what time they wish to go to sleep.

Because the purpose of a theory of autonomy is to identify when people act from a self-governed standpoint, autonomy theories should focus on the necessary and sufficient conditions for making an autonomous choice rather than on the necessary and sufficient conditions for what constitutes an autonomous person. Autonomous choice requires certain mental capacities for being able to formulate self-governed choices, or choices that reflect one's values and beliefs about what is in one's best interest.

In focusing on autonomous choice, it is necessary to realize that it does little good to be able to make self-governed choices if a person cannot exercise her choices in the world. Thus, in addition to considering people's capabilities for formulating autonomous choices, a theory of autonomy also should consider the ways in which an individual's social context affects her ability to exercise her choices. This aspect will become more apparent in my discussion in Chapter 3 regarding the ways in which oppressive socialization and external restraints arising from social structures impede a person's ability to exercise autonomous choices in the world.

Throughout this dissertation, I often refer to making autonomous choices. However, sometimes for the sake of brevity, I simply refer to the ability to make an autonomous choice as autonomy. It should be understood that, in both cases, I am

referring to an agent's ability to make an autonomous choice.

2.4 Level of Specificity Required in Autonomy Theories

Given that the purpose of a theory of autonomy is to spell out the ways in which an individual's ability to make autonomous choices can be enhanced or impeded, the question arises regarding how specific a theory must be. A theory of autonomy need not, nor could it, list all of the things that increase or decrease a person's ability to make autonomous choices. For this reason, theorists provide general categories of what enhances autonomous choice and what impedes it. For example, having certain mental capacities enhances one's ability to make autonomous choices, while coercion and manipulation impede this ability.

The question of specificity is related to the question of how to determine when to reject a theory of autonomy. Because autonomy theories provide general categories of how autonomy can be impeded, we should not reject a theory simply because it fails to include some of the specific ways in which autonomy can be decreased. Instead, recall from Chapter 1 that I explained that the test of whether we should reject an autonomy theory is whether it makes conceptual room for attending to problems that it may have overlooked. The extent to which an autonomy theory leaves conceptual room for something is reflected by the account of the person that informs the theory. For example, if the account of the person insists that people's identities, values, and beliefs can be isolated from their social context, then it would be inconsistent for this account to claim that people's social context can affect the way that they internally structure their values and identities.¹⁵

¹⁵ In the chapters that follow, I argue that it is impossible for traditional accounts of

Having clarified the specificity required for autonomy theories and the measure for when we should reject an autonomy theory, I am now in a position to discuss what I call general accounts of personal autonomy. After briefly explaining how I have categorized theories of autonomy into general accounts, I present the most common general account, the traditional account. In the next chapter, I address the remaining two general accounts, the embedded and relational accounts.

2.5 Categorizing Theories into General Accounts

I categorize theories of autonomy into what I call general accounts of autonomy based on the account of the person that informs each theory. Accounts of the person provide descriptive facts about those who have personhood, the necessary and sufficient capabilities for moral agency. These descriptive facts, in turn, inform ideas about how people can and should make self-governed or autonomous choices. For example, one might believe that people are capable of isolating their interests, beliefs, identities, and values from others' influences. Moreover, one might believe that others' influences taint people's ability to make self-governed choices. Based on these beliefs about the person, one would conclude that it is necessary for individuals to isolate their beliefs and values from others' influences in order for their choices to be self-governed ones.

In presenting the three general accounts of personal autonomy in this chapter and the next, I draw from accounts of the person that became popular in political philosophy. I do so for a few reasons. First, in responding to problems with liberal political theory,

autonomy to incorporate many of the ways that social structures, or differences in race, class, gender, and disability, impede autonomy. As I explain in Chapter 4, doing so is inconsistent with the account of the person that informs traditional accounts of autonomy.

communitarians and feminists critiqued the account of the atomistic person that underlies liberal political theory. Their analysis points to problems with the atomistic account of the person. Second, in response to these problems, communitarians and feminists presented different accounts of the person. Their arguments demonstrate the various accounts of the person that appear in the philosophical literature. And finally, the interpretations by liberal political theorists, communitarians, and feminists of what constitutes harmful interference by others in the political realm says something about how different accounts of the person result in different interpretations of harmful interference by others in the personal realm. Notably, because I draw from political philosophy to understand accounts of the person and how these affect interpretations of harmful interference by others, the reader should be careful to keep in mind that I am addressing personal and not political autonomy.

Prior to explaining the atomistic account of the person that arose from liberal political theory and how this has informed traditional accounts of autonomy, allow me to respond to a question that some might have at this point regarding my choice of terminology. In introducing what I call the traditional account of autonomy, some might wonder why I do not refer to accounts of autonomy that rely on the account of the person that stems from liberal political theory as liberal accounts of autonomy. I intentionally refrain from using the term liberal because it indicates a political doctrine that deals with the extent of state intervention. Although my analysis begins with the account of the person that underlies liberalism, recall that I apply the account of the atomistic person to the realm of personal autonomy. In order to distinguish between political and personal autonomy, I refer to the general account of personal autonomy that relies on the atomistic

account of the person as the traditional account rather than the liberal account. My referring to accounts of personal autonomy that rely on an atomistic account of the person as traditional accounts also is meant to highlight the popularity of such accounts in the traditional philosophical literature.

With the distinction between political and personal autonomy in the forefront of our minds, I begin my explanation of traditional accounts of autonomy by addressing the atomistic account of the person that informs these accounts. Because this account first arose in political philosophy, I begin here. I then explain how the atomistic account of the person informs the traditional account of personal autonomy. In the next chapter, I address the remaining two general accounts of personal autonomy that rest on the communitarian and Feminist accounts of the person.

2.6 The Atomistic Individual

The West is known for espousing individualism. The emphasis on individualism became so dominant in Western thought that the French sociologist, Emile Durkheim, insisted that it “functioned in much the same way as a religion”.¹⁶ When asked to picture the main character of this religion, many picture the caricature of the self-made, self-sufficient rational chooser who can and should isolate himself from others in order to make self-governed choices. For example, Iris Marion Young charges traditional theories of autonomy as “positing the self as a solid, self-sufficient unity, not defined by or in need of anything or anyone other than itself”.¹⁷ Others, such as Lorraine Code, have focused on the normative force of the Western ideal of stark self-sufficiency. As she

¹⁶ Applebaum, Lidz, and Meisel 1987, 25.

¹⁷ Young 1995, 239.

explains, the Western ideal of the autonomous man is one who “is – and should be – self-sufficient, independent, and self-reliant, a self-realizing individual who directs his efforts towards maximizing his personal gains”.¹⁸

Despite this common caricature, I believe that it is incorrect. For this reason, in what follows, I explain where the common interpretation of the atomistic individual is mistaken. In doing so, I clarify what I believe is a more accurate account. As I previously mentioned, the atomistic account of the person is derived from political theory. Hence, I begin with a brief overview of the tenants of liberal political theory as a means of deriving a more clear-cut picture of this account of the person.

2.6.1 Liberal Political Theory

The primary tenant of liberalism is respect for individual liberty, or “freedom from interference either by others or by the state”.¹⁹ Respect for individual liberty includes protecting people’s ability to decide what constitutes the good life rather than insisting that there is an account of the good to which all should adhere.²⁰ To enable people to formulate their own account of the good, liberalism advances a system of individual rights and the need for individuals to approve of any state intervention that may be necessary to protect these rights.²¹ Their prioritizing of individual interests and individual rights reflects liberal political theorists’ belief that the right is prior to the good. Individual rights take priority over and are not justified by a common account of

¹⁸ Code 1991, 78.

¹⁹ Young 1995, 174.

²⁰ For an explanation of the ways in which liberalism, in practice, departs from their commitment against positing a general account of the good, see Jaggar 1983, 174-5.

²¹ Waldron 1993, 44.

the good.²² These aspects of liberal political theory, (a) the requirement that individuals must consent to state authority, (b) the insistence that each individual, and not the state, should formulate an account of the good, and (c) the prioritizing of the right over the good, illustrate liberalism's prioritizing individuals' liberty over the authority of the state.²³

2.6.2 The Atomistic Individual

These tenants of liberalism indicate a particular account of the person. What is it about human beings that warrant prioritizing individual liberty? According to liberal political theorists, the answer is the unique human capacity for rationality. Human rationality grounds the claim that individuals are capable of consenting to state authority. Rationality also assists individuals in constructing their account of the good. Finally, the special capacity for rationality grounds distinctly human rights, such as the right to freedom of thought and conscience.

The most telling characteristic of the human capacity for rationality that is reflected in the atomistic account of the person is the idea that this capacity is not reliant on society. The idea that rationality does not rely on society rests on liberal political theorists' assertion that the person is ontologically prior to society, meaning that "logically, if not empirically, human individuals could exist outside a social context; their

²² Admittedly, this is a simplistic description of the parameters for defining the role of the state and what constitutes harm. Nonetheless, it suffices for the purpose of providing the reader with an overview of liberal political theory that will help highlight the aspects of the liberal self that come into play in my discussion of autonomy.

²³ Admittedly, this is a simplistic description of the parameters for defining the role of the state and what constitutes harm. Nonetheless, it suffices for the purpose of providing the reader with an overview of liberal political theory that will help highlight the aspects of the liberal self that come into play in my discussion of autonomy.

essential characteristics, their needs and interests, their capacities and desires, are given independently of their social context and are not created or even fundamentally altered by that context".²⁴ In other words, those who espouse an atomistic account of the person believe that society does not constitute, even in part, what it is to be a person.^{25,26} Because rationality is a defining characteristic of what it is to be a person, the insistence that a person is not constituted by society includes the claim that rationality is not reliant on society. I will refer to this idea as the self-sufficiency of rationality.

Notably, this self-sufficiency of rationality does not mean that people are capable of formulating their beliefs, values, and choices from mere nothingness. People are born into a family, community, etc. that provides them with a belief system. What defines the atomistic person is the idea that, once an individual has developed the capacity for rationality during his formative years, he is able to isolate this capacity from others' influence, using it to do such things as freely formulating his account of the good and making self-governed choices.

In addition, this self-sufficiency of rationality deals with the mental and not the physical. Those who espouse an atomistic account of the person oftentimes acknowledge that people are physically dependent on others, such as in cases of illness, disease, and disability. In Chapter 4, I provide examples of how traditional autonomy theorists, who by definition advance an atomistic account of the person, attend to the ways that physical dependency can impede autonomy.

²⁴ Jaggard 1983, 28-9.

²⁵ For discussions of the atomistic account of the person, refer to Friedman 1995, 187; Jaggard 1983, 46-7; and Taylor 1979.

²⁶ Because liberalism is oftentimes charged with conceiving of individuals as atoms that can abstract themselves from the larger whole of society, the atomistic account of the person also is referred to as the abstract individual or the abstract self.

With this in mind, we can see that the insistence that a person can isolate his essential characteristics from society amounts to insisting that a person is capable of mental self-sufficiency once he has developed the human capacity for rationality during his formative years. What I am referring to as mental self-sufficiency has two characteristics that are relevant for our present purposes. First, mental self-sufficiency means that a person is able to exercise his rationality free from his social relationships. Second, in doing so, he is able to isolate essential characteristics, or identity, beliefs, and values, from his social relationships. As will later become apparent, these characteristics have important implications for how one defines autonomous choices.

2.7 The Traditional Account of Autonomy

I believe that the same account of the person that informs liberal political theory also underlies the most common general account of autonomy that is found in the philosophical literature, an account that I have been referring to as the traditional account. My purpose in this section is to briefly introduce the traditional account of autonomy. In doing so, I describe traditional accounts in their most general form. Recall that I do not present a more concrete description of traditional accounts until Chapter 4. As I previously explained, my reason for doing so is to be able to respond to objections to the traditional account of autonomy, which I present in Chapter 3. This enables me to provide a more concise description of the atomistic account of the person than has become popular in the literature. I close this section by mapping the traditional account onto a particular case, in order to give the reader an idea of how the account works in practice.

2.7.1 Overview of the Traditional Account

The idea that a person's essential characteristics are not reliant on others influences the way that traditional autonomy theorists define self-governed choices. In insisting that a person can isolate his essential characteristics, including his identity, values, beliefs, and his ability for rationality, from others, those who espouse an atomistic account of the person believe that the self exists independently of society. If it is true that the self exists independent of others, then the most self-governed choices are those that stem from a self that is isolated from others' influences.

This is not to say that traditional autonomy theorists deny that others can negatively affect a person's autonomy. Traditional autonomy theorists acknowledge that a person's attempts to exercise his choices can be impeded by others. To understand the extent to which traditional autonomy theorists acknowledge how others can impede a person's autonomy, it is helpful to address how they define controlling influences by others. In discussing this in the next section, I draw a distinction between internal and external restraints. As I will explain, traditional autonomy theorists attend to external restraints but not to internal ones.

2.7.2 Interpreting the Three Necessary Conditions for Autonomy

To better understand the extent to which traditional autonomy theorists address restraints to autonomy, it is helpful to take a moment to attend to how they would interpret the three necessary conditions for autonomy. Recall that, in addition to critical reflection and intentionality, autonomy theorists insist that autonomy requires freedom from controlling influences. Addressing this last condition illustrates how traditional autonomy theorists attend to restraints to autonomy.

To begin, traditional autonomy theorists insist that a person must critically reflect on his beliefs and values when making an autonomous choice. Self-governed choices are not ones that an individual makes by blindly adhering to beliefs and values that he may have been indoctrinated to adopt. In addition, traditional autonomy theorists insist that self-governed choices are ones that a person intentionally formulates and carries out.

With regard to the final condition for autonomy, freedom from controlling influences, traditional autonomy theorists consider manipulation and coercion as paradigmatic cases of negative controlling influences by others. However, not all traditional theorists who provide particular instances of manipulation and coercion agree on what exemplifies these cases. Because I am examining accounts of autonomy in their most general form, I believe it suffices to address the question of what constitutes controlling influences by others as a matter of scope.

In attending to the question of scope, I divide the types of influences by others into what I call external and internal restraints. Although I present more concrete examples of these kinds of restraints in the next chapter, allow me to define these and provide a brief explanation as to why I believe traditional autonomy theorists attend to external but not internal restraints. In Chapter 4, I provide examples of how they attend only to external restraints in my examination of particular traditional autonomy theories.

Internal vs. External Restraints

In order to highlight different ways in which others can negatively impact a person's autonomy, I distinguish between external and internal restraints. External restraints are those that exist out in the world that impede a person's ability to carry out a choice that she has formulated. Although an individual may have the capabilities to

formulate a self-governed choice, or a choice that both reflects her beliefs and values and is in her best interest, she is unable to carry out her choice. For example, others might coerce her into making a choice that does not align with her values and beliefs. Or, she may be unable to exercise her choice due to sexist practices in society.

In comparison, what I am referring to as internal restraints result from how a person has been socialized due to her race, class, disability or gender. These can take the form of internalized oppressive beliefs that an individual uses to formulate choices that further her own oppression or they can take the form of not having fully developed some of the requisite skills for autonomy, such as self-assertion and self-worth. A good way to think of internal restraints is that they deal with a person's capabilities, or what she brings to the table, so to speak, when formulating a self-governed choice.

Although I refer to these restraints as internal, I do so for lack of a better word. I am aware that using the term, internal, may make the reader think of as person's mental capacities or thought process, both of which occur internally within a person. My use of the term, internal restraints, is meant to include more than the mental aspects that come into play when a person makes a self-governed choice. By internal, I wish to include the relevant aspects of a person's constitution that affect her ability to make a self-governed choice. This includes the mental aspect of her thought process, which raises concerns about whether she has internalized oppressive beliefs in making her decision. It also includes other aspects of her constitution, such as the autonomy skills she has developed as a result of her socialization. In my discussion of internal restraints, the reader should keep in mind that these extend beyond the mental realm to include other aspects of a person's constitution, which come into play when making self-governed choices.

Traditional Autonomy and External Restraints

Because traditional autonomy accounts rest on an atomistic account of the person, they only attend to external restraints. Because I do not provide examples of the particular restraints that a traditional autonomy theorist addresses until Chapter 4, I will provide a general explanation as to why reliance on the atomistic account of the person limits the scope with which theorists attend to internal restraints.

Recall that those who espouse an atomistic account of the individual insist that a person can isolate his essential characteristics from his relationships to others. I have referred to this as a kind of mental self-sufficiency. If one insists that a person has this kind of mental self-sufficiency, then he will not recognize nor attend to the ways that a person's socialization can affect the self from which one makes self-governed choices. Specifically, he will overlook how socialization based on race, class, gender, or disability can affect whether someone adopts oppressive beliefs or whether they have not fully developed some of the necessary skills for autonomy. Because I have provided a very general description of the extent to which traditional autonomy theorists address restraints to autonomy, it will help to illustrate how this account works by mapping it onto a particular case. Prior to doing so, however, it is necessary to dismiss a possible mistaken interpretation that some might have at this point with regards to traditional autonomy accounts.

2.7.3 Dismissing a Mistaken Interpretation

Recall that I previously pointed out that the common interpretation of the atomistic individual is inaccurate; liberalism does not insist that people must be completely independent. Due to the common interpretation of the atomistic individual as

starkly independent and self-sufficient, however, some might construe the account of autonomy that rests on this account of the person as asserting that individuals must be free entirely from others in order to make self-governed choices. This is incorrect. As I have explained, those who espouse an atomistic account of the person oftentimes acknowledge that people may be physically dependent on others. Recall that the defining characteristic is not that people physically isolate themselves; instead, traditional autonomy theorists insist that truly self-governed choices are ones wherein an individual has isolated their identity, values and beliefs from others' coercive or manipulative influence. This will become more apparent in the next section, wherein I illustrate how traditional autonomy theorists would interpret a particular case.

2.7.4 Applying the Traditional Account to a Particular Case

Because I do not provide a detailed analysis of specific traditional accounts of autonomy until Chapter 4, in order to help illustrate how the traditional account works, I have chosen to map it onto a particular case. To demonstrate the differences between the three general accounts of autonomy, I revisit this case in the next chapter. There I explain how proponents of the embedded and relational accounts would determine whether the person's choice is autonomous choice.

I have the following kind of scenario in mind. A terminally ill patient who has been hospitalized is faced with the decision whether or not to have her life support systems withdrawn, which would result in her more immediate death. She is emotionally at ease with her situation and is not in any pain. In other words, her illness has not diminished her ability to make an autonomous choice. She believes that it is in her best interest to end her life. An important part of her identity has been as an athlete. She has

been an avid runner for much of her adult life and had always promised herself that she did not want to prolong her life if it meant being confined to a hospital bed. At the same time, however, part of her identity is as a member of her local church community. She is active in her church and has many close friends in this community. Her church friends disagree with her wish to terminate her life, believing that life is one of God's greatest gifts to humanity. They have expressed their sadness and disappointment regarding the woman's wishes. They are not being coercive or manipulative; they are merely expressing their own desires. In considering all of these factors, the woman does not sign the requisite papers for removing her life support systems.

According to traditional autonomy theorists, the woman has made an autonomous choice. Her decision has not been impeded by external factors, such as being coerced or manipulated by others or not being able to carry out her choice due to sexism. Traditional autonomy theorists would likely view the scenario as a woman who initially felt that terminating her life would be best but, after considering other things that are important to her, like her church community, changed her mind and decided not to terminate her life.

It is important to note that traditional autonomy theorists would focus on whether there are any external restraints to autonomy. However, this is only part of the concern regarding restraints to autonomy. As will become apparent in my mapping the relational account of autonomy onto this same scenario in the next chapter, an account of autonomy must also attend to possible internal restraints to autonomy. Because the traditional account of autonomy fails to recognize internal restraints to autonomy, it does not provide us with the correct interpretation of the scenario. Thus, we need to answer questions regarding whether the woman's autonomy is impeded by internal restraints,

which include internalized oppression and not having fully developed some of the requisite skills for autonomy, before being able to correctly determine whether she has made an autonomous choice.

2.8 Conclusion

In this chapter, I introduced the notion of autonomy and presented the most popular example of a general account of autonomy. In doing so, I provided three necessary conditions for all theories of autonomy: (1) critical reflection, (2) agency, and (3) freedom from controlling influences. I also explained that the purpose of a theory of autonomy is to define what constitutes self-governed choices. In defining autonomous choices, theorists provide general categories for identifying those things that either impede or enhance autonomy.

Having introduced the reader to the notion of autonomy, I explained my categorization of autonomy theories into what I call general accounts. A general account of autonomy is defined by the account of the person that informs how a theorist defines self-governed choices. I ended the chapter by explaining how the atomistic account of the person informs the most popular general account of autonomy, what I call the traditional account, along with indicating possible shortcomings of this account.

Chapter 3: Embedded and Relational Autonomy Accounts

In this chapter, I address the remaining two general accounts of personal autonomy, the embedded and relational accounts. In the process of presenting these accounts, I argue for two conclusions. First, I argue that we should reject the embedded account of autonomy. Second, I provide good reason for favoring the relational account.

As I explain, the primary reason for preferring the relational account of autonomy is that it attends to the ways in which dependency and social structures impede autonomy. In order to conclude that relational accounts are the best, I must explain why traditional accounts fail to adequately attend to the problems relating to dependency and social structures. This is the task of the next chapter.

3.1 Clarifications

Before proceeding, allow me to make two clarifications. First, although I refer to feminists as presenting the relational account of autonomy, I by no means intend to imply that all feminists present this account. For the sake of brevity, I will refer to feminists as arguing for the relational accounts of the person and of autonomy. The reader should understand this to mean that some feminists have done so.

Second, although I refer to the account of personal autonomy that rests on the communitarian account of the embedded person as the embedded account, I do so for lack of a better term. There is a problem in relying on this term. As will become apparent, both the accounts of the embedded person and of the relational person rest on the idea that people's relationships inform their essential characteristics, such as their identities, beliefs, and values. Each agrees that people are embedded in their relationships to some inescapable degree.

Due to this similarity, some might assume that the accounts of personal autonomy that are informed by the embedded and relational accounts of the person should be similar. This is not the case. As I explain in my discussion of relational accounts, the two general accounts of personal autonomy differ with regards to the scope with which they attend to how relationships enhance or impede autonomy.

3.2 The Embedded Account of Autonomy

Having made this clarification regarding embedded accounts, I now present the embedded account of personal autonomy. I begin by explaining the embedded account of the person that underlies the embedded account of autonomy. This account of the person was a response by communitarians to problems they found with liberalism's account of the atomistic individual. Because the communitarian response was in the context of political philosophy, I explain how the embedded account of the person that stemmed from political philosophy comes into play in the embedded account of personal autonomy.

After describing the embedded account of personal autonomy, I clarify how those who espouse this account would interpret the second necessary condition for autonomy, controlling influences by others. I then illustrate how the embedded account of personal autonomy works by applying it to the scenario that I presented in the previous chapter in my discussion of the atomistic account of autonomy. In the next section, I argue why we should reject the embedded account of personal autonomy.

3.2.1 The Embedded Self

Not surprisingly, communitarians disagree with the atomistic account of the person. Contrary to the belief that people's essential characteristics are not reliant on

society, communitarians insist that people are born embedded in a society that provides them with their identities, beliefs and values. Although, as I have explained, the account of the atomistic individual makes conceptual room for acknowledging that people may be born into particular roles and belief systems, recall that the atomistic individual is able to mentally isolate his essential characteristics from his social context. Communitarians disagree and insist that people are embedded in their social contexts to the extent that they cannot isolate their essential characteristics. For example, Alasdair MacIntyre explains, “I am brother, cousin and grandson, member of this household, that village, this tribe. These are not characteristics that belong to human beings accidentally, to be stripped away in order to discover ‘the real me’.”¹ Similarly, Michael Sandel asserts:

[C]ommunity describes not just what [people] have as fellow citizens but also what they are, not a relationship they choose (as in voluntary association) but an attachment they discover, not merely an attribute but a constituent of their identity.²

This insistence that people’s essential characteristics are at least partly constituted by their membership in a community is a characteristic of communitarianism, in general. In emphasizing that people’s essential characteristics are derived from their inescapable embeddedness in society, communitarians oftentimes refer to their account of the person as the embedded self.

3.2.2 The Communitarian Account of Autonomy

Just as the atomistic account of the person stemmed from political theory, so has the communitarian account of the embedded self. With this in mind, I begin with a brief discussion of the communitarian account of political autonomy.

¹ MacIntyre 2007 (third edition), 33.

² Sandel 1998 (second edition), 150.

The difference between liberal and communitarian accounts of political autonomy can be understood better by examining differences in their approaches to the relationship between the right and the good. In insisting that individuals are able to independently formulate their own accounts of the good, liberals argue that the right is prior to the good; individuals have certain rights regardless of whether these align with and can be justified by any agreed upon account of the good. In contrast, communitarians insist that the good is prior to the right. Because they believe that individuals are inescapably born into a particular social context that provides them with an account of the good, communitarians insist that community values define what is just, including what rights individuals have.³

Oftentimes, the communitarian insistence that the good is prior to the right leads people to mistakenly conclude that communitarians valorize community values and disregard individual rights. However, this is not true. In the second edition of *Liberalism and the Limits of Justice*, Michael Sandel responds to this objection, explaining that communitarians respect individual rights. The difference between liberal and communitarian respect for individual rights lies in how they justify rights. Whereas liberals insist that rights are independently justified, communitarians assert that rights gain their moral force from “the values commonly espoused or widely shared in a particular community or tradition”.⁴ Communitarians also believe that their respect for individual rights is illustrated further by the fact that their theories make room for social criticism. As Sandel explains:

³ *Ibid*, ix-x.

⁴ *Ibid*, x.

There can be disagreement, of course, about what rights the shared understandings of a particular tradition actually support; social critics and political reformers can interpret traditions in different ways that challenge prevailing practices. But these arguments always take the form of recalling a community to itself, of appealing to ideals implicit but unrealized in a common project or tradition.⁵

Although communitarians insist that they respect individual rights, it is important to note that rights must operate within and be justified by community values, practices and traditions. Even in the case of social criticism, changes to current traditions are justified only when one can prove that the current traditions do not correctly reflect the community ideals that provided the basis for originating the practice.⁶

This last point, the ability for people to exercise social criticism, highlights what is often overlooked in communitarianism. Communitarians insist that individuals can and should critically reflect on the beliefs and values that they are born into. Even as embedded selves, individuals are able to reflect on the belief system that they have been given and decide which beliefs to retain and which to dispose of.⁷

3.2.3 The Embedded Account of Personal Autonomy

This examination of the communitarian account of political autonomy helps us understand how a general account of personal autonomy would look that is informed by

⁵ *Ibid*, x–xi.

⁶ An example of an argument justifying changes to current community practices by referring to the belief system that informs these practices is Maysam J. Al-Faruqi's argument regarding the Qu'ran and Muslim practices. According to Al-Faruqi, sexism in Muslim practices does not correctly reflect the Qu'ran. Moreover, she insists that a correct reading of the Qu'ran provides avenues for women to change these practices. (Al-Faruqi 2000)

⁷ Sandel admits that the individual is embedded to the extent that he cannot dispose of all beliefs and aspects of his identity. Rather than this being a detriment, he argues that this provides the necessary consistency of character upon which to ground one's identity and those things one values. (Sandel 1998, 180)

the embedded account of the person. As I previously mentioned, I refer to the account of personal autonomy that is informed by the embedded account of the person as the embedded account of autonomy.

There appear to be two main characteristics of the embedded account of autonomy. First, those who espouse this account insist that one who makes an autonomous choice critically reflects on aspects of his essential characteristics, such as his values and beliefs, to ensure that these stem from his self and not from blindly adopting other's beliefs and values. Second, those who believe in the embedded account of the person insist that an individual should be free to carry out his choices when respecting these choices aligns with community values.

3.2.4 Interpreting the Three Necessary Conditions for Autonomy

Recall that, in the previous chapter, I explained that there are three necessary conditions for all theories of autonomy. Here, I briefly explain how those who espouse an embedded account of personal autonomy would interpret these conditions. As I have explained, the embedded account includes the first necessary condition of critical reflection of one's identities, beliefs, and values. Since I have dismissed discussing the second necessary condition, intentionality, suffice it to say that the embedded account also requires this. That leaves us with the third necessary condition, freedom from controlling influences by others. Based on their insistence that community practices and traditions provide the justification for individual rights and social criticism, those who espouse an embedded account do not consider community practices and traditions as controlling influences that impede people's autonomy.

3.2.5 Applying the Embedded Account of Autonomy to a Particular Case

To better understand the embedded account of personal autonomy, let us examine how those who advance this account would interpret the case that I presented in the previous chapter in my discussion of the traditional account of autonomy. Recall that the case is one in which a terminally ill patient, an avid runner, believes that it is in her best interest to terminate her life support system. Her church community members disagree and have expressed their disappointment and sadness in her desire, though they have not coerced nor manipulated her. With this in mind, the woman decides to remain on life support.

In what follows, I begin by providing a simple interpretation that most might assign to those that advance the embedded account. Yet, as I later explain, interpreting whether respecting a person's choice is justified by community values turns out to be a more complicated task than one might imagine. This points to problems with the embedded account. In the next section, I explain why, even if we grant that we are able to overcome this problem, we have good reason to reject the embedded account of autonomy.

Initial Interpretation

Upon first glance, it might appear that those who espouse an embedded account of autonomy would respect the woman's choice as an autonomous one. Recall that the embedded account of personal autonomy justifies respect for autonomy based on whether doing so aligns with community values. As a member of the church community, the woman's choice to remain on life support aligns with her church community's value of not interfering with God's plan. Notably, had the woman decided to terminate her life,

her decision would not be respected, since this choice flies in the face of the community's highest value, not interfering with what they believe is Divine will.

Problems with Interpreting Community Membership

At this point, some might correctly object that it is not at all clear whose community values should define whether to respect the woman's decision since she is a member of more than one community. In addition to being a member of the church community, recall that the woman also is a member of the running community. Moreover, these communities have conflicting values with regards to terminating life support. One of the church community's highest values is not to interfere with God's plan. According to church members, terminating one's life amounts to interfering with God's plan. In contrast, the running community values the quality of a person's life, which might include terminating one's life if one will suffer a poor quality of life.

The woman's multiple community membership and the resultant conflicting values point to problems with the embedded account of personal autonomy. Recall that those who espouse an embedded account of personal autonomy insist that respect for individual autonomy is justified by how well it aligns with community values. When a person belongs to various communities whose values conflict, it is unclear to which community values we should turn to determine whether her choice should be respected.

Communitarians do not appear to address the concern that a person's identity can be constituted by multiple communities whose values might conflict. Nonetheless, the most likely communitarian response would be to insist that, in cases in which a person is a member of multiple communities, which is oftentimes the case, she prioritizes one community over the others. Thus, for example, communitarians might insist that the

woman in our previous case identifies more as a church member than as a runner (as supposedly exemplified by her final decision not to terminate her life).

Although I agree that some who belong to multiple communities most identify with a particular community above the others, I disagree that this must always be the case. I see no reason why a person's identity cannot be equally constituted by a number of communities to which she belongs. For example, the woman in our previous case may equally identify as an athlete and as a church member. She might consider it a primary part of her identity, meaning it is one of the most important aspects of herself, to be a Christian. In doing so, she embraces many of the primary tenants of the church, such as the belief that God exists, the belief that Jesus was His son, and the belief that the Bible provides general guidelines for morally good behavior. We also can imagine that she is a professional runner; as such, she considers it part of her primary identity to be a runner. In doing so, she embraces many of the primary beliefs of the running community, such as eating healthy, running on a regular basis, and valuing an active lifestyle.⁸ Once we understand the previous case in this way, it becomes apparent that, at least in some cases, a person's membership in multiple communities makes it difficult to determine which community values should determine whether her choice should be respected. This ambiguity provides us with a good reason to reject the embedded account of autonomy.

⁸ Notably, in identifying both as a Christian and as an athlete, the woman need not embrace all of the beliefs of these communities. While she embraces many of the primary tenants of each, she may disagree with some beliefs. For example, she might embrace the primary beliefs of her church community that God exists and that Jesus is His son, but she may disagree with the belief that she should not interfere with what some construe as God's plan.

3.3 Further Reason to Reject the Embedded Account of Autonomy

Notably, even if we grant that we can identify a clear cut set of community values and are able to determine whether respecting a person's choices aligns with these, we have further reason to reject an embedded account of autonomy. In asserting that respect for personal autonomy must be justified by community values and traditions, those who espouse an embedded account of autonomy fail to recognize that some traditions are oppressive. For example, consider a community value that champions the traditional family, comprised of a heterosexual man and woman joined together for the purpose of procreating. This fails to provide a basis for respecting homosexuals, polygamists, those wishing to have a poly-amorous marriage, and those not wishing to have children. Of course, those who embrace an embedded account of autonomy would not consider it problematic to have community values trump individual autonomy.⁹ Regardless of their acceptance, however, we have good reason to reject a foundation for respecting individual choice that is so exclusionary. Some choices demand that individual choice be prioritized.

This points to an additional reason to be concerned with the embedded account. Although this account does not necessarily lead to the conclusion that community values trump respect for individual choice, respect for personal autonomy is precariously perched on how well it aligns with community values. This depletes the moral force of

⁹ To overcome the problem of oppressive community values, one might suggest limiting the application of embedded autonomy to non-oppressive communities. Even if we grant that this might overcome the problem of oppressive community values, the limited scope of the embedded account makes it inapplicable in the global context of international informed consent guidelines for research on human subjects.

respect for autonomy, making it possible for community values to take priority over respect for people's self-governed choices.

3.4 The Relational Account of Autonomy

Having rejected the embedded account of autonomy, I now examine the third general account of autonomy that appears in the philosophical literature, the relational account. Since this account rests on the relational account of the person, I devote this section to explaining the relational account of the person that feminists presented in response to the atomistic account of the person. I further clarify the relational account of the person by explaining how it differs from the embedded account. After doing so, I explain the relational account of personal autonomy that rests on the relational account of the person. Because I am concerned with how general accounts of autonomy interpret what influences by others negatively impact autonomy, I end this section by explaining which factors a relational autonomy theorist would consider to be controlling influences by others.

Because the relational accounts of the person and of autonomy were responses by feminists to problems that they insisted traditional autonomy accounts encountered, I address the feminist objections to the traditional account in the next section. I begin by dismissing what I believe is a non-problematic objection, the egoism objection. I then address the remaining two objections, namely, that such accounts fail to attend to the ways in which dependency and social structures, or differences in race, class, and gender, can impede autonomy. In my discussion of dependency and social structures, I explain why it is important for an account of personal autonomy to attend to these concerns. This sets the stage for being able to analyze traditional accounts of autonomy in the next

chapter in order to determine whether they address these problems.

Having presented the relational account of autonomy and explained how it attends to the ways that dependency and social structures impede autonomy, I end the chapter with a final section in which I map the relational autonomy account onto the same scenario that I used to help illustrate the traditional and embedded accounts.

3.4.1 The Relational Self

Based on the popularity of the Western ideal of independence and self-sufficiency that I spoke about in Chapter 2, many feminists responded with what they argue is a more accurate account of the person. While those who espouse an atomistic account of the person insist that a person's essential characteristics are not dependent on society, those who espouse a relational account of the person disagree. They insist that a person's essential characteristics are constituted, at least in part, by society. A person's social context, including her relationships, social institutions, social practices, and so forth, directly affect and inform a person's essential characteristics, including her identity, values, and beliefs. As a means of emphasizing the relational aspect of the person, feminists refer to their account of the person as the relational self.

3.4.2 Differences Between the Relational and Embedded Accounts of the Person

At this point, it may appear that the relational and embedded accounts of the person are the same since both assert that a person cannot abstract his essential characteristics from his relationships with others. However, these accounts differ. Specifically, they differ in the way they address a person's positioning in the

communities and relationships in which he is embedded.¹⁰ Communitarians approach communities in broad brushstrokes. For example, Sandel addresses the “particular people we are – as members of this family or that community or nation or people, as bearers of this history, as sons and daughters of the revolution, as citizens of this republic”.¹¹ In attending to communities in general, communitarians overlook important differences between members based on race, class, sexuality, and gender. In doing so, they overlook how some members of communities are oppressed. Consider how Sandel refers to people as sons and daughters of a particular revolution. In doing so, he fails to provide a more in-depth analysis and uncover differences between the ways that men and women have been able to reap the benefits from revolutions.¹²

In comparison, feminists insist on examining differences between people in relationships, especially differences that can decrease some people’s autonomy. As I will explain, they are specifically concerned with differences resulting from dependency and social structures, such as race, class, sexuality and gender.

3.4.3 The Relational Account of Autonomy

In recognizing that a person’s essential characteristics are constituted, at least in part, by a person’s relationships with others, feminists insist that an account of autonomy

¹⁰ See Friedman 1995, 193 & Weiss 1995, 197.

¹¹ Sandel 1998, 179. Similarly, as the previous quote from MacIntyre illustrates (see p.13), he addresses individuals as members of households, villages and tribes. Despite his reference to our being sons and daughters of these communities, nowhere does he address the different impact that gender socialization has (MacIntyre 2007, 33).

¹² As is well known, the Constitution – one of the proclaimed victories of the sons and daughters of America’s revolution – established voting rights for its citizens (Article I). Notably, it wasn’t until 1920 that women were granted the right to vote throughout the nation.

should attend to the ways that relationships either enhance or impede one's autonomy. Their emphasis on the role of relationships in autonomy led feminists to refer to their account of autonomy as relational autonomy.

Just as there are several traditional theories of autonomy, there are several theories of relational autonomy. In 1989, Jennifer Nedelsky introduced the notion of relational autonomy from a feminist perspective, arguing against the atomistic account of the person and the individualistic account of autonomy that stemmed from this.¹³ Since then, autonomy theorists have presented various versions of relational autonomy. For example, Lorraine Code argues that autonomy theorists must recognize the extent that the self is embedded in society to the extent that they are “second persons”, or only come to be persons through their relationships with others.¹⁴ Other relational autonomy theorists have focused on the ways in which a person's relations with others impacts specific aspects of their autonomy skills. For example, Trudy Govier, Susan Sherwin, Carolyn McLeod, and Marina Oshana explain that oppressive socialization causes people from oppressed groups to not fully develop some of the necessary skills for autonomy, such as self-trust and self-respect.¹⁵ Some argue that the way that society is structured along race, class, and gender lines negatively impacts autonomy. Relational autonomy theorists, such as Marina Osh, emphasize that having access to a range of relevant options is among the necessary conditions for autonomy.¹⁶ Eva Kittay, in her discussion of the ways that

¹³ Nedelsky 1989.

¹⁴ Code 1991.

¹⁵ Govier 1993; McLeod and Sherwin 2005; Oshana 2006, Chapter 4.

¹⁶ Oshana 2006, Chapter 4.

disability can negatively impact both disabled people and caregivers, points out the need to recognize dependency relationships and how these impact autonomy.^{17,18}

Despite differences between their theories, relational autonomy theorists share common commitments. In highlighting the constitutive aspect of autonomy, they point out that people's relationships function within a larger social context. In doing so, they insist that an account of autonomy should attend to the impact that social structures, such as race, disability, class, and gender, can have on autonomy. In addition to being concerned with social structures, relational autonomy theorists insist on recognizing that all people are dependent on others at least during some part of their lives. In recognizing people's dependency on others, they insist that a theory of autonomy should address how dependency affects a person's autonomy.

I will have more to say about the ways that dependency and social structures impede autonomy in my discussion of the feminist objections to traditional accounts of autonomy. For now, I wish to leave the reader with the overall picture that relational accounts of personal autonomy attend to the ways that dependency and social structures, or differences in race, disability, gender, and class, can affect autonomy.

3.4.4 Interpreting the Three Necessary Conditions for Autonomy

Having described the relational account of autonomy, I briefly explain how relational autonomy theorists would interpret the three necessary conditions for autonomy that I introduced in Chapter 2: critical reflection, intentionality, and freedom from controlling influences. This will help the reader better understand how relational

¹⁷ Kittay 1997.

¹⁸ For other examples of relational autonomy theories, see Meyers 1989; Donchin 1995; Minow and Shanley 1996; Friedman 1997; Sherwin, 1998; Lindemann and Nelson 2007.

autonomy accounts fulfill the necessary conditions that theorists agree upon. It also illustrates how relational autonomy theorists differently define controlling influences by others than embedded and traditional autonomy theorists do.

Similar to the traditional and embedded accounts of autonomy, relational autonomy theorists insist that an individual must critically reflect on her beliefs and values when making a self-governed choice. Also, just as I dismissed discussing the necessary condition of intentionality in my discussion of the previous accounts, I do so here. Suffice it to say, like embedded and traditional autonomy theorists, relational autonomy theorists also insist that an individual must intentionally formulate and carry out her self-governed choices.

Relational autonomy theorists' emphasis on attending to dependency and social structures illustrates how they would interpret the third condition, freedom from controlling influences. Recall that, in addressing this question, I am focusing on differences in scope, or what each includes in their analysis of what they believe constitutes controlling influences.

Because relational autonomy theorists recognize that a person is embedded in society, they broaden the scope of what constitutes controlling influences to include both the internal and external ways that society can enhance or impede autonomy. Recall from Chapter 2 that the atomistic account of the person overlooks the ways in which others can internally restrain a person's ability to make an autonomous decision due to their insistence that a person can isolate his essential characteristics, such as his beliefs and values, from others. Unlike those who espouse an atomistic account of the person, those who advance a relational account do not insist that a person can isolate his essential

characteristics from society. This enables relational autonomy theorists to recognize the ways that others can negatively impact one's overall constitution, including her mental processes and autonomy skills.

I will have more to say about this in the following section wherein I discuss relational autonomy theorists' objections to traditional accounts. For now, it suffices for the reader to note that relational accounts of autonomy approach the problem of controlling influences by others with a broader scope than traditional autonomy theorists. Whereas traditional theorists attend to external restraints, relational theorists attend to internal and external restraints.

3.5 Feminist Objections to the Traditional Account of Autonomy

Not surprisingly, many feminists objected to the traditional account of autonomy. Although many of their objections shed light on problems with this account, not all of their objections are problematic. In order to focus on the strongest objections, I begin by dismissing what I believe is an unproblematic objection, the egoism objection. I then discuss what I believe are stronger objections, those pertaining to the ways that dependency and social structures can impede autonomy.

3.5.1 Dismissing the Egoism Objection

To begin, we should dismiss the objection that the atomistic account of the person espouses egoism, or the idea that people not only are inclined to act from self interest but that they should do so.¹⁹ Feminists, such as Penny A. Weiss, Virginia Held, Seyla Benhabib, and Eva Kittay, have argued that the insistence that people always act from

¹⁹ Communitarians have also charged liberalism with espousing self-interest: MacIntyre 2007, 24; Sandel 1998, 53.

self-interest overlooks the way that many women act in relationships.²⁰ They point out that, as a result of gender socialization, many women are raised to make sacrifices for others and prioritize others' needs. Moreover, Eva Kittay argues that it excludes caregivers, who prioritize others' interests. Notably, women are oftentimes the primary caregivers in society.²¹

In all fairness, their interpretation is not unsubstantiated.²² The traditional philosophical literature contains many theorists who have asserted that people act from self-interest. Among the more obvious is Hobbes, who argued that people's reasons for forming society are to formulate government and construct laws in order to protect themselves from harm by others.²³ Yet, even those who insist that people can be motivated by altruism paint a picture of people as needing to overcome their egoistic tendencies in order to attain this ideal, thereby reinforcing the belief that human beings are naturally inclined to be egoistic.²⁴

Rather than attempt to establish whether human beings are motivated by self-interest, I believe that we can grant that people act from self-interest while at the same time acknowledging that self-interest can be framed to accommodate others' interests. For example, individuals can desire to be held in high esteem for acts that benefit others,

²⁰ Weiss 1995, 169; Held 1995, 210 & 212; Benhabib 1992, 155-7; Kittay 1997.

²¹ Kittay 1997.

²² Rather than debate the validity of the egoism claim, Lorraine Code argues that the picture of the self-interested person has become part of the Western ideal of the autonomous man as one who "is – and should be – self-sufficient, independent, and self-reliant, a self-realizing individual who directs his efforts towards maximizing his personal gains (1991, 78)". Due to the normative, rather than the descriptive, implications of this ideal, Code argues that we need to address its underlying mistaken assumptions.

²³ Hobbes 1962/1651.

²⁴ For example, refer to Alison Jaggar's discussion of Rawls (Jaggar 1983, 31).

such as being generous. Although I am neither condoning nor condemning this type of motivation, it is important to note that acting from self-interest can include others' interests. With this in mind, we can dismiss the egoism objection.

3.5.2 Dependency

While some have objected to traditional accounts of autonomy based on the egoism objection, others have objected that these accounts fail to address dependency. There appear to be two objections that feminists present with regards to dependency. Although both deal with dependency, I believe that the second objection belongs under discussions of the ways in which social structures impede autonomy. For this reason, I describe the first objection in this section and address the second in the next section when I address the feminist objections regarding social structures.

The first objection deals with the failure to acknowledge dependency relationships. According to relational autonomy theorists, traditional autonomy theorists mistakenly assume that individuals, once they have matured, can voluntarily enter and exit their relationships. Feminists object that this valorization of independence overlooks those who necessarily depend on others due to disabilities or disease and, as a result, cannot exit their relationships. Because all of us at some and, often, several points, throughout our lives are dependent on others, feminists insist that an account of autonomy should recognize that not all our relationships are voluntary.²⁵

In presenting examples of traditional accounts of autonomy, I address the objection that these theories fail to acknowledge that some relationships are dependency

²⁵ Barclay 2000; Donchin 2000; Sherwin 1998; Kittay 1997.

ones. I do so to illustrate that the feminist objection is mistaken; traditional theories often account for dependency relationships.

The second objection builds on the first. Once autonomy theorists recognize dependency relationships, the next step is for them to attend to the ways that dependency can impede a person's autonomy. Although many traditional autonomy theorists acknowledge dependency, they fail to attend adequately to how it affects autonomy. Because, as I have already mentioned, I believe that this further objection belongs in discussions about the impact that social structures have on autonomy, I now turn to explaining why feminists insist that autonomy theorists should attend to the problem of social structures.

3.5.3 Social Structures

In addition to objecting that traditional autonomy accounts fail to acknowledge dependency relationships, feminists also insist that these accounts do not attend to the ways in which social structures, or differences in race, class, gender, and so forth, can impede autonomy. Recall, from Chapter 1, that 'social structures' refers to patterned social arrangements in society and the ways that these arrangements influence the actions of the people who are socialized into this structure.²⁶ Also recall that I am concerned with social structures in the form of how people are categorized into oppressive groups within society, based on their race, class, and gender, and how they are differently socialized as a result of their group membership.

In addressing the impact that social structures have on autonomy, it is necessary to clarify that I am not asserting that membership in a particular race, class, or gender

²⁶ Abercrombie 2000, 326–327.

necessarily decreases autonomy. Some members of oppressed groups manage to escape the problems of racism, classism or sexism.²⁷ However, because membership in an oppressed group often impedes autonomy, it is necessary to attend to its possible impact. Although I do not address the increased impact that membership in multiple oppressed groups can have, such as being a woman of color, an account of autonomy also should attend to the complexities surrounding multiple group membership.²⁸

The problems regarding social structures can be categorized into two general types of problems, internal and external restraints. Recall that I first introduced the distinction between internal and external restraints in the previous chapter in my discussion of how traditional autonomy theorists would interpret what constitutes controlling influences by others. In doing so, I explained that internal restraints deal with the ways in which others' influence affects a person's constitution or what she brings to the table at the point at which she makes a self-governed choice.

Here, I explain the types of internal restraints that can arise from the way that one has been socialized as a member of an oppressed race, class, disability, or gender. After doing so, I explain how the ways that dependency impacts autonomy belongs in discussions of social structures. After discussing these aspects of internal restraints, I explain the ways in which social structures result in external restraints, or restraints that exist out in the world that impede a person's ability to carry out the choices she has made.

²⁷ Importantly, examples such as President Obama and Oprah Winfrey do not illustrate that racism or sexism no longer negatively affects most members of oppressed groups.

²⁸ For a discussion of how oppression affects members of multiple oppressed groups, see Kimberlé W. Crenshaw, "Mapping the Margins: Intersectionality, Identity Politics, and Violence against Women of Color," *Stanford Law Review* (1991): 1241–1299.

Internal Restraints Arising from Social Structures

Within the area of oppressive socialization that results in internal restraints, people's autonomy can be impeded by either internalized oppression or by not fully developing some of the necessary skills for autonomy. In the latter case, the way in which an individual is socialized based on his or her membership in a certain race, class, gender, or disability can result in him or her not fully developing certain necessary skills for autonomy. For example, Meyers explains how women are encouraged not to develop fully the autonomy skills of self-direction and self-definition.²⁹

In the former case, the case of internalized oppression, members of an oppressed race, class, gender, or disability internalize oppressive societal beliefs. When they internalize these mistaken beliefs to the extent that they allow these to condition their desires, they end up further perpetuating their oppression through the choices they make.^{30, 31} For example, Diana Teitjens Meyers points out how gender socialization can cause women to overlook their own needs in order to be good wives, mothers, and daughters (what Weiss refers to as self-abnegation).³² Others have pointed out how members of certain races, classes, or genders internalize mistaken beliefs about their being less competent and not worthy of respect, which, in turn, results in decreased self-

²⁹ Meyers 1987.

³⁰ Meyers 1989.

³¹ Recall, from Chapter 1, that although members of privileged groups may also make choices based on mistaken societal beliefs about their group, they do not suffer from internalized oppression. This is due to the fact that their choices do not decrease their privileged position of power within society.

³² *Ibid.*

trust and self-worth.³³ Because one must respect oneself and learn to trust one's ability to make self-governed choices, self-distrust and internalized beliefs about incompetence decrease autonomy.

Internal Restraints and Dependency

Prior to proceeding, allow me to explain why I believe some aspects of dependency belong in discussions of how social structures impede autonomy. It is important to note that, in addressing those who are disabled, I am concerned with disabled people who have the requisite mental capabilities for autonomy but must rely on others to provide care to meet their basic needs, either due to physical disabilities or mental disabilities that are not related to the requisite mental skills for making self-governed choices.

Disabled people within society are grouped into a patterned social arrangement of being 'disabled', as opposed to those who are categorized as not disabled or as able-bodied. As a result of being a member of the social group we call 'disabled people', they oftentimes are socialized differently than able-bodied people. In these instances, those who are disabled encounter similar internal and external restraints as those who are members of other social structures, such as race and gender.

With regards to internal restraints, a disabled individual may internalize mistaken societal beliefs about his disability, such as being less competent or less worthy. He also

³³ McLeod and Sherwin 2000, 263-4. For articles regarding the importance of self-worth for autonomy, see Robin Dillon, "Toward a Feminist Account of Self-Respect," *Hypatia* (Winter 1992): 52-69, and Paul Benson, "Free Agency and Self Worth," *Journal of Philosophy* (1994): 650-668. For an explanation of why self-trust is important for autonomy, see Trudy Govier, "Self-Trust, Autonomy and Self-Esteem," *Hypatia* (Winter 1993): 99-120.

might have been socialized to not develop fully some of the requisite skills for autonomy, such as self-assertion. In introducing the external restraints to autonomy in the next subsection, I explain how disability can lead to these restraints.

External Restraints Arising from Social Structures

In addition to internal restraints that arise from oppressive socialization, social structures also can result in external restraints to autonomy. In referring to external restraints, recall that I am referring to restraints that we can identify out in the world at the time at which a person attempts to exercise her choices. These restraints relate to social structures, or race, class, gender, and disability, in that they arise from racism, sexism, classism, and ableism that is either practiced by individuals or has become a part of social practices or institutions.

There are two ways in which social structures result in external restraints. First, racism, sexism, and so forth can unjustly decrease people's available options. Although some have argued that unjustly limited options do not impede autonomy,³⁴ many autonomy theorists acknowledge that external restraints that arise from social structures, such as racism and sexism, can impede autonomy. As will become apparent in my discussion of specific autonomy theories in Chapter 4, even traditional autonomy theorists acknowledge that unjustly limited options arising from social structures can impede autonomy. Because my purpose is to test the extent to which traditional autonomy theorists attend to problems arising from social structures and because I explain that they attend to problems arising from unjustly limited options that result from social structures, I believe it suffices to grant that this is a problem.

³⁴ Refer to Wertheimer 1996, 269-271.

Sometimes the way that people's options are unjustly limited is apparent, as when a doctor, acting from racist or sexist beliefs, limits a patient's options. For example, a sexist doctor might assume that a female patient is incapable of handling the pain involved in a particular treatment and, consequently, does not offer this treatment as an option.

Sometimes the ways that racism, sexism, and so forth unjustly limit people's options are not as obvious. As Susan Dodds points out:

Decisions about medical research priorities and funding of the health-care system affect what alternatives are available for the physician to offer the patient. These decisions may reflect discriminatory or biased practices that affect the particular patient's autonomy, and yet in most bioethical discussions these alternatives are thought of as a given set that does not require ethical scrutiny.³⁵

The fact that racism, sexism, and so forth limit a patient's available choices can be obscured by the fact that the patient is free to consent whether to choose among the unjustly limited options available to her.

The ways that disability, as a social structure, can impede autonomy oftentimes are less apparent. The way that society is structured for able-bodied people might force one to make choices that he otherwise wouldn't make if these societal limitations were not present. For example, a disabled person who must use a wheelchair to get around may be unable to go to a voting booth to cast his vote because there is no handicap accessible entrance and the hallways and booths are too narrow for a wheelchair. When this occurs,

³⁵ Susan Dodds, "Choice and Control in Feminist Bioethics" in *Relational Autonomy: Feminist Perspectives on Autonomy, Agency and the Social Self* (eds.) C. Mackenzie and N. Stoljar (Oxford University Press, 2000): 213-235. Ann Donchin makes a similar claim (1995, p.49).

structural restraints impede his ability to make a self-governed choice, or in this case, cast his vote.

The second way that racism, sexism, classism, and ableism impede autonomy is that these often result in oppressed people having far less power in a relationship.³⁶ Social structures can lead to disparate power between those who are oppressed and those who are not, as when doctors are racist or sexist in their interactions with patients and fail to allow them to exercise their autonomy in the doctor/patient relationship. Similarly, dependency can result in disparate power in relationships.³⁷ Because disabled people oftentimes depend on others to provide life's necessities, they are vulnerable and have far less power.

Much of the concern regarding disparate power is that it makes it easier for others to manipulate or coerce those who are less powerful. However, concerns about disparate power are not always concerns about coercion and manipulation. In some cases, the mere fear of no longer receiving necessary care (even when based on mistaken beliefs) can cause vulnerable people to not make autonomous choices. Also, power differences can cause less powerful people to feel intimidated and not provide necessary input regarding their treatment. For example, they may fail to ask questions about their treatment options. They also may feel uncomfortable offering information about what may be in their best interest, beyond what medical professionals explicitly ask about.

³⁶ Although racism, sexism and classism can enhance autonomy for members of the privileged group, the concern is that those with less power are less able to exercise autonomy.

³⁷ For example, see Sherwin 1998, Donchin 2000, and F. Baylis, J. Downie and S. Sherwin, "Reframing Research Involving Humans" in *The Politics of Women's Health: Exploring Agency and Autonomy* (ed.) The Feminist Health Care Ethics Research Network (Philadelphia: Temple University Press, 1998): 234-259.

3.6 Applying the Relational Account of Autonomy to a Particular Case

Having explained the relational account of autonomy and how it focuses on internal and external restraints that arise from social structures and dependency, I illustrate how relational autonomy theorists would interpret the particular scenario that I have been using to illustrate the general accounts of autonomy. Once again, recall that the case is one in which an athletic woman decides not to terminate her life support. Although she believes that it is in her best interest to terminate her life due to a drastic decrease in quality of life, her church community has expressed their sadness over her desire based on their value of respecting God's will, though they have not coerced nor manipulated her.

Based on the apparent external conditions, such as a lack of coercion and manipulation, it might appear that the woman's decision is an autonomous one. However, relational autonomy theorists also would be concerned whether the woman's ability to make an autonomous choice has been impeded by internal restraints. As a result, they would need to gather additional information. For example, they would be concerned whether the woman has made her choice based on internalized oppressive beliefs. They might ask if she believed that her desires are not as important as others. Relational autonomy theorists would also ask questions directed towards understanding whether the woman is operating from decreased levels of autonomy skills due to her gender socialization. Given that the woman believes that it is in her best interest to end her life because she does not want to be inescapably confined to a hospital bed, they would question the extent to which oppressive socialization might have impeded her ability to

express this choice as a result of her not having fully developed self-worth, self-trust or self-assertion.

3.7 Conclusion

In this chapter, I have explained the embedded and relational accounts of autonomy. In doing so, I concluded that we should reject the embedded account. In cases in which a person belongs to multiple communities whose values conflict, it is not clear whose community values determine whether to respect an individual's personal choice. Moreover, even if we can identify which community values come into play, there is a larger problem. Insisting that respect for personal autonomy must be justified by how well it aligns with community values opens the door for community values to trump respect for autonomy. Although those who espouse an embedded account of the person do not find this problematic, we have good reason to be concerned, especially when it comes to respect for a person's choice whether to participate in a research trial on human subjects (which, as I mentioned in Chapter 1, is my larger focus).

Having argued against the embedded account of personal autonomy, I presented the relational account. The benefit of relational accounts is that they attend to the internal and external restraints to autonomy that arise from dependency and social structures, or differences in race, class, gender, and disability. Given the need to attend to these problems, I devote the next chapter to examining the extent to which traditional autonomy theorists address these concerns.

Chapter 4: Traditional Autonomy Theorists Respond

In this chapter, I examine whether traditional accounts of autonomy overcome the two objections that I presented in the previous chapter, failure to acknowledge dependency and failure to adequately attend to how social structures, or differences in race, class, gender, and disability, impede autonomy. In doing so, I conclude that traditional autonomy theorists recognize dependency but fail to adequately attend to problems relating to social structures. As I explain, this failure is due to the fact that traditional accounts rest on the atomistic account of the person, which makes it impossible for them to adequately attend to the ways that social structures affect autonomy.

Because traditional accounts fail to adequately address social structures' impact on autonomy, I draw the further conclusion that we should reject such accounts. Notably, this conclusion combines with the conclusions from Chapter 3 to result in the overall conclusion that the relational account of autonomy is best. Recall that, in Chapter 3, I concluded that we should reject the embedded account of autonomy. This left us with the traditional and relational autonomy accounts. Having argued against traditional accounts of autonomy in this chapter, we are left with relational accounts. As I explained in the previous chapter, only relational autonomy accounts adequately attend to social structures. Consequently, relational accounts of autonomy are the best general accounts. This conclusion will come into play in the next few chapters, where I explain how the relational account of autonomy is the best philosophical foundation for international informed consent guidelines for research on human subjects.

4.1 Chapter Overview

As a means of analyzing how well traditional autonomy theorists recognize dependency and attend to social structures, I analyze three contemporary autonomy theories, not all of which turn out to be traditional accounts. My reason for addressing contemporary theories that represent both traditional accounts and contemporary accounts is to help highlight important differences between these accounts. A further benefit is that this demonstrates that, contrary to popular belief, not all contemporary autonomy theories are traditional accounts that rely on the atomistic account of the person.

Among the contemporary theories that I examine, I begin with a contemporary theory by Tom L. Beauchamp and James F. Childress that is a traditional account. Their principle of autonomy is part of their principlist approach to addressing biomedical ethical issues in their well-known book, *Principles of Biomedical Ethics*.¹ Because their approach is one of the most influential within the biomedical context, I have chosen to address it here.

In response to their account, Ann Donchin has attacked their contractarian approach to autonomy and informed consent in biomedical cases, arguing that it overlooks interdependent relationships in the medical context.² In what follows, I take a different approach and analyze how well they attend to dependency and the ways in

¹ Beauchamp and Childress 2009.

² Anne Donchin, “Reworking Autonomy: Toward a Feminist Perspective”, *Cambridge Quarterly of Healthcare Ethics* (1995): 46-7 and “Autonomy and Interdependence: Quandaries in Genetic Decision Making”, in *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* (eds.) C. Mackenzie and N. Stoljar (Oxford: Oxford University Press., 2000): 236-7.

which social structures impede autonomy. In doing so, I conclude that theirs' is a traditional account of autonomy, and, as such, does not adequately address problems relating to social structures.

I also analyze two other prominent contemporary autonomy theorists, Thomas E. Hill and Gerald Dworkin. I conclude that Hill presents a traditional account, while Dworkin provides a relational one. In "Autonomy and Social Relationships: Rethinking the Feminist Critique", Marilyn Friedman addresses these theories. Her reason for doing so is to show that many autonomy theories in mainstream philosophy overcome relying on the stark independence that oftentimes has been attributed to them.³ My critique differs in that I analyze the extent that mainstream theorists who specifically attend to the role of relationships in autonomy attend to how social structures impact autonomy.

Although I examine specific theories in this chapter, I do so to demonstrate an overall problem with traditional accounts of autonomy. Namely, their reliance on the atomistic account of the person makes it impossible for their theories to adequately attend to the ways that social structures impede autonomy. In comparing contemporary traditional accounts with a relational one, I explain why relational autonomy theorists' reliance on the relational account of the person enables them to overcome this problem.⁴

4.2 Social Structures

Since my conclusion in this chapter is that traditional autonomy theorists fail to adequately attend to the ways in which social structures, or differences in race, class,

³ Friedman 1997.

⁴ For examples of other contemporary traditional autonomy theories, see Feinberg (1989) and Benn (1982). For examples of contemporary relational autonomy theories, see Oshana (2006) and Christman (1995).

gender, and disability, impede autonomy, allow me to address and dismiss a possible response at this point. There are two ways in which traditional autonomy theorists can respond to this objection. They can deny that social structures are a problem for autonomy. Or they can argue that their theories attend to this problem. My analysis of traditional autonomy theories demonstrates that traditional theorists indicate that social structures are a problem. Given that some traditional autonomy theorists recognize some of the problems for autonomy that result from social structures, I will grant that they wish to attend to these problems.

4.3 Examining Contemporary Autonomy Theories

At this point, we are able to analyze how well traditional autonomy theorists attend to the two objections: recognizing dependency relationships and attending to the external and internal restraints that arise from social structures. I begin by analyzing Beauchamp and Childress' account, followed by Hill and Dworkin's theories.

4.3.1 Beauchamp and Childress

In analyzing Beauchamp and Childress' principle of autonomy, I draw two conclusions. First, they acknowledge dependency relationships. Second, they attend to external restraints to autonomy but fail to attend to internal restraints. I explain how their reliance on the atomistic account of the person explains their inability to attend to internal restraints, or the ways that oppressive socialization can impede autonomy. Because all traditional autonomy accounts rest on an atomistic account of the person, the inability to overcome this problem is characteristic of all traditional accounts.

Beauchamp and Childress' Theory

In *Principles of Biomedical Ethics*, Beauchamp and Childress present a principlist approach to addressing ethical issues in the medical context.⁵ Simply put, a principlist approach posits moral principles as the framework for guiding ethical behavior. According to Beauchamp and Childress, biomedical behavior should adhere to four principles: respect for autonomy, beneficence, nonmaleficence, and justice.⁶ They derive these principles from common morality, meaning that these principles represent ethical norms that people agree come into play in the biomedical context.⁷ Because they represent common morality, the principles are universal, meaning that they apply to all people at all times within the biomedical context.⁸

Moreover, the principles are intended to be content-thin, and abstract.⁹ Their lack of specificity provides the flexibility for addressing the diverse ethical issues that arise in the biomedical context. Whereas the principles provide the general framework for ethical behavior in the biomedical context, they gain specificity through rules that come into play in particular medical contexts. For example, the principle of respect for autonomy contains the general provision that doctors must respect a patient's self-governed choices about his medical care. This principle lacks specific guidance for how to respect a

⁵ Beauchamp and Childress 2009, sixth edition.

⁶ Although they present four general principles, there is good reason to address their theory in my discussion of traditional accounts of autonomy – not only because their theory is well known, but also because their theory of respect for autonomy highlights problems with traditional theories of autonomy that specifically attempt to address relationships.

⁷ For a more detailed discussion of how common morality informs their principlist approach, refer to Beauchamp and Childress 2009, 2-5.

⁸ Beauchamp and Childress 2009, 3.

⁹ *Ibid*, 5.

patient's choices when the patient is in a coma and cannot express his choice. In this case, the rule to "[r]espect the autonomy of incompetent patients by following all clear and relevant formulations in their advance directives" provides specific guidance on how doctors can respect the patient's autonomy.¹⁰

Addressing Feminist Concerns

Having briefly spelled out Beauchamp and Childress' theory, we can now ask whether they adequately respond to the feminist concerns that I previously mentioned. Recall that I am concerned with the extent to which traditional theorists respond to two objections: (1) that such theorists mistakenly overlook dependency relationships; and (2) that they fail to address the impact that social structures, including dependency, can have on autonomy. Also, with regards to social structures, recall that I drew a distinction between internal and external restraints, arguing that an account of autonomy should address both. In what follows, I address these types of restraints separately in order to highlight differences in how Beauchamp and Childress deal with each. I begin by addressing concerns about dependency, followed by my analysis of how well they attend to internal and external restraints that arise from social structures.

Dependency

Recall that a common feminist objection is that traditional autonomy theorists overlook dependency relationships. In discussing this objection, recall that I stated that it rests on the mistaken assumption that traditional autonomy theorists rely on an account of

¹⁰ *Ibid*, 14.

the person which valorizes supreme self-sufficiency. Here, I provide support for this claim by illustrating how Beauchamp and Childress overcome this objection.

In their most recent edition of *Principles of Biomedical Ethics*, Beauchamp and Childress acknowledge that dependency relationships exist. Throughout their discussion of autonomy, they oftentimes refer to problems that arise from patients' dependency on medical professionals. For instance, in their discussion of controlling influences, they explain, "Influences that ordinarily are resistible can become controlling for abnormally weak, *dependent*, and surrender-prone patients".¹¹ In addition, in their discussion of authority and community, they point out, "We encounter many problems of autonomy in medical contexts because of the patients' *dependent condition* and the medical professional's authoritative position".¹² In acknowledging dependency, Beauchamp and Childress overcome the first feminist objection that traditional autonomy theorists ignore such relationships.

External Restraints

Although Beauchamp and Childress overcome the first objection, they attend only to part of the second objection. Recall that the second objection dealt with traditional autonomy theorists' failure to attend adequately to the ways that internal and external restraints arising from social structures impede autonomy. In this section, I explain how they attend to external restraints. In the next section, I explain how they fail to attend to internal restraints.

¹¹ *Ibid*, 135 (italics added).

¹² *Ibid*, 102 (italics added).

Recall that external restraints are restraints to autonomy that result from racism, sexism, classism and ableism. These –isms result in two types of external restraints, unjustly limited options and disparate power. As I will explain, Beauchamp and Childress attend to both kinds of external restraints.

Recall that, in my discussion of social structures in Chapter 3, I explained that dependency, as it relates to impeding people’s autonomy, is a type of social structure. In their discussion of the principle of autonomy, Beauchamp and Childress attend to the external restraint of disparate power by acknowledging that a patient’s dependency on her doctor can impede autonomy. As they explain:

Conflict arises because authority has not been properly delegated or accepted. In these circumstances, the patient’s autonomy is sometimes compromised because the physician has assumed an unwarranted degree of authority.¹³

Notably, the fact that they address how one of the social structures, dependency, can lead to disparate power makes it consistent for them to incorporate discussions of the remaining ways in which other social structures, such as race, class, and gender, also lead to this problem.

Whereas they adequately attend to disparate power in their principle of autonomy, they do not address the other type of external restraint, unjustly limited options, in their discussion of autonomy. Instead, they deal with unjustly limited options in their principle of justice. The principle of justice deals with the fair distribution of goods. According to Beauchamp and Childress, part of the purpose of this principle is to attend to the ways that discrimination based on race and gender can unjustly limit patients’ access to health

¹³ *Ibid.*

care.¹⁴

Although they do not address unjustly limited options in the context of respect for autonomy, it appears that they would attend to this problem by combining the principle of autonomy with the principle of justice. Recall that Beauchamp and Childress' principles are meant to work together; the way they combine will depend on the particular biomedical context. To attend to the ways that unjustly limited options limit autonomy in a specific context, one might rely on the principle of justice to identify the unjustly limited options. One can then apply this to the principle of autonomy to determine whether and to what extent the unjustly limited options decrease autonomy.¹⁵

Internal Restraints

Notably, Beauchamp and Childress' approach of combining principles does not enable them to attend to the ways that internal restraints impede autonomy. Recall that internal restraints to autonomy, both internalized oppression and not fully developed autonomy skills, arise from oppressive socialization. As with the external restraint of unjustly limited options, Beauchamp and Childress do not discuss the ways that oppressive socialization might impede autonomy by resulting in either decreased autonomy skills or internalized oppression in their principle of autonomy. Moreover, acknowledging this problem is inconsistent with the way that they have formulated the

¹⁴ *Ibid*, 250-251.

¹⁵ As I explain in Chapter 6, relational autonomy theorists insist that, in addition to addressing issues of social justice under the principle of justice, we also must address these under the principle of autonomy. Only in this way can the principle of autonomy acknowledge that social injustices inescapably bear on autonomy as a result of people being constituted, at least in part, by their social relationships.

remaining principles. (Recall that one combines the principles in attending to various biomedical problems.)

Recall that, in addition to the principle of respect for autonomy, Beauchamp and Childress promote the principles of justice, beneficence, and nonmaleficence. Recall that the principle of justice deals with the fair distribution of goods, such as health care. In focusing on the distribution of goods, it does not attend to the ways that internal restraints, such as internalized oppression and underdeveloped autonomy skills, impede autonomy.

Similarly, the principle of beneficence also is not directed towards internal restraints. According to Beauchamp and Childress, beneficent actions are those that are intended to benefit others. Beneficent acts may be either general or specific. General beneficence is those actions meant to benefit people in general who may need help. According to Beauchamp and Childress, general beneficence, in most cases, is impractical and demands too much of people.¹⁶ Most biomedical issues deal with specific beneficence, or beneficence that is directed towards specific individuals. Specific beneficence usually relates to special relationships (such as family) or role responsibilities (such as contracted medical providers).¹⁷ Given the confines of the principle of beneficence as focusing on providing benefits for others, whether general or specific, this principle does not apply to internal restraints that impede autonomy.

Whereas the principle of beneficence deals with performing certain actions, the principle of nonmaleficence deals with refraining from certain actions. This principle requires medical practitioners to refrain from inflicting harm. Beauchamp and Childress

¹⁶ Beauchamp and Childress 2009 (sixth edition), 200.

¹⁷ *Ibid*, 199.

define harm as “thwarting, defeating, or setting back some party’s interests”.¹⁸ The atrocities at Nuremberg, where physicians performed harmful, invasive procedures on human subjects without their consent that were not in the patients’ best interests represent violations of the principle of nonmaleficence.

Because the internal restraints of internalized oppression and underdeveloped autonomy skills relate to a person’s ability to formulate self-governed choices that reflect her best interest, it might at first appear that these concerns could be addressed under the principle of nonmaleficence. However, doing so would be inconsistent with how Beauchamp and Childress have framed the principle. The reason for this is that they limit the principle to individual actions by parties engaged in medical services, much like a contract. Throughout their discussion of nonmaleficence, they refer to parties or agents that engage with each other and are bound by the principle. For example, in their discussion of the physical harms to which the principle of nonmaleficence is directed, Beauchamp and Childress refer to actions that the physician should abstain, such as killing, causing pain and suffering, incapacitating, causing offense and depriving others of the goods of life.¹⁹

In focusing on individual actions isolated to a particular time at which medical services are provided, Beauchamp and Childress fail to make room for the ways in which internal restraints from social structures can harm people. Internalized oppression occurs over time as a result of oppressive socialization. Hence, it goes beyond particular individuals and is incorporated into social practices and traditions. In addition, oppressive

¹⁸ *Ibid*, 152.

¹⁹ *Ibid*, 153.

socialization occurs over time and is not something that results from one person's interaction with another in a specified time in which services are provided.

Reliance on Atomistic Individual

To understand which general account of autonomy Beauchamp and Childress' account is, let us briefly review the conclusions I drew in my analysis. First, I concluded that their account acknowledges dependency and attends to the external restraints of disparate power and unjustly limited options. Second, I concluded that they overlook internal restraints and make no room in their principlist approach for correcting this.

Recall from Chapters 2 and 3 that it is consistent with the account of the person that informs both relational and traditional autonomy accounts to recognize dependency relationships. Hence, we are unable to determine how to classify Beauchamp and Childress' account of the person by looking to how they address dependency.

In comparison, the second conclusion indicates that Beauchamp and Childress' theory is a traditional autonomy account. Based on the second conclusion, Beauchamp and Childress fail to attend to internal restraints that arise from social structures. Once again, the failure to recognize how oppressive socialization can impede autonomy speaks to their oversight of how embedded people are in their social context and how this affects autonomy. In positing individuals as conceptually isolated from their social context, those who espouse an account of the atomistic individual fail to recognize how social structures inform people's essential characteristics, such as their identities, beliefs, and values. As a result, they are unable to recognize, and thus attend to, the ways in which oppressive socialization leads to internalized oppression and differences in the development of autonomy skills.

It is important to note that Beauchamp and Childress' failure to discuss internal restraints amounts to more than a mere oversight. Given their reliance on the atomistic account of the person, which insists that people are able isolate their essential characteristics in order to formulate self-governed choices, they are unable to acknowledge how a person's essential characteristics can be impeded by their social context.

4.3.2 Thomas E. Hill, Jr.

In "The Importance of Autonomy", Thomas E. Hill, Jr. presents a modified Kantian account of autonomy.²⁰ According to Hill, respect for autonomy is "a right to make otherwise morally permissible decisions about matters deeply affecting one's own life without interference by controlling threats and bribes, manipulations, and willful distortion of relevant information".²¹ In other words, a person acts autonomously if her choice does not result from coercion, manipulation, threats, or lies. Although Hill does not place restrictions on the content of individuals' choices, he insists that an individual must critically reflect on her choices. Also, a person's choices must align with her other values, such as compassion.²²

Like Kant, Hill asserts that a person's capacity for formulating and following his self-governed choices provides the reasons for respecting human dignity. However, he modifies Kant's account of autonomy. Specifically, he disagrees with the Kantian assertion that autonomy requires people to be self sufficient, independent, and

²⁰ Hill 1991.

²¹ *Ibid*, 48.

²² *Ibid*, 51.

emotionally detached.²³ According to Hill, respect for self-governed choices must include respecting people's choices to depend on others, to prioritize others' interests, and to incorporate emotions into their reasoning.

In presenting an account of autonomy that avoids asserting the starkly independent individualism oftentimes attributed to Kant, Hill acknowledges that dependency relationships exist. Thus, he overcomes the first objection towards traditional autonomy theories, which deals with the need to acknowledge dependency relationships.

However, he fails to attend to the second objection regarding how dependency and other social structures impede autonomy. To understand why this is, let us examine Hill's discussion of the ways in which others can impede a person's autonomy. According to Hill, physical coercion, threats, manipulation, and concealing or distorting relevant information can impede autonomy.²⁴ In examining these categories of undue influence by others, it becomes apparent that incorporating concerns about internal restraints to autonomy is inconsistent with how he has structured his categories.

Physical threats and coercion deal with a person's specific intent to alter another's choices, such as when a person threatens to slander someone if she does not vote as the person who threatens wishes.²⁵ In contrast, internal restraints to autonomy that arise from oppressive socialization need not involve intent. For example, it may be the case that a parent, in unwittingly perpetuating harmful societal stereotypes, raises her daughter to not fully develop self-trust. Although the parent does not intend to negatively impact the daughter's ability to make an autonomous choice, her actions have this effect.

²³ *Ibid*, 47

²⁴ Hill 1991, 48-9.

²⁵ *Ibid*, 48.

Similarly, the category of manipulation, as Hill defines it, deals with intentional acts directed towards altering another's choices. According to Hill, manipulation is intended to control a person's choice that should rightfully be hers to freely make.²⁶ Just as in the case of physical threats and coercion, manipulation cannot account for the ways in which oppressive socialization, which is not usually directed towards altering another's choices, impedes autonomy.

Finally, Hill's category of concealing or withholding relevant information does not pertain to oppressive socialization. Instead, it deals with the fact that, when others conceal or distort information for the purpose of altering a decision that a person has a right to make, this impedes autonomy. As such, Hill's category of concealing or withholding information fails to accommodate concerns about oppressive socialization in two ways. First, oppressive socialization does not deal with the requirement to provide relevant information for the purpose of making an informed, self-governed choice. Second, and similar to his other categories of undue influence, an agent who conceals or distorts information does so with the intent to alter another's choice. As I have explained, intent need not be present for oppressive socialization to impede autonomy.

The shared feature of all of Hill's categories of undue influences by others indicates that his theory represents a traditional autonomy account. Each of his categories focuses on specific agents who intend to change a person's choice that the person should be free to make. In focusing on the interaction between two parties, Hill overlooks the effects of the larger setting in which the interaction occurs. Namely, he overlooks the

²⁶ *Ibid.*

ways that social structures, or differences in race, class, gender, and disability, can have on a person's autonomy.

To illustrate, consider his example regarding how manipulation, even when stemming from good intentions, impedes autonomy. As he explains:

For example, a father, however well intentioned, might unduly interfere with his shy daughter's important life choices if, to comfort her, he tried to persuade her that women in law and other competitive professions are always unattractive.²⁷

In this example, Hill recognizes how the father's intentional manipulation of his daughter influences her choice. However, in focusing on the father's direct affect on the daughter, he overlooks the larger social picture in which their interaction occurs. Specifically, he fails to attend to how the daughter's oppressive gender socialization throughout her life has resulted in her emphasizing attractiveness and how this inhibits her desire to become a lawyer.

4.3.3 Gerald Dworkin

Having presented my analysis of two contemporary autonomy theories that represent traditional autonomy accounts, I now present my analysis of a contemporary theory by Gerald Dworkin, which I believe is a relational account of autonomy. The contrast between these contemporary theories helps illustrate subtle, but important, differences between traditional and relational autonomy accounts. In comparison with Hill, Beauchamp and Childress' reliance on an atomistic account of the person that makes it impossible to adequately attend to the ways that social structures impede autonomy,

²⁷ *Ibid*, 49.

Dworkin's reliance on a relational account of the person enables him to incorporate both internal and external restraints that can result from social structures.

Dworkin's Theory of Autonomy

In *The Theory and Practice of Autonomy*, Dworkin argues for a content neutral, otherwise known as procedural, account of autonomy.²⁸ In doing so, he places a few conditions on the procedure a person uses to make an autonomous choice. First, an individual must not be coerced or manipulated in formulating her self-governed choices. Second, she must critically reflect on her beliefs, values, etc. And third, she must be capable of changing these if she so chooses.²⁹

In general, Dworkin argues that a person acts autonomously when she critically reflects on her second order preferences, or her particular choices, to determine whether these align with her first order preferences, or the life she desires to live. In cases in which these do not align, the autonomous person can change either her first order or her second order preferences. For example, I may have a first order preference to be thin and a second order preference to eat rich foods and drink a lot of wine. I can change either my second order preference and choose to eat a healthy diet, or I can change my first order preference and desire to be someone who enjoys fine food and wine and is not thin.

How Dworkin Addresses the Feminist Concerns

In presenting his theory, Dworkin aims to present an account of autonomy that does not require people to be starkly independent. As he explains, this requirement runs

²⁸ Dworkin, Gerald. *The Theory and Practice of Autonomy* (New York: Cambridge University Press, 1988).

²⁹ *Ibid*, 20 & 108.

contrary to many self-governed choices that people may wish to make. For example, “To be committed to a friend or cause is to accept the fact that one’s actions, and even desires, are to some extent determined by the desires and needs of others”.³⁰ In acknowledging people’s interdependency, Dworkin rejects the idea that autonomy equates with stark self-sufficiency. This, in turn, makes it consistent for him to acknowledge dependency relationships, thereby overcoming the first feminist concern.

With regard to the second objection regarding how social structures impede autonomy, Dworkin does not mention all of the external and internal restraints that I have presented. However, unlike the other contemporary autonomy theorists that I have addressed, it would be consistent for him to do so.

The difference lies in differences in the account of the person that underlies each autonomy account. Unlike Hill, Beauchamp and Childress, Dworkin recognizes that people are embedded in their relationships with others and that these relationships inform people’s identities, beliefs, values, and choices. For example, he realizes that individuals formulate their self-governed choices from within a culture that informs their beliefs and values.³¹ As he explains:

Our dispositions, attitudes, values, wants are affected by the economic institutions, by the mass media, by the force of public opinion, by social class, and so forth. To a large extent these institutions are not chosen by us; we simply find ourselves faced with them.³²

In acknowledging the extent to which social structures, such as social class, can affect one’s essential characteristics, Dworkin acknowledges the embeddedness that is part of

³⁰ *Ibid*, 23.

³¹ *Ibid*, 7.

³² *Ibid*, 11.

the relational account of the person. The fact that he does not rely on an atomistic account of the person is further substantiated by his statement, “If the notion of self-determination is given a very strong definition – the unchosen chooser, the uninfluenced influencer – then it seems as if autonomy is impossible.”³³ In rejecting the completely unaffected chooser, Dworkin seems to recognize that a person cannot isolate her essential characteristics from her relationships with others. In other words, he does not rely on an atomistic account of the person. Thus, although his theory appears in mainstream philosophy, I believe that it represents a relational account of autonomy.

In concluding that Dworkin’s theory makes conceptual room for attending to oppressive socialization, I am not arguing that it is the best type of account for doing so. Dworkin provides a procedural account of autonomy. Although I think that there are problems with such accounts, I do not discuss differences between procedural and substantive autonomy theories. This is due primarily to my larger concern of examining accounts of autonomy that serve as a philosophical foundation for public policy. Within this particular context, I believe that it is acceptable to rely on a general account of autonomy that makes conceptual room for attending to problems and to leave the details of how to attend to these problems to the specific policies.

4.4 Conclusion

In this chapter, I have analyzed three popular mainstream autonomy theories, those by Beauchamp and Childress, Hill, and Dworkin, which are directed at overcoming the reliance on stark individualism that is oftentimes attributed to traditional accounts. In doing so, I have examined whether they: (1) acknowledge that some people are

³³ *Ibid*, 12.

necessarily dependent on others, and (2) recognize the ways in which social structures, or differences in race, class, gender, and disability, impede autonomy. I concluded that all attended to (1), while only Dworkin's theory is consistent with attending to (2). Beauchamp, Childress and Hill isolate their concerns for restraints to autonomy to individuals' interactions and intentions, thereby overlooking the ways that oppressive socialization can impede autonomy. In comparison, Dworkin acknowledges people's embeddedness in society, which enables his theory to make room for restraints that arise from oppressive socialization.

I then explained why I believe that the difference lies in differences in the account of the person that underlies each theory. I provided reasons to believe that Beauchamp, Childress, and Hill rely on an account of the atomistic individual and Dworkin relies on a relational account. Although I have not presented a thorough examination of all traditional accounts of autonomy, my analysis points to a general problem with all traditional accounts. The reason for this is that such accounts rest on an atomistic account of the person, which insists that individuals' identities, values, and beliefs are not reliant on society. In isolating individuals' essential attributes in this way, traditional theories focus on people's essential characteristics as essentially separable from the social context in which they live. Consequently, it is inconsistent to both hold that people's essential characteristics are essentially separable and to acknowledge that their essential characteristics can be altered to the extent that they suffer internal restraints to autonomy, such as internalized oppression and not fully developed autonomy skills.

Because traditional autonomy accounts are unable to adequately attend to the ways in which social structures impede autonomy and because relational accounts are able to

attend to these problems, we have good reason to prefer relational accounts of autonomy. In the next chapter, I strengthen my arguments in support of the conclusion that relational autonomy accounts are best by explaining why these best respect important cross cultural differences and how they best attend to particular problems that arise in international research on human subjects.

Chapter 5: Relational Autonomy in the Context of International Research on Human Subjects

Having concluded in the previous chapter that relational autonomy is the best general account of autonomy, I explain the benefits of relying on relational autonomy in the context of informed consent in international research on human subjects, especially those from less developed countries. First, I illustrate the global applicability of relational autonomy by explaining how it is best suited to address people who insist on including community in the informed consent process. To do so, I once again turn to the relationship between accounts of the person and accounts of autonomy. This time, I introduce a fourth account of the person that is popular in a less developed country in which researchers conduct a lot of research on human subjects. Due to the current AIDS epidemic in Africa and the resultant increase in research there, I have chosen an African account of the person called the *Akan*.

After explaining why relational autonomy is best suited for respecting important cross cultural differences in accounts of the person, I emphasize the benefits of relying on an account of autonomy that attends to social structures by explaining the ways that social structures impact autonomy in the context of international research on human subjects, especially those from less developed countries. In doing so, I explain how dependency, class, gender, and liberalism's influence negatively affect subjects' autonomy. In the next chapter, I argue for ethical conditions for remedying these problems in the context of informed consent in international research on human subjects.

5.1 Cross-Cultural Applicability

In Chapters 2 and 3, I examined the three accounts of the person that are popular in the philosophical literature, the liberal, communitarian, and feminist accounts. In what follows, I describe a fourth account of the person, one that has more recently appeared in the literature.¹ Due to the current AIDS epidemic in Africa, I have chosen to examine an account of the person that is popular among the *Akan*. The *Akan* refers to a particular ethnic group of persons within West Africa and includes people in Zambia, Ghana and the Cote d'Ivoire; the Ibos of Nigeria; and the Nso of Cameroon.² As I explain, due to the value that the *Akan* place on community, they would be among those wishing to involve community in the informed consent process. Because involving community often increases problems that arise from differences in race, class, and gender, community involvement magnifies the need to attend to the ways in which social structures impede autonomy.

After describing the *Akan* account of the person, I explain the particular ways in which social structures impede autonomy within the context of research on human subjects, especially those from less developed countries. Together, the need to respect the cultural difference of involving community in the informed consent process and the many problems that arise in the research setting that result from social structures illustrate the importance of relying on an account of respect for autonomy that attends to the impact that social structures, such as race, class, gender, and dependency, can have on autonomy.

¹ See Wingo 2007, Wiredu 1997, and Gyekye 1985.

² Wingo 2007; Wiredu 1997, 157.

5.1.1 The Akan Account of the Person

The *Akan* word for person (*onipa*) has a dual meaning. First, it refers to the biological fact that one is a human being. This biological basis accords all persons a minimum level of respect. At the same time, *onipa* also refers to the moral aspect of a person—the degree to which one provides for family and helps within the community (all of which are considered to be virtues). In cases in which one fulfills one’s social responsibilities to the fullest, one receives the highest compliment of *oye onipa paa* (a “real person”).^{3,4}

It is important to note that both aspects of the *Akan* account of the person rely on the individual’s relation to community. It is one’s membership in the human community that grants one the minimum respect owed to all persons. In addition, it is the way in which one chooses to interact with others in the community that determines the degree to which one achieves greater levels of respect within society.

While the *Akan* emphasize community, it is also important to note that respect for individual choice is not lost. The *Akan* emphasize individual responsibility and freedom of choice, including critical reflection of one’s beliefs, values and choices.⁵ Moreover, they recognize that individuals also must be able to exercise their choices. Consequently,

³ Wingo 2007, 1.

⁴ The suggestion that personhood can occur in varying degrees may seem metaphysically troubling for some. It is important to note that, within the context of the cross cultural applicability of international policy, I am concerned with deeply held societal beliefs about the person. This is not to say that I condone all possible interpretations of what constitutes the moral category of ‘person’. Instead, I believe that there a range of acceptable definitions, ones that are restrained by other moral constraints. For example, I would reject a definition that places value on vicious actions.

⁵ Wiredu 1997, 53.

each person retains the right to criticize community values.⁶ In “Person and Community: Ghanaian Philosophical Studies”, Kwasi Wiredu and Kwame Gyekye explain:

[I]ndividual persons as participants in the shared values and practices, and enmeshed in the web of communal relationships, may find that aspects of those cultural givens are inelegant, undignifying or unenlightening and *can thoughtfully be questioned and evaluated*. The evaluation may result in individual's *affirming or amending or refining* existing communal goals, values and practices; but it may or could also result in the individual's *total rejection* of them. The possibility of reevaluation means, surely that the person cannot be absorbed by the communal or cultural apparatuses.⁷

In placing the value of the person in her relationship to her community, along with valuing her ability to formulate and exercise self-governed choices, the *Akan* emphasize the importance of community and of individual autonomy.

5.1.2 Relational Autonomy as Globally Applicable

Given their emphasis on community, it appears that those who embrace an *Akan* account of the person would wish to include community in the informed consent process. This inclusion may at first seem counterintuitive based on the fact that I previously pointed out how the *Akan* encourage critical reflection of social practices. Because social criticism entails disagreement with community, it may seem odd to insist that the *Akan* would want to include community in an important life decision. However, it is important to note that the desire to include community does not rest on the desire to have others reinforce one's decision. Instead, it reflects the importance that community has for the *Akan*. Whether community agrees with one or not, an *Akan* individual cannot conceive of making important life decisions without involving community, much like some life

⁶ Wingo 2007, 7-8.

⁷ Wiredu and Gyekye 1992: 112 (italics added).

partners would not fathom making an important life decision without input from his/her significant other.

Including community in the informed consent process brings the individual subjects' relationship with others to the forefront, giving us all the more reason to rely on a relational account of autonomy that recognizes the negative impact that social structures can have on the relationship between researchers, subjects and the community. Although the *Akan* insist that individuals should exercise critical reflection as well as be able to exercise their dissenting choices, there is no guarantee that they will recognize and attend to the problems that arise from social structures. For example, although they might respect an individual's choice, they may fail to attend to the ways in which race, class, and gender can create power disparities that can impede a person's ability to formulate and exercise self-governed choices.

5.1.3 Where to Draw the Line

Although I have argued that the current informed consent guidelines should be revised to reflect relational autonomy, I do so with the realization that this account of autonomy will not be applicable to all cultures. Admittedly, no account of autonomy is applicable to cultures whose beliefs and practices prioritize community values at the expense of individual autonomy. When this occurs, international guidelines for research on human subjects must draw the line in respecting cross-cultural differences. In other words, in communities that do not provide a place for respecting individual autonomy, informed consent guidelines for research on human subjects must forgo respecting cultural differences and protect research subjects' ability to make an autonomous choice regarding medical interventions that directly impact them. I will have more to say about

this in Chapter 6, when I discuss the need to implement a specific safeguard for protecting subjects' autonomy in the research context.

5.2 Social Structures

In the previous chapter, I concluded that only relational autonomy attends adequately to the ways that social structures, such as race, class, gender, and disability, impede autonomy. In what follows, I explain some of the restraints that result from social structures when it comes to international medical research on human subjects. Doing so illustrates the need to rely on an account of relational autonomy in this context.

5.2.1 Dependency

Many who participate in research trials have a particular illness or disease. In research in less developed countries, those who suffer from disease and illness live in areas with inadequate (if any) healthcare. Even though research may not be directed towards treatment, participation becomes a means by which the unhealthy can get better healthcare than they would otherwise be able to obtain had they not participated. The need for medical attention increases subjects' reliance on researchers. This dependency increases subjects' vulnerability, making it easier for others to manipulate or coerce them.⁸ Although dependency and the disparate power that results from it oftentimes raise concerns about possible manipulation or coercion, recall from Chapter 3 that this is not the only way that disparate power can impede autonomy. Even in the absence of

⁸ For example, refer to Sherwin 1998, 20.

manipulation or coercion, subjects may fear making certain choices if they believe that such choices would result in researchers providing less or no care.⁹

In cases of research in less developed countries, the incidence of disease and illness are even greater. For this reason, an account of autonomy that serves to guide informed consent guidelines should recognize and address the negative impact that the combination of poor health and poor healthcare systems have on subjects' ability to exercise autonomy in the informed consent process.

Even in cases in which subjects are not ill, they may require medical benefits from services that only medical professionals can provide. Again, due to the lack of health care resources in less developed countries, subjects may rely on medical professionals to monitor their well-being. For example, general health check-ups are oftentimes included in research protocols.

5.2.2 Class

Differences in levels of education and social status between researchers and subjects can increase the power disparity in the researcher/subject relationship. Similar to dependency, power disparities resulting from class differences can impede autonomy by increasing the ability of those with more power to manipulate or coerce those with less power. Also, those who are dependent on those with more power might refrain from making self-governed choices because they mistakenly believe that doing so will result in their not getting the care they need.

⁹ In response, some might insist that the belief that researchers will not provide care if one makes certain decisions has a coercive effect. However, a coercive effect differs from coercion and manipulation. In cases of coercion and manipulation, the agent has the intent to alter another's decision.

Notably, power disparities resulting from differences in class oftentimes are present in the relationship between medical practitioners and recipients. As Sherwin explains:

In most cases, the relevant interactions are between patients and physicians [and we could add, researchers and subjects], where, typically, patients have less social power than their physicians: doctors are well educated and they tend to be (relatively) healthy and affluent, while the patients they care for are often poor, and lacking in education and social authority. In fact, according to most of the standard dichotomies supporting dominance in our culture – gender, class, race, ability status – odds are that if there is a difference between the status of the physician and the patient, the physician is likely to fall on the dominant side of that distinction and the patient on the subordinate side.¹⁰

In less developed countries, power differences are even greater due to subjects' lack of adequate education and healthcare. Given that research oftentimes requires subjects to voice concerns, questions, and objections, respect for autonomy should attend to power disparities that can impede subjects' ability to make autonomous choices in the researcher/subject relationship.

When community becomes involved in the informed consent process, an account of autonomy must be careful to attend to differences in class between researchers and community and between community members and subjects. Due to the drastic differences in class between researchers and those in less developed countries, researchers have greater power in their relationship with community members. Thus, additional concerns come into play once we involve community in the informed consent process. In these cases, respect for autonomy should also include ensuring that community members are able to voice their concerns and questions in the informed consent process and that research subjects are able to voice their concerns to other community members.

¹⁰ Sherwin 1998, 22.

5.2.3 Gender

Another social structure that can negatively impact autonomy is gender. As will become apparent in my discussion of gender and autonomy, these problems are relevant to any research involving women, whether national or international. Although gender's impact is not unique to international research, it is of particular importance in the context of AIDS research in Africa. According to the 2008/2009 UNIFEM report, *The Progress of the World's Women*, sub-Saharan Africa has the greatest percentage of women who suffer from AIDS (sixty-one percent).¹¹ Not only does sub-Saharan Africa have the greatest percentage of women infected with AIDS, but women in that region suffer from AIDS much more than men. In 2007 in sub-Saharan Africa, 12 million women had HIV or AIDS, compared to 8.3 million men.¹²

Despite women being more affected by AIDS than men, less women than men participate in AIDS research in Africa. According to a study by the International Center for Research on Women regarding AIDS research in East Africa, the ratio of female to male participants in 2007 and 2008 was 1:8.¹³ This discrepancy is due to women encountering gender specific barriers, which I discuss shortly.

The smaller numbers of women in AIDS research is problematic, given that there are good reasons for involving (at least) an equal amount of women as men in AIDS research. First, due to the biological differences between men and women, it is necessary to test the specific ways in which AIDS and any possible treatments specifically affect women. Second, among the two million children affected by AIDS in sub-Saharan Africa

¹¹ UNIFEM 2008/2009.

¹² UNAIDS December 11, 2008.

¹³ ICRW 2008.

in 2007, most contracted the disease from their mothers, either in vitro, during childbirth or by breastfeeding.¹⁴ Mother-to-child-transmission (MTCT) provides additional reasons to want to involve more women in research. In order to better ensure women's autonomy regarding research participation, an account of autonomy that informs informed consent guidelines should attend to how gender can impede autonomy.

In examining the extent to which gender influences the informed consent relationship, it is necessary to briefly define what I mean by gender. Whereas 'sex' refers to one's biological constitution (male or female), 'gender' refers to differences between men and women resulting from social factors, such as social role, social position, behavior, or identity.¹⁵ As a result of differences in education, socialization, and treatment, women are oftentimes in positions of less power in their relationships. In arguing that gender can negatively impact autonomy, it is important to note that I am not arguing that women necessarily share inherent characteristics that make them less capable of making autonomous choices. Instead, I am here concerned with identifying the results of differences in education, socialization, and so forth that oftentimes impede women's autonomy in the informed consent process, whether women are research subjects or are acting as part of the community that may be involved.

In examining the effects of the social structure of gender on women, it becomes clear that a number of relevant factors affect women's autonomy. First, because gender maps onto poverty, women feel the negative impact of class more so than men. According to the United Nations Development Fund for Women (UNIFEM), women

¹⁴ *Ibid.*

¹⁵ Mikkola 2008, 1.

comprise a greater percentage of the world's poor than men do.¹⁶ Part of this is due to the fact that fewer women than men are employed. In sub-Saharan Africa in 2007, fifty-four percent of working-age women were employed, compared to seventy-seven percent men.¹⁷ Among the women who are employed, more often than not, they do not hold secure employment. Eighty-one percent of women who were employed in 2007 in sub-Saharan Africa held vulnerable employment (meaning temporary or non-contracted employment), compared to sixty-four percent of men.¹⁸ These differences in employment result in differences in class, which, in turn, enhance power disparities between researchers and women subjects, as well as between women subjects and male community members.

Recall from my previous discussion of how class impedes autonomy that this difference in power raises two concerns with regards to subjects' autonomy. First, it makes it easier for a researcher or community members to manipulate or coerce a subject, thereby impeding the subject's autonomy. Second, a subject may refrain from making autonomous choices based on mistaken beliefs that the researcher (or community) will not act in the subject's best interest. Thus, based on the effects of gender, women oftentimes are more vulnerable to the ways that power disparities can impede autonomy in the research context.

Another impact of gender that can impede women's autonomy is the fact that many women are in relationships in which men control them. A majority of abuse victims are women. According to the UNIFEM report, *Violence against Women: Facts and Figures*:

¹⁶ UNIFEM 2005, 4.

¹⁷ UNIFEM 2008/2009, Goal 1.

¹⁸ *Ibid.*

In no country in the world are women safe from this type of [domestic] violence. Out of ten countries surveyed in a 2005 study by the World Health Organization (WHO), more than 50 percent of women in Bangladesh, Ethiopia, Peru and Tanzania reported having been subjected to physical or sexual violence by intimate partners, with figures reaching staggering 71 percent in rural Ethiopia.¹⁹

In addition to domestic violence, women suffer from additional forms of violence: rape, trafficking, and violence that have become part of social practices, such as dowry murders, genital mutilation, and honour killings.²⁰ This cycle of abuse oftentimes leaves women less able to determine and exercise their own choices, diminishing their ability to exercise autonomy.

Moreover, instances in which women report a decreased ability to exercise autonomy are not limited to overtly abusive relationships. In a study of women infected with HIV, Pulerwitz, Gortmaker, and DeJong noted that there was an increased incidence of HIV infection among women who reported being controlled by their male partners.²¹ This is due to the fact that women in relationships in which men control them do not feel empowered to ask their partners to use condoms.

In addition to altering the power dynamics between researchers and subjects, gender also impacts women in relation to community. Because many communities are patriarchal ones, including community in the informed consent process raises additional concerns about the extent to which women's voices are heard, either as research subjects or non-subject community members who are participating in the informed consent process. This concern is exemplified by a research study supported by the United Nations

¹⁹ UNIFEM 2007.

²⁰ *Ibid*, 2-5.

²¹ Pulerwitz, Gortmaker and DeJong 2000.

Programme on HIV/AIDS (UNAIDS) that studied the perinatal AIDS transmission in developing countries, including Thailand, the Ivory Coast, and Uganda. In an attempt to be sensitive to community values, researchers consulted community leaders. The resultant research protocol included measuring a placebo group of pregnant women with HIV/AIDS against a group who were given levels of AZT (zidovudin) that were below the standard level of care in the United States. After the details of the research were made public, concerns arose regarding the exploitation of the women who comprised the pool of research subjects. In response to these concerns, spokespersons from the nations and agencies involved in the research defended the researchers' actions by pointing out that they had consulted local community leaders prior to constructing the protocol.

Regardless whether community leaders were consulted, we have good reason to question the extent to which the women in the community would have chosen a trial in which subjects received no AZT. Because AZT is a proven treatment for fetal AIDS transmission,²² some objected to researchers' use of placebos.²³ They insisted that it was in the women's best interest to compare lower level doses of AZT to the higher doses that were given in previous studies in order to determine the effectiveness of lower level doses. Thus, many concluded that community leaders did not choose what was in the research subjects' best interest.²⁴ Regardless of how one thinks the female research subjects would have chosen, it is important to note that the only way to ensure that the

²² AZT studies in the U.S. and France showed that the following decreased the likelihood of AIDS transmission from mother to child by two-thirds: a pregnant woman took AZT daily beginning the middle of her pregnancy; she received AZT intravenously during delivery; she did not breastfeed; and the infant took AZT until six weeks old (National Institutes of Health 1996).

²³ Warigi 1997.

²⁴ Eckenwiler 2000, 273.

women subjects would have made the same choice as community leaders is to structure informed consent guidelines so that they include mechanisms by which women's voices can be heard.

Even when women do not suffer from an illness or disease that is being researched, the diseases and illnesses that plague a community oftentimes have more of an affect on women than men in the community. As the UNIFEM report, *Care-giving in the Context of HIV/AIDS*, explains, "Around the world, gender norms assign women the primary role in caring for people who are ill and dying from HIV and AIDS, along with the orphans left behind".²⁵ Due to lack of adequate health care, UNIFEM estimates that ninety percent of the care for those suffering from HIV/AIDS occurs in the home, where women are the primary care providers.²⁶ In 2003 in South Africa, women headed seventy-one percent of the households with orphaned children.²⁷ This additional caregiving burden results in women having less time and energy to participate in the informed consent process. Because they are most affected by the diseases to which the majority of research is directed and because their voices are oftentimes not heard within communities, it is extremely important that informed consent guidelines make provisions for women to have a powerful voice in the informed consent process when community is involved.

As I have explained, gender oftentimes can impede women's autonomy in the informed consent process in research on human subjects. To summarize, gender can negatively impact women's autonomy due to: (1) differences in education and wealth; (2)

²⁵ UNIFEM 2008.

²⁶ *Ibid.*

²⁷ The Global Coalition on Women and AIDS 2004.

abusive or controlling relationships; (3) patriarchal practices and traditions within the community; and (4) bearing the burden for caring for the ill and diseased within the community. The concern is that these can decrease women's ability to exercise autonomy in the informed consent process, whether as a research subject or as a community member. As I have explained, these problems are prominent in AIDS research on women in Africa, the specific context with which I am concerned. With this in mind, we have good reason to insist that an account of respect for autonomy should attend to how gender can impede autonomy in the context of research on human subjects.

5.2.4 Liberalism's Impact

Although relational autonomy theorists have focused on the impact of social structures within particular societies, it is important also to take into account the fact that we are part of a global community. Consequently, respect for autonomy in international contexts requires an examination of the negative impact that global social structures can have on autonomy. In the context of international policy, the West's adherence to liberalism influences how policy is formulated. My arguments regarding how the majority of the current informed consent guidelines for international research on human subjects reflect a philosophical foundation of a traditional autonomy account are meant to illustrate the overall effect that the West's influence has had on international policy.

Specifically, the West's adherence to liberalism is reflected in informed consent being framed as a contract between researchers and subjects. Recall, from Chapter 2, that the tenants of liberalism ontologically prioritize the individual over the community, insisting that respect for individual liberty should be prioritized. The contract model of informed consent focuses on the individual and emphasizes the need to respect individual

liberty. Based on this model, subjects should be free to either consent or dissent to participate in research once they have received the relevant information. Many have argued that the framing of informed consent as a contract mistakenly assumes that medical practitioners and patients are “comparably situated independent contractors”.²⁸

Yet, as I have explained, researchers and subjects are not equally situated due to differences in race, class, gender, and disability. Recall that I presented two primary reasons for being concerned with disparate power as it affects autonomy. First, disparate power enables the more powerful party, such as researchers or physicians, to coerce or manipulate those who are dependent on their care. Second, disparate power can impede autonomy in the absence of coercion, as when subjects operate from fear and mistaken beliefs that certain choices might result in researchers terminating their care. In Chapter 9, I explain which current informed consent guidelines reflect the Western liberal framing of informed consent as a contract. For now, I am introducing the notion that framing informed consent according to the contract model reflects the impact of global social structures and harms subjects because it overlooks the ways that disparate power can impede autonomy.

In response to problems with the contract model of consent, some have proposed addressing interactions involving disparate power from an ethic of care. Virginia Held and Sarah Ruddick propose a model that reflects a mothering/parenting relationship, wherein the more powerful person is motivated to protect or advance the less powerful person’s best interest.²⁹ Joan Tronto’s consent-as-authority, which I address in Chapter 8,

²⁸ Donchin 2000, 238. Also see Fox and Swazey 1997 and Held 1995.

²⁹ Held 1995; Ruddick 1989.

represents a model of consent that relies on an ethic of care. As I explain, her proposal is problematic and ends up harming vulnerable persons.

As an alternative to relying on an ethic of care model, I suggest a model that differs from both the contract and care models. Rather than posit the parties as equally positioned (as the contract model does) and rather than resting the relationship on the subject's trust in the researcher (as the care model does), I propose making the research process more participatory by identifying and attending to power disparities between researchers, subjects, and communities.

5.3 Conclusion

In this chapter, I explained why relational autonomy is the best account of autonomy in the context of international research on human subjects. To do so, I presented two arguments regarding why we should rely on an account of relational autonomy in this context. First, I highlighted the global applicability of relational autonomy by explaining how it best addresses an African account of the person, called the *Akan*. After explaining why the *Akan* would be among those who wish to include community in the informed consent process, I argued that involving community highlights the need to attend to how social structures affect autonomy. Given the fact that only relational autonomy adequately addresses the ways that social structures impede autonomy, I concluded that it is the best general account of autonomy for addressing the *Akan* account of the person.

To further emphasize the benefits of relying on an account of autonomy that adequately attends to the ways in which social structures impede autonomy, I presented a second line of argument in which I described the particular social structures that come

into play in the context of international research on human subjects, focusing especially on those from less developed countries. In doing so, I explained how dependency, class, gender, and Western liberalism's influence on how informed consent has been framed as a contract negatively impact subjects' autonomy. Once again, because only relational autonomy adequately attends to these problems, I concluded that it is the best general account of autonomy as this relates to informed consent in international research on human subjects.

Chapter 6: Ethical Conditions for Respecting Autonomy

My aim in this chapter is to arrive at a set of minimally sufficient conditions of a practice for promoting subjects' autonomy in research on human subjects. No set of ethical conditions can completely ensure subjects' autonomy. Some of the problems regarding social structures require more than ethical guidelines to remedy. Remedying inequalities, such as scarce health care resources, may require aid from other countries and restructuring within less developed countries at the government level. Due to the AIDS pandemic in Africa, however, researchers should continue research while doing their best to ensure subjects' autonomy. The fact that some of the problems that deal with social inequalities and poverty will take a long time to resolve provides further reason to construct a set of ethical conditions that can guide researchers in working as ethically as possible within the constraints of a hierarchical and impoverished society.

In comprising a set of ethical conditions, I aim to arrive at a set of minimally sufficient conditions that leave enough flexibility for adapting informed consent guidelines to particular cultural contexts. To arrive at this list, I analyze the following ethical conditions to determine how well they ensure respect for autonomy in international research on human subjects: critical reflection, support mechanisms, and participation.

I begin by examining critical reflection, which, you may recall from Chapter 2, all autonomy theorists agree is necessary for autonomy. I briefly explain the need for all those in the research process to reflect critically on their beliefs, values, and choices as these relate to the research process.

Next, I address the ethical conditions that others have introduced, implementing support mechanisms and including research subjects and community in various aspects of the research process, or what I am calling participation. In analyzing each, I address the extent to which each attends to the internal and external restraints that arise from social structures, or differences in race, class, gender, and disability, which I previously introduced in Chapter 3. Since the ethical conditions I will examine have been introduced in the general medical context, I analyze the extent to which each might be useful in the context of international research on human subjects. In doing so, I argue that neither is sufficient in itself for respecting autonomy in the research context. I also explain why relying on critical reflection alone is problematic.

Having argued against relying on just one of the previously proposed ethical conditions, I explain why combining critical reflection, support mechanisms, and participation also fails to adequately respect autonomy in international research on human subjects. With this in mind, I end the chapter by arguing that we must supplement these conditions with additional ones in order to arrive at a list of minimally sufficient ethical conditions for ensuring subjects' autonomy in medical research.

6.1 Requiring Critical Reflection

As I mentioned in Chapter 2, most autonomy theorists, regardless of what general type of account they present, agree that autonomous choice necessarily involves some degree of critical reflection of one's beliefs, values, and choices. Given the importance of critical reflection, one might assume that informed consent guidelines for research on human subjects include guidelines for this. However, even the most progressive guidelines, the CIOMS Ethical Guidelines, only briefly refer to the need for subjects to

consider their choices.¹ Notably, there is no mention of the need for researchers and community members to reflect critically on their beliefs, values, and choices, including how their failure to do so can impede autonomy in the research context. As a result, we must add guidelines that require and guide critical reflection for all those involved in the research process. This is a task I attend to in Chapter 10. Prior to doing so, it is necessary for me to briefly explain what already may be apparent to most, the need for critical reflection in the context of research on human subjects.² After doing so, I lay out the ethical condition that deals with critical reflection, which provides the basis for my proposed guideline in Chapter 10.

Because I am concerned with cultures in which subjects wish to include community in the research process, an account of critical reflection is of utmost importance. Given the emphasis on community, we must be wary that the choices that a research subject makes are ones that she has critically reflected on and not ones that she follows as a result of being pressured to blindly adopt the values and beliefs that society has provided her. In addition, if community members are involved, they too should reflect critically on their beliefs, values, and choices as a means of reflecting on how their mistaken beliefs might impede others' autonomy and in order to better ensure that their own choices are self-governed ones. So as to better ensure that subjects and community have reflected critically on their choices, they should be allotted a reasonable amount of time in which to critically think about their beliefs, values, and desires prior to making a decision.

¹ CIOMS 2002, Commentary on Guideline 4.

² This most likely is already apparent given my explanation in Chapter 2 regarding why autonomy requires critical reflection.

In addition to requiring the research subject and, when applicable, community members to reflect critically on their choices, it is important for the researcher also to exercise critical reflection. Prior to presenting research subjects with the relevant information to be able to make an informed decision regarding their participation in a research trial, researchers have already chosen the particular medical issue, formulated the research protocol, and calculated the type of information that they deem to be adequate for obtaining subjects' informed consent. The common belief is that, in order for research to be untainted and equitable, researchers can, and should, address these issues as unemotional, disinterested persons. Given this common belief, it is important to acknowledge that researchers may be influenced by their emotions and biases.³ Consequently, they should deliberately reflect on their choices, being especially wary to identify the ways in which they might have allowed biases regarding race, class, gender, and disability to influence their structuring of the research protocol. In doing so, they should ask to what extent possible stereotypes impede their ability to recognize subjects' competency. For example, Susan Sherwin points out that women, racial minorities, indigenous people, those with disabilities, welfare recipients, and people from developing countries oftentimes are presumed to lack the requisite rationality for making autonomous decisions.⁴ In addition, researchers should ask if possible stereotypes have negatively influenced their determination of what constitutes relevant and adequate information that must be provided in obtaining subjects' informed consent to participate

³ Baylis, Downie, Sherwin 1998, 236.

⁴ Sherwin 1998, 26.

in the research trial by, for example, mistakenly underestimating the level of understanding that subjects may have of the relevant information.⁵

As with the ethical condition regarding subjects' critical reflection, an ethical condition regarding researchers would state the importance of critical reflection and require researchers to implement this. In doing so, it can provide suggestions for things on which researchers should deliberate, such as how possible stereotypes might have influenced how they structure the research protocol or how they have determined what constitutes adequate information for the purpose of obtaining informed consent.

6.2 Previously Proposed Ethical Conditions

In this section, I explain the ethical conditions that relational autonomy theorists have proposed for respecting autonomy, support mechanisms and participation. In cases in which the condition has been introduced in a medical context other than the research setting, I first explain how the theorist intended its use in the initial medical context. I then analyze the extent to which it might be useful for promoting subjects' autonomy in the research setting.

6.2.1 Support Mechanisms

As a means of ensuring respect for autonomy, some have proposed providing support systems for those who are less powerful in medical relationships, such as patients or research subjects. Although they have presented this as a solution for remedying power disparities (which, recall, raises concerns about coercion), I believe that support mechanisms also attend to two other problems regarding subjects' autonomy. Providing

⁵ *Ibid*, 26 and 44.

subjects with support can help them identify internalized oppressive beliefs and desires that impede their ability to make self-governed choices. It also can benefit subjects by helping them develop some of the requisite autonomy skills they may be lacking as a result of how they have been socialized based on their race, class, gender, or disability. After explaining the various proposals that others have made regarding providing support for less powerful individuals in medical decision-making contexts, I explain how implementing this condition in the research setting attends to these three problems.

Support as an Ethical Condition

In order to ensure respect for autonomy in the medical context, Susan Sherwin recommends providing patients support in the form of counseling. Notably, her focus is on patients from oppressed groups. As she explains, such patients oftentimes have not had the opportunity to make autonomous choices in other areas of their lives due to their oppressed positions in society. As a result, they may require more counseling than other patients. Counselors can assist patients from vulnerable populations in understanding that medical decisions are theirs to make and help them more fully develop some of the necessary skills for autonomy, such as self-assertion.⁶ Although her focus is on oppressed populations, she also believes that counseling can help patients in general. Because there oftentimes is a power disparity between patients and doctors, counseling can help patients identify and voice their concerns and choices.

Allow me to add that, in all cases, support should be offered as an option for patients and should never be forced on someone simply because she is a member of an oppressed group. Requiring those from oppressed populations to participate in counseling

⁶ Sherwin 1998, 42-3.

or support groups as a necessary condition for providing valid consent further perpetuates their oppression by mistakenly assuming that all members are unable to provide valid consent without the help of support groups. Although people from oppressed populations are predisposed to suffer from internal restraints, such as internalized oppression and not fully developed autonomy skills, not all members suffer this fate. Moreover, among those who experience internalized oppression and not fully developed autonomy skills, some will be able to provide valid consent while others cannot. For this reason, it is best to offer patients the opportunity for counseling or to participate in support groups rather than mandate that they do so.

Support in the Research Setting

Notably, the need for, and the benefits derived from, providing support mechanisms is as relevant to the research context as it is to the doctor/patient relationship. As I explained in Chapter 3, differences in gender and class between researchers and subjects oftentimes result in subjects having less power. In addition, the way that subjects have been socialized as members of vulnerable populations can mean that they have difficulty making self-governed decisions. As I explained, this can be due to their adopting mistaken beliefs about themselves based on their group membership, which can lead to what I referred to as internalized oppression. It also can result from not having been raised to develop fully some of the requisite autonomy skills due to their socialization as members of an oppressed race, class, gender, or disability.

Counselors or support groups can assist research subjects from vulnerable populations in addressing these problems. First, they can help them in reflecting critically on their identities and beliefs to identify internalized oppressive beliefs. They also can

help subjects to more fully develop autonomy skills, such as self-assertion, self-trust, and self-worth. So as to respect the autonomy of members of oppressed groups, counselors should not assume to be able to speak for others. Instead, their role is to assist people in more fully developing skills that they might not have fully developed due to oppressive socialization. Finally, having counselors or support groups back subjects' choices can help balance the power difference between subjects and researchers or community.⁷

Addressing an Objection

Although support systems can better promote subjects' autonomy, some might object to their use on practical grounds. Some of the support systems, such as hiring counselors, cost money. Some might insist that requiring researchers to pay for these services will discourage them from conducting research on vulnerable populations. Given the benefits of research, such as health monitoring and benefit sharing,⁸ the concern is that requiring researchers to pay for support systems might end up being counterproductive.

Prior to presenting a possible solution to this problem, I wish to emphasize the extent to which current policy and practice reflects the need to conduct research in less developed countries. This allows us to see the larger context of support that underlies

⁷ Notably, some of the current guidelines emphasize the need for researchers to hire professionals to provide support for subjects as a means of attending to the fact that people from vulnerable populations have more difficulty making self-governed choices in the research context. For example, the Federal Code of Regulations (otherwise known as the Common Rule) authorizes Institutional Review Boards (IRBs) to appoint third parties to oversee the consent process. (HHS 2005, Title 45, Part 46.109[e].)

⁸ Benefit sharing refers to sharing the results of research, such as drugs to treat disease, with the community at large.

further pleas for increasing research expenditures in order to better ensure respect for subjects' autonomy in research in less developed countries.

First, many of the guidelines for international research include provisions that declare that researchers have an ethical obligation to conduct research in less developed countries. For example, the Universal Declaration on Bioethics and Human Rights states that part of researchers' ethical obligation is to conduct research in less developed countries as a means of "promot[ing] equitable access to medical.. technologies... with particular attention to the needs of developing countries."⁹ Similarly, the CIOMS Ethical Guidelines state that justice calls for researchers to "be responsive to the health conditions or needs of vulnerable subjects",¹⁰ including those from underdeveloped countries.¹¹

Second, researchers already conduct a lot of research in less developed countries. In fact, their interest in doing so has increased over the years. From 1998 to 2000, research on human subjects in less developed countries tripled.¹² Although this reflects researchers' current desire to conduct research in less developed countries, it is difficult to determine whether the additional cost of providing support mechanisms would cause a decrease in the amount of research in less developed countries.

This brings me to my proposed solution. If it turned out that the additional cost of support mechanisms would deter researchers, a possible solution is to revise current policy to redirect money that is spent on unnecessary policy requirements. Although it is

⁹ UNESCO 2005, Article 2 (f).

¹⁰ CIOMS 2002, General Ethical Principles, 18.

¹¹ *Ibid*, Background, 8.

¹² Carpentier 2000.

beyond the scope of this dissertation to perform a budgetary analysis of research expenditures, some have insisted that many of the current IRB requirements are redundant, adding unnecessary additional expenses for researchers.¹³ With this in mind, one possible solution would be to revise IRB requirements to avoid this redundancy. This then would make funds available for support mechanisms for vulnerable subjects.

6.2.2 Participation

Another ethical condition that others have presented as a means of ensuring subjects' autonomy in research is to include subjects and community in various stages of research.¹⁴ I will refer to this ethical condition as 'participation'. Although those who have proposed this condition oftentimes refer to their proposal as implementing a democratic process, I explain how their proposals fail to ensure that research is a successful democratic process. In other words, despite their insistence that having subjects and community participate in various stages of research enables them to have an equal say in research decisions, I explain how this fails in practice. As I explain in the next section, we need more than just declaring that subjects and community should be involved in order to ensure their active participation in the research process. Consequently, the proposal to involve subjects and community in various research stages is a necessary but not a sufficient condition for ensuring that the research process is democratic in practice.

¹³ Gilman and Garcia 2004.

¹⁴ For arguments regarding the need to have patients more involved in the various stages of decision-making in areas of Medicine beyond medical research, see Sherwin 1998; Donchin 1998 and 2000; and Eckenwiler, et. al. 2008. In addition to the medical context, relational autonomy theorists have argued for making aspects of the legal process more participatory. (See Minow and Shanley 2001 and Nedelsky 1989.)

A primary problem that increasing participation is intended to address is the disparate power between researchers and subjects. Recall from Chapter 3 that, among all of the dichotomies regarding power, education, class, race, gender, and disability, researchers are most often on the dominant side. Subjects' less powerful position in the researcher/subject relationship raises concerns that vulnerable subjects are more easily coerced or manipulated. Yet, also recall not all concerns about disparate power deal with coercion and manipulation. Vulnerable subjects may feel intimidated to provide valuable input in the research process. For example, subjects with little education may feel uncomfortable asking questions regarding details of the protocol that they need in order to make an informed choice. When subjects wish to include community in their decisions regarding research participation, subjects with less power than community members are more open to coercion and to feeling that they cannot or should not provide their input.

In addition to involving subjects and community during the research trial, some argue that they also should be involved in the pre-trial stages of research. Notably, "subjects" in this stage differ from the subjects involved during the research trial itself. In the pre-trial stage, researchers do not know which individuals will participate in the research trial. However, the specific illness, disease, or disability towards which the research is directed narrows down the pool of possible participants. In referring to subject participation in the pre-trial stage, I am referring to this group of potential participants.

One of the problems that including subjects in the pre-trial stages of research is intended to overcome is the problem of unjustly limited options that can impede subjects' autonomy. Recall from Chapter 3 that what makes unjustly limited options problematic for autonomy is not that they limit a person's choices per se but that the limitations result

from unfair discriminatory practices in society. When a person's options are unjustly limited in this way, she is unable to choose among options that she otherwise would be able to which reflect her values and what she believes is in her best interest.

Some might insist that problems relating to unjustly limited options fall under the domain of social justice and the ways in which this can affect autonomy. However, relational autonomy theorists insist that issues of social injustices that bear on autonomy also should be addressed within a principle of respect for autonomy. While relational autonomy theorists acknowledge that the principle of justice should attend to problems regarding unjustly limited options, they also insist that these issues should be attended to within the principle of autonomy as a means of recognizing and attending to how one's social context inescapably bears on one's autonomy.

Notably, problems regarding unjustly limited options can occur as early as the pre-trial stages of research. Prior to beginning the research trial, researchers determine which options they will make available to subjects. Recall from Chapter 3 that this raises concerns regarding researchers failing to reflect critically on possible mistaken beliefs, such as racist, sexist or classist beliefs, which can result in their providing research options that are unjustly limited for certain populations.¹⁵ Involving subjects in the pre-trial stages of research enables them to act as a checks and balances against unjustly limited options by identifying and providing valuable input regarding mistaken beliefs about the characteristics of potential research subjects.

¹⁵ Although some of the options include post-trial activities that directly affect the subject, such as continued monitoring and support, the decision whether and to what extent to make this option available is determined prior to beginning the research.

In addition, some add that the traditional approach of having researchers formulate the agenda and present it to subjects for their approval or disapproval problematically posits researchers as active agents and subjects as passive agents, further perpetuating power differences between them.¹⁶ Baylis, Downie and Sherwin suggest a model of “pursuing research as a collegial activity; under this model, subject-participants and researcher-participants collectively negotiate the terms of participation and the goals of the activity”.¹⁷ Having subjects actively participate in the formulation of the research protocol is intended to make the research process more democratic by having subjects and researchers work together to balance the relevant needs of all participants. For example, subjects can provide input regarding their beliefs and values and how these might best be respected while balancing these considerations with researchers’ interests regarding budgetary restraints and testing the efficacy of particular treatment alternatives.^{18,19}

In addition to involving subjects, some insist that community should be involved in the formulation stage. According to Eckenwiler, Feinholz, Ells, and Schonfeld, lay

¹⁶ Baylis, Downie and Sherwin 1998.

¹⁷ *Ibid.*

¹⁸ As I previously pointed out in Chapter 3, given the differences in race, class, gender, and disability that oftentimes exist between researchers and subjects, researchers are unlikely to understand what may be in subjects’ best interest (see Sherwin 1998, 42). Subjects who are involved in the pre-trial stage can assist researchers by providing this necessary information.

¹⁹ Because the aim of research is to acquire generalizable knowledge about a particular disease, some might insist that researchers are not concerned with looking out for the subjects’ best interest. However, the current guidelines attend to the concern that researchers must balance their goal of acquiring generalizable knowledge with the obligation to look out for the subjects’ best interest, oftentimes insisting that the latter take priority. (See, for example, the Declaration of Helsinki (A:6); the CIOMS Ethical Guidelines (GL8); and the Belmont Report (C:2).

people in the community “often have rich perspectives when it comes to important research questions and to the values that might be at stake in a proposed project”.²⁰ Thus, obtaining community input in the pre-trial stage can help researchers better understand values and concerns that may be important to potential subjects.

Despite the purported benefits of involving subjects and community in the pre-trial stages of research, some might object. There appear to be two primary arguments against involving subjects and community in the early stages of research. First, doing so involves additional expenditures of time and money. My response here is similar to my response to those who object to paying for support mechanisms for vulnerable populations that I presented earlier in this chapter. We can change current guidelines to remove current unnecessary redundancies. This would enable researchers to use this money to implement guidelines that reflect more productive ethical conditions that ensure respect for autonomy in research on human subjects, such as funding support groups and paying for the additional time and effort required to make research more participatory.

Aside from the additional time and money it would take to involve subjects and community in the pre-trial stages, some might object in the name of science, so to speak. They may be concerned that involving lay people in the planning stages of research taints the scientific structuring of the research trial. Researchers have the medical training to understand how to structure a research trial, while subjects and community members most likely do not.

Although researchers have the medical knowledge that is needed to structure certain aspects of the research protocol, they may be ill-equipped to deal with other

²⁰ Eckenwiler, et. al. 2008,163.

aspects that go into formulating a research trial that respects subjects' autonomy. Recall that current guidelines require researchers to act in the subjects' best interest. Yet, given the differences in race, class, gender, and disability between researchers and subjects that I pointed out in Chapter 5, researchers may be unable to adequately determine what is in subjects' best interest. This holds true with regards to differences between researchers and community too. Having subjects and community involved in the pre-trial stage to provide this information can assist researchers in formulating more equitable compensation and care. Thus, involving subjects and community in the pre-trial stage does not taint the research process; in fact, it enhances the overall process by providing necessary, albeit non-medical, information for formulating the research protocol.

Involving subjects and community in the pre-trial stage also helps researchers arrive at a research trial that respects subjects' autonomy by providing a checks and balances against racist, sexist, etc. tendencies. Recall from my discussion earlier in this chapter that involving subjects and community in the pre-trial stages of research can help identify racist, sexist, and classist beliefs from which the researcher may be operating and to correct for these. Hence, contrary to the concern that involving lay people in the pre-trial stages of research will impede the formulation of the research trial, doing so brings many benefits that can lead to a research trial that better ensures respect for subjects' autonomy.

6.3 Problems with Relying on Just One of the Proposed Conditions

Having explained the ethical conditions that others have proposed, I am now in a position to be able to analyze the extent to which relying on any one of these adequately attends to critical reflection and to the negative influences of social structures. Recall that

critical reflection is important because it helps people identify mistaken beliefs that impact their choices. In addition, social structures can negatively impact subjects' autonomy in many ways. The way in which one is socialized based on their race, class, or gender can result in internalized oppression and in not developing fully some of the requisite skills for autonomy. Also, racism, sexism, and classism can result in subjects having far less power in relation to researchers and community members. It can also result in unjustly limited options, which affect subjects' choices.

Although the proposals for requiring critical reflection, incorporating support groups, and increasing subject and community participation attend to these to some degree, none adequately attends to these problems on its own. In what follows, I explain how relying on any one these conditions fails. In the next section, I consider whether a combination of the previously proposed conditions adequately attends to these concerns.

6.3.1 Critical Reflection

As I previously mentioned in my discussion of critical reflection, this is an important condition of autonomous choice. However, critical reflection in itself is insufficient for promoting that subjects' choices regarding research participation are self-governed ones. Due to problems that arise from social structures, subjects may not be able to adequately reflect on their beliefs, values, and choices to determine whether these are in their best interest. For example, problems arising from oppressive socialization, such as internalized oppression or not having fully developed some of the skills necessary for autonomy, can impede their critical reflection. Consequently, additional ethical conditions are needed to attend to the problems that arise from social structures.

6.3.2 Support Mechanisms

Recall that support mechanisms include support groups and counselors. These are intended to remedy several of the problems that arise from social structures. First, support groups and counselors can assist subjects in identifying internalized oppressive beliefs. Second, they can help subjects develop some of the requisite skills for autonomy that they may be lacking as a result of having been socialized as members of oppressed groups. Third, support can strengthen subjects' ability to voice their concerns and express their choices in what otherwise is an imbalanced relationship with researchers and community members.

Despite these many attributes, support mechanisms are too limited when relied on as the only ethical condition to ensure respect for autonomy. The reason is that these mechanisms are bound by the current structure of research; if research only invites subjects' input during the research trial stage, then support mechanisms cannot come into play to assist with problems that arise in the pre-trial stages of research. Yet, as I have explained, subjects' input is needed in the pre-trial stage in order to assist researchers in understanding what may be in the subjects' best interest when formulating the research protocol and in identifying racist, sexist, etc. beliefs that might unjustly limit the options offered as part of the research.

6.3.3 Participation

Whereas support fails to attend to unjustly limited options and inadequate information, recall that these are two of the problems that participation is supposed to address. In addition, the proposal to increase subject and community participation also is directed towards remedying power disparities between subjects, researchers, and

community. Recall that what I have been referring to as the ethical condition of participation refers to the recommendation to include subjects and community in the pre-trial and research trial stages of research. The degree to which this condition addresses the problems to which it is directed (gathering adequate information, addressing power disparities, and attending to unjustly limited options) depends on whether subjects and community are able to provide input in the various research stages in practice.

Notably, inviting subjects and community to participate in the pre-trial and trial stages of research does not necessarily mean that they will become active participants. As Jennifer Nedelsky points out:

Stipulating these requirements does not make them a reality. In particular, it does not mean that [participants] actually take an active part, that they are listened to, or that they feel as though they are actors in the decision-making rather than (indirect) subjects of it.²¹

To illustrate these problems, Nedelsky examines the efficacy of implementing a federal law that is aimed at protecting handicapped children and respecting parents' autonomy regarding decisions about their children's education (Education for All Handicapped Children Act, P.L. 94-142). Part of the provisions of the law includes fostering a democratic process for making educational decisions about handicapped children in state funded schools, including "requiring ongoing participation by the parents in the decision-making, flexibility, individual tailoring of programs, hearings, and full rights of appeal".²² Despite these provisions, a case study by Joseph A. Handler shows that attempts to have parents actively participate in the decision-making process failed in

²¹ Nedelsky 1989, 28.

²² *Ibid.*

many of the schools.²³ The measure of success for making the decision-making process more democratic was the degree of parental involvement in discussions regarding how to structure educational programs for their children. The most common reason cited for the failure to meet this goal was that parents were unable to exercise their autonomy due to power differences between them and members of the educational community. Hence, despite specific provisions for including parent participation, power disparities continued to impede parents' autonomy. This illustrates that relying on formal provisions for increasing participation is insufficient for addressing disparate power in the informed consent relationship.

In addition to encountering problems in practice with regards to remedying power disparities, inviting subjects and community to provide input in the pre-trial and research stage does not attend to problems arising from oppressive socialization. Recall that oppressive socialization impedes autonomy when it results in internalized oppression and in not fully developed autonomy skills. Even if subjects get to provide input in the various stages of research, there is no guarantee that their input will not reflect internalized oppressive beliefs. Also, they may be provided the opportunity to provide input but may fail to do so due to their not having fully developed some of the skills for autonomy, such as self-trust and self-assertiveness. Similar problems regarding internalized oppression and not fully developed autonomy skills arise with community members who are members of oppressed groups. Thus, the ethical condition of insisting that subjects and community provide input in the pre-trial and research stages does not, in itself, ensure respect for their autonomy.

²³ Nedelsky utilizes information from Joseph A. Handler, *The Conditions of Discretions: Autonomy, Community, Bureaucracy* (New York: Russell Sage Foundation, 1986).

6.4 Arriving at a List of Minimally Sufficient Ethical Conditions

Although none of the conditions is sufficient in itself for respecting relational autonomy, some might argue that a combination adequately promotes subjects' autonomy as it relates to informed consent in research. Recall that the various conditions that relational theorists have proposed are critical reflection, support, and participation.

Let us examine how these might work together to promote autonomy. First, those involved in the research process would reflect critically on their beliefs and values in order to identify mistaken beliefs that can impede autonomy. Researchers would check that they were not unjustly limiting subjects' option based on mistaken stereotypes. Subjects would reflect on their beliefs and values as a means of checking that these are self-chosen and do not result from coercion or manipulation.

Support mechanisms would assist subjects in their critical reflection. Support groups and counselors would help subjects identify oppressive beliefs that they may have internalized. In addition, these support mechanisms would help subjects more fully develop some of the requisite skills for making an autonomous choice, such as self-worth, feelings of competency, self-assertion, and self-trust.

Finally, the ethical condition, participation, would enable subjects, and in some cases community, to be involved in the pre-trial stage of research, providing researchers with information regarding the values and concerns of subjects and community so as to arrive at a more equitable research protocol. In addition, subjects would continue to provide their input throughout the duration of the trial, so as to balance power disparities. Support mechanisms would be available during these times to further assist subjects in

identifying oppressive beliefs and nurturing autonomy skills to assist them in providing their input.

Initially, combining the three ethical conditions seems to attend to the various problems that can impede autonomy. Critical reflection enables people to reflect on their beliefs, values, and choices as a means of making them one's own, so to speak. Although critical reflection fails to attend to problems that arise from social structures, support mechanisms and participation are directed towards remedying these problems. Adding support mechanisms attends to problems that arise from oppressive socialization, such as internalized oppression and not fully developing necessary autonomy skills, which can impede autonomy. Including subjects and community in various stages of the research process is directed towards the remaining problems that arise from social structures, unjustly limited options and disparate power. Recall that including input from subjects, and when applicable community, helps reduce the likelihood of unjustly limited options. Including subjects and community in the pre-trial stage and during the trial aims to remedy power differences between them and researchers, thereby addressing the problem of disparate power. With this in mind, it appears that combining these ethical conditions promotes subjects' autonomy in the context of research on human subjects.

Despite the initial appeal, however, this combination is still insufficient. Recall from Handler's analysis of implementing the federal law for educating handicapped children that formal requirements for participation do not ensure the actual inclusion of all participants. Therefore, what we need are conditions that can better promote subjects, and when applicable, community participation.

6.4.1 The Need for an Additional Condition

In order to understand what else is required for respecting people's relational autonomy, it will help to examine a case in which people were able to make autonomous choices amidst many of the impediments to autonomy that I have been discussing. In the previous section, I referred to Handler's analysis of implementing a federal law meant to respect parents' autonomy in the educational decision-making process for their handicap children. Among the different school systems that Handler surveyed, the schools in Madison, Wisconsin were the only ones who created an environment that fostered parents' autonomy in the decision-making process.²⁴ Their success can be attributed to specific methodological differences. Some aspects of their method include conditions already presented, while others provide insight into what additions we can make to our list.

Recall that the ethical condition of participation included having participants provide input in the pre-trial stage. Schools in Madison incorporated this condition by inviting parents to participate "in the earliest stages of assessing the child's needs and planning a program, rather than being called in merely to consent to a diagnosis and plan already formulated (as was generally the case in the other schools)".²⁵ In addition, Madison also incorporated support systems to help alleviate power imbalances between teachers and parents. Parent advocates were appointed to assist parents in understanding the information and supporting them in voicing their concerns. Notably, these parent advocates fulfilled a role similar to Sherwin's proposed counselors.

²⁴ Nedelsky 1989, 29-31.

²⁵ *Ibid*, 29.

In addition to implementing measures much like those encompassed by the ethical conditions of support and participation, teachers in Madison implemented other conditions aimed at encouraging parental involvement in the decision-making process. First, when conflict arose, teachers and parents addressed the conflict, using it as a constructive tool for arriving at a better decision. Second, “the decision-making process was ongoing and open-ended with room for readjustment”.²⁶ In addition, Madison’s success can be attributed to the way in which they framed their overall objective. As Nedelsky summarizes:

Throughout the Madison approach, there is a recognition that the parents are in a *continuing relationship* with the school. The objective is not simply to arrive at a decision to which the parents will not object, but to sustain a relationship such that the necessary ongoing decisions can be *collectively made* in the best interests of the child.²⁷

The Madison schools’ framing of the decision-making process as dynamic and flexible with an overall commitment to gathering the input of all participants explains their unique success.

Although those involved in the Madison schools accomplished this on their own, it is possible to translate this requirement into an ethical condition. For example, an external review board could monitor the process. Among their goals, they could gauge and encourage participation, as well as assist participants in working through conflict. Adding an external board for monitoring the decision-making process to our previous three ethical conditions would address the problem of decreased participation.

²⁶ *Ibid.*

²⁷ *Ibid*, 30 (italics added).

6.4.2 The Need for a Specific Safeguard

At this point, it might appear that our list is complete. First, we have an ethical condition that requires critical reflection to assist in autonomous decision-making. In addition, we have two ethical conditions that attend to the various problems that arise from social structures, providing support systems and participation. As a means of attending to problems regarding participation in practice, we added a fourth condition of having an external review board monitor and encourage subject and community participation.

Yet, our list is not quite complete. Although these provisions ensure that each individual involved in the research process has equal input, not all aspects of the research process should be decided by equally weighting input from subjects and community. In decisions regarding research that directly impact the research subject, such as whether to participate in or withdraw from research, the subject's input must necessarily trump input by community members and researchers. This is due to the fact that, in these cases, the research subject bears the greatest burden. To protect the subject, we must add the safeguard of prioritizing her input in decisions in which she bears the greatest risk of harm.

Although this safeguard appears in many current international guidelines for research on human subjects, it needs further specifications. I propose that prioritizing the subject's decisions should be limited to the time during which the subject is a direct participant of the research. My reason for this insistence is the research subject does not bear the greatest burden in decisions regarding the early and late stages of research, such as formulating the protocol and post trial benefits. In such cases, this burden is shared

between subjects and community. Consequently, I propose including a limited but necessary safeguard of prioritizing subjects' choices in the stages of the informed consent process in which they bear the greatest burden.

6.5 Conclusion

In this chapter, I have argued for a list of minimally sufficient ethical conditions for promoting subjects' autonomous decision-making with regard to participation in research. To do so, I began by addressing the ethical condition, critical reflection. In addition, I presented two previously proposed conditions directed towards promoting relational autonomy in the medical context, support mechanisms and participation.

After explaining why none of these is sufficient in itself for promoting autonomy, I examined whether the combination of critical reflection, support, and participation adequately attend to the problems relating to respecting autonomy in the research setting. Due to problems that arise with regard to getting subjects to participate in the research process, I argued for a fourth ethical condition, an external review board for monitoring and encouraging participation during the pre-trial period and throughout the research trial. Lastly, I insisted we should add a fifth condition to ensure that subjects' choices trump community members' input in aspects of research in which subjects bear the greatest risk.

To summarize, I concluded this chapter with a list of five ethical conditions intended to promote autonomy as it relates to informed consent in research on human subjects: critical reflection, support mechanisms, participation, external monitoring, and prioritizing subjects' choices. I intentionally arrived at a list of minimally sufficient conditions as a means of leaving enough flexibility for different cultural contexts. I will

return to this list in the final chapter, where I provide an example of how these conditions can be implemented in current informed consent guidelines.

Prior to doing so, however, it is necessary to highlight the relationship between autonomy and informed consent (Chapter 7) and explain how this is reflected in the current guidelines for informed consent in research on human subjects (Chapter 9). This will enable us to better understand the extent to which the various guidelines incorporate the ethical conditions I have presented for promoting respect for relational autonomy as it relates to informed consent in research.

Chapter 7: Informed Consent & Autonomy

Having spent the previous chapters focusing primarily on autonomy, I now broaden my focus to include informed consent in research on human subjects. In this chapter, I discuss informed consent and how it is commonly justified by the principle of respect for autonomy within the medical context. I also explain how the principle of respect for autonomy has taken on this role in international informed consent guidelines for research on human subjects. After providing this background information, I end the chapter by addressing primary objections to relying on the principle of respect for autonomy to justify informed consent.

In doing so, I address what I believe are the strongest objections to insisting that respect for autonomy justifies informed consent. The first objection I address is by Neil C. Manson and Onora O'Neill.¹ They insist that the principle of autonomy does not justify informed consent in practice. If it did, Manson and O'Neill insist that relying on autonomy would justify too much in some ways and too little in other ways. In response, I explain that their objections rest on a mistaken interpretation of what it means to justify informed consent by the principle of autonomy.

The second objection I address is by Joan Tronto.² She insists that the way that the principle of autonomy has come to justify informed consent results in structuring consent so that it overlooks the ways that social injustices can impede a person's ability to make a self-governed choice. She also insists that this reliance results in structuring informed consent so that it fails to remedy problems that arise with regards to power disparities. In

¹ Manson and O'Neill 2007.

² Tronto 2009.

responding to her objections, I explain how an account of informed consent that is justified by respect for relational autonomy attends to these problems.³

7.1 Informed Consent

As one can well imagine, the literature on informed consent is vast and controversial. There is no universally agreed upon theory that spells out the necessary and sufficient conditions for valid informed consent. Although each theory differs with regard to specifics, there appears to be a general definition from which each theory builds. In general, informed consent deals with a person's choice to either participate in or abstain from something, for example, a medical procedure or a research study.

There are two minimal conditions of informed consent, disclosure and consent. Medical practitioners are under an obligation to disclose an adequate amount of information to patients regarding possible treatment. Various accounts of informed consent will differ with regards to what constitutes an adequate amount of information. For example, as will become apparent later in this chapter, Manson and O'Neill insist that the common account of informed consent requires practitioners to disclose as much information as possible to patients.

Upon receiving this information, patients either choose a particular treatment or not; this is the consent component for informed consent. Admittedly, this amounts to consent in its most simplistic form. My reason for insisting that this simple definition of consent is one of two minimal conditions for informed consent is to be able to

³ By an account of informed consent, I mean the way that we structure how we obtain informed consent. Our justification for informed consent will dictate how we structure an account of informed consent. My arguments regarding differences in informed consent accounts that result from justifying informed consent either by a traditional or a relational autonomy account illustrates this.

incorporate differences in how theorists define consent. For example, many argue that patients must understand the information that they receive in order to provide valid consent. In insisting that we should focus on informed consent as a communicative process, Manson and O'Neill emphasize the importance of comprehension.⁴ Yet, others, such as Gopal Sreenivasan, argue that disclosure is enough; comprehension is not required for valid informed consent.⁵ A simplistic definition of consent as approving or disapproving of a particular treatment allows for both of these definitions of consent.

Of course, we can argue that certain accounts are better than others. In defending an account of informed consent that is justified and guided by the principle of respect for relational autonomy, I address this issue. Prior to doing so, it is necessary first to explain how informed consent currently rests on the principle of autonomy within the context of research on human subjects.

7.2 The Emergence of Informed Consent in Research

The importance of obtaining research subjects' informed consent came into the public eye during the Nuremberg Trials of the 1940s, wherein the military court at Nuremberg tried Nazi doctors for mistreatment of concentration camp victims who served as research subjects. In order to determine whether this treatment amounted to torture, the courts sought the advice of expert witnesses to determine the ethical standards that should guide research. In clarifying and elaborating on the physician witnesses' recommendations, the court arrived at a set of ethical standards for protecting research

⁴ Examples of others who also insist that valid informed consent requires understanding, see Berg, Appelbaum, Lidz and Parker 2001, c.3; Dodds 2000.

⁵ Sreenivasan 2003.

subjects. The standards that were included in the court's statement have become known as the Nuremberg Code.⁶

Among the ten guidelines contained in the Nuremberg Code, Guideline 1 deals with informed consent. It begins with the statement, "The voluntary consent of the human subject is absolutely essential".⁷ Because the Code was derived from the military court's brief, it lacked enforceability.⁸ However, it set the stage for focusing on the need to promote subjects' informed consent in research.

In 1966, the United States took the lead with regards to passing the first administrative regulatory guidelines for research on human subjects. At this time, the Public Health Service issued a policy statement, which spelled out the requirements for research funded by the National Institutes of Health. Included in the requirements was the obligation for researchers to obtain research subjects' informed consent.⁹ To date, informed consent continues to be mandatory in the various regulatory guidelines for research on human subjects. This will become more apparent in my discussion of these guidelines in Chapter 9.

7.3 Autonomy as the Philosophical Foundation for Informed Consent Guidelines

Although the Public Health Service 1966 policy statement spelled out guidelines

⁶ *Nuremberg Code* 1949.

⁷ *Ibid.*

⁸ Although the World Medical Association created the Declaration of Helsinki in 1974 as a means of clarifying the ethical guidelines set out in the Nuremberg Code, the Declaration also was not legally binding. However, the Declaration continues to be referred to as the guiding document on which many current ethical guidelines for research on human subjects were constructed. I explain more about the Declaration in Chapter 9.

⁹ Berg, Appelbaum, Lidz, and Parker 2001, 255.

for research funded by the NIH, it did not address the justification for informed consent. Discussions of the justification for informed consent officially began in 1974, when the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. One of its first tasks was to identify the ethical principles that should guide research on human subjects and explain how these are linked to specific guidelines. The need to clarify the ethical guidelines for research on human subjects was a response to the discovery of numerous unethical research trials that had occurred. For example, in 1973, it was discovered that researchers at the Jewish Chronic Disease Hospital had injected elderly patients with live cancer cells without informing them of this.¹⁰ In 1971, it was discovered that researchers had failed to inform African American research subjects enrolled in what has become known as the Tuskegee Trials that penicillin was an available treatment for the last two decades of this trial.¹¹

Unethical research practices like these provided the impetus for setting up the Commission to determine what principles should guide ethical research. In 1978, the Commission arrived at the Belmont Report. Based on this report, the requirement to obtain subjects' informed consent stems from the need to respect subjects' autonomy.¹²

The connection between autonomy and informed consent in the research context is not surprising. Insisting that research subjects must consent to participating in a research trial is a means of recognizing and respecting that they can be harmed by research. Insisting that protection come in the form of requiring that researches obtain

¹⁰ Hyman v. Jewish Chronic Disease Hospital 1965.

¹¹ Jones 1993.

¹² Department of Health, Education and Welfare. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979, Part B:1.

subjects' informed consent in order to enroll them in a research trial is a means of recognizing and respecting subjects' right to make self-governed choices regarding important life choices, such as research participation. Additionally, requiring informed consent as a means of respecting subjects' autonomy in the research context provides an important protection for subjects from oppressed populations who are in a more vulnerable position of being more easily coerced or manipulated.¹³ As I explained in Chapter 5, differences in race, class, gender, and disability oftentimes result in subjects having far less power than researchers. Since subjects are the ones most affected by interventions that are part of research trials, it is necessary to ensure that their decisions are self-governed.

7.4 Objections to Autonomy as Justifying Informed Consent

Having discussed the relationship between informed consent and autonomy, I am now in a position to address what I believe are some of the strongest objections to relying on the principle of autonomy to justify informed consent. As I previously mentioned, I have chosen to address objections by Manson, O'Neill, and Tronto.

Prior to addressing their objections, allow me to address a concern that the reader may have at this point. Some might wonder why I do not defend the principle of autonomy against other proposed justifications for informed consent. For example, informed consent could be justified by the principle of non-maleficence, or the duty of medical practitioners not to inflict evil or harm patients. When justified by this principle,

¹³ For an argument in support of maintaining a reliance on autonomy as justifying informed consent in the medical context because it helps protect vulnerable subjects, refer to Donchin 1995, 50.

informed consent is meant to protect patients against harmful medical interventions.¹⁴

As I mentioned in Chapter 1, my reason for not attending to other possible justifications for informed consent is that I prefer to attempt to work within the already existent framework of the principle of autonomy as justifying informed consent. Whenever problems can be resolved by working within an already existent framework, this provides a more feasible solution. Because I believe that my proposal to revise the principle of autonomy to reflect a relational autonomy account remedies the problems that the traditional autonomy account encounters, I do not feel the need to examine other possible justifications for consent. This is not to imply that these other justifications are not noteworthy; they simply go beyond the scope of this dissertation. Having explained my reasons for focusing on objections to relying on the principle of autonomy as justifying informed consent, I now turn to examining those objections.

7.4.1 Autonomy Justifies Too Much and Too Little

In *Rethinking Informed Consent*, Neil C. Manson and Onora O'Neill argue that relying on the principle of autonomy to justify informed consent encounters insurmountable problems.¹⁵ Because their larger concern is with informed consent as a communication process, it is necessary to understand the model of communication that they believe underlies the common account of informed consent. This enables us to understand how they interpret the principle of autonomy and why they believe that relying on this principle to justify informed consent is problematic.

According to Manson and O'Neill, the standard account of informed consent

¹⁴ For an overview of justifications for informed consent other than the principle of autonomy, refer to Beauchamp and Childress 2009, and Levine 2003.

¹⁵ Manson and O'Neill 2007.

reflects what they refer to as the conduit-container model of communication.^{16,17} Based on the conduit-container model, information is something that is possessed by some people and is conveyed to others. Information is seen as quantifiable stuff that is neatly contained.¹⁸ For example, computer software contains bits of information, books contain chapters of information, and people contain (know) various details about things. In communication, those who hold the information convey it or transfer it to others, thereby acting as a conduit, while others, the recipients, receive the information. To illustrate, you might know a lot about car maintenance. I do not. In communicating this information to me, you act as a conduit that conveys the information to me, while I am the passive recipient who receives the information.

Manson and O'Neill insist that the conduit-container model of communication underlies the standard account of informed consent, which they refer to as consent-as-disclosure-for-decision-making or what I will refer to as consent-as-disclosure for short.¹⁹ Based on this account of informed consent, researchers or doctors disclose information about research trials or medical treatments, at which point subjects or patients make a decision regarding their participation. The purpose of consent-as-disclosure is to provide people with information for the purpose of enabling them to make self-governed

¹⁶ Manson and O'Neill derive the conduit-container label from Michael Reddy, "The Conduit Metaphor: A Case of Frame Conflict in Our Language about Language" in A. Ortony (ed) *Metaphor and Thought* (Cambridge: Cambridge University Press, 1979).

¹⁷ It is important to note that Manson and O'Neill are not arguing that the conduit-container model of communication is mistaken; they point out that it correctly describes part of the communication process. However, as will become apparent in my discussion of their alternative informed consent account which relies on a different communication model, the conduit-container model fails to attend to all of the relevant aspects of successful communication.

¹⁸ Manson and O'Neill 2007, 36-7.

¹⁹ *Ibid*, 69.

decisions about their medical treatment or research participation. In other words, the reason for obtaining informed consent is to respect people's ability to make autonomous choices.

As Manson and O'Neill insist, the account of autonomy that justifies current informed consent practice is not respect for mere choice. Instead, it is respect for what they refer to as rational or reasoned choice, those choices that people make once they have reflected on them and have good reason for choosing them.²⁰ According to them, the focus on rational choice emphasizes the content of the information. Thus, they insist that the quality of the consent that is provided is determined by the amount of information that is disclosed. In other words, they believe that those who espouse respect for rational autonomy believe the more information a person has, the more he will be able to determine whether he has good reason to make particular choices, and, consequently, the more rational his choice will be. Mapping this onto informed consent, then, they insist that consent-as-disclosure demands that practitioners should provide all the information about treatments or research to subjects in order for subjects to make a self-governed choice regarding their medical treatment.

Manson and O'Neill argue that there are several problems with the standard approach of justifying informed consent by appealing to the principle of autonomy. In objecting to the justification of autonomy and how it informs consent, they begin by pointing out problems they believe would occur if informed consent ensured autonomy in practice. Recall that consent-as-disclosure is justified by respect for rational autonomy, which aims to ensure that people make the most reasoned choices regarding medical

²⁰ *Ibid*, 95.

treatment and research. Manson and O'Neill argue that using informed consent to ensure rational autonomy would justify too much in some ways, while justifying too little in others.

First, they insist that ensuring respect for rational autonomy justifies too much because it justifies too many kinds of choices, including those entailing great risk.²¹ According to Manson and O'Neill, respect for rational autonomy requires there be no restrictions on people's choices so long as they reflected on and reasoned through their choices.²² Consequently, respect for autonomy would include respecting a person's choice to participate in a risky drug trial (one with a high probability of harm and very little, if any, benefit to the subject) as long as she had reasoned through this decision. We can imagine how a person might decide to participate in risky research. Perhaps the subject has little regard for her own well-being and is not bothered by the harm and the lack of benefits.

In responding to this objection, it is necessary to carefully reflect on what we find problematic in people choosing to enroll in risky research. When we do, I believe it will become apparent that concerns other than risk make these choices problematic. To illustrate, consider the fact that, though we might disagree with their decisions, we oftentimes do not interfere with people's autonomous choices that entail great risk and are offset by the remote possibility of a benefit. For example, we allow a person to make an autonomous decision to invest in a business venture that has little or no chance of

²¹ Manson and O'Neill 2007, 70.

²² Manson and O'Neill note that current regulations for informed consent in research on human subjects limit subjects' choices. Later in this chapter, I address their arguments regarding how this indicates that principles other than respect for autonomy bear on informed consent, indicating problems with insisting that informed consent ensures autonomy.

success. We also allow people to make risky choices with regards to their physical well-being, such as doing what is called a solo ascent, which entails vertically climbing hundreds of feet along the face of a rock formation without any safety mechanisms. Admittedly, we oftentimes are more concerned with people making choices that involve physical risk than those that involve financial risks.

Since medical treatments and research entail physical risks, we tend to be more concerned about these decisions. However, I believe that when we stop to think about it, this concern stems from factors that come into play in these contexts that can impede autonomy. Consider the example of someone who is extremely sick and is unable to get medical care because she lives in a less developed country where healthcare is unavailable. In hopes of receiving some level of care for her illness, she enrolls in a risky research trial that offers a remote chance of benefit. In this case, we are concerned that the research subject's dire circumstances have forced her hand, so to speak. When dire circumstances force one's hand, we refer to this as a coercive offer. Notably, it is not the risk that is problematic as much as it is the concern that a coercive offer might impede a research subject's ability to make an autonomous decision regarding her research participation.

Prior to addressing Manson and O'Neill's other objections, allow me to briefly attend to a concern that the reader might have at this point. Some have insisted that dire circumstances are not coercive, and, thus, do not impede a person's ability to make an autonomous choice. For example, Martin Wilkinson and Andrew Moore insist that a necessary condition for being a coercive offer is that the researcher "must be responsible

for at least one of the unacceptable options”.²³ In the previous example, the subject has two options; she can participate in research and receive the necessary medical care, or she can choose not to, in which case she will not get the appropriate care. In this case, there is only one unacceptable option, not getting the necessary medical care. Because it appears that the researcher is not responsible for poor healthcare in less developed countries that result in this bad option, one might conclude that my previous example is not a coercive offer.

Initially, this argument is convincing. After all, researchers do not seem to be causally responsible for the subject’s dire circumstances. Yet, some have argued that individuals that support social institutions that lead to dire circumstances are responsible for those circumstances. Thomas Pogge insists that social institutions in developed countries are responsible for the impoverished conditions in less developed countries, including ill health and poor healthcare.²⁴ Researchers support these social institutions by receiving funding from corporations and government agencies. In supporting these social institutions that have caused poor healthcare in less developed countries, researchers become causally responsible for the dire circumstances. If Pogge is correct, then, contrary to Wilkinson and Moore’s insistence, researchers are causally responsible for the bad option of poor healthcare. Consequently, when ill health and poor healthcare force subjects to enroll in research trials, these amount to coercive offers that impede autonomy.²⁵

²³ Wilkinson and Moore 1997, 378.

²⁴ Pogge 2002.

²⁵ Whereas Wilkinson and Moore insist that the researcher must be causally responsible for at least one of the bad options, others have argued that a necessary condition for coercive offers is that the researcher must intend to use the bad circumstance to force

In addition to justifying too much, Manson and O'Neill insist that relying on respect for autonomy justifies too little.²⁶ Recall that they believe that truly respecting autonomy requires providing people with as much information as possible as a means of enabling them to make as informed, or as reasoned, a choice as possible. It is important to clarify that the current practice of informed consent does not mandate providing all information, nor do Manson and O'Neill think it should. Instead, their point is that, if we were to take respect for autonomy as seriously as it should be taken were it to justify informed consent in practice, we would adopt this rigorous standard.

Because very few people would be able to make an autonomous decision when provided with as much information as possible, Manson and O'Neill insist that implementing this rigorous standard would justify too little. Providing people with too much information oftentimes overwhelms their ability to comprehend the information necessary for making an informed choice. They also insist that relying on autonomy to justify informed consent would justify too little because it fails to guide us in how to treat those who cannot meet the competency requirements for consent, such as severely mentally handicapped people or very young children.

At this point, we should question why Manson and O'Neill insist that consent-as-disclosure mandates providing all possible information. Recall that they explain that the

one's hand (Wertheimer 1999, 269-71; Brody 2003, 127-8; Faden and Beauchamp 1986, 344-46). Those who argue for this necessary condition do not believe that dire circumstances, in themselves, impede autonomy. So long as the subject is able to freely choose an option, she is considered to have made an autonomous choice. However, this objection frames subjects as making a sovereign choice regarding research participation. As such, it overlooks the ways that social structures can bear on consent, as I explained in Chapter 5. (Also see, Sample 2003). For an argument directed specifically towards the way in which dire circumstances in less developed countries amount to coercive offers, see Moodley 2002.

²⁶ Manson and O'Neill 2007, 71.

purpose of consent-as-disclosure is to enable patients and research subjects to make informed decisions regarding treatments and research participation. It appears that they conclude that this necessarily entails providing all information based on their insistence that consent-as-disclosure rests on the conduit-container model of communication. Researchers and physicians have information that subjects and patients need to receive to make decisions.

Yet, we have reason to question this assumption. The current guidelines for informed consent do not appear to rest on the linear conduit-container model of communication that posits practitioners as acting as a conduit to convey all information to the passive container we call the research subject or patient. Instead, guidelines for informed consent recognize and address the importance of subjects and patients understanding enough of the details of their options in order to make a self-governed choice. As the Belmont Report explains, it is generally accepted that there are three primary aspects to informed consent: “information, *comprehension*, and voluntariness”.^{27,28}

Although the current informed consent guidelines emphasize the need for subjects to comprehend the information about their research participation, there will still be those who lack the requisite capabilities to comprehend this information. Manson and O’Neill are correct that the severely mentally handicapped and very young children cannot provide informed consent. They also are correct in pointing out that informed consent

²⁷ Belmont Report 1979, Part C:1.

²⁸ Some insist that valid informed consent does not require comprehension; disclosure alone is sufficient. For example, refer to Screenivasan 2003. Although we can disagree about whether informed consent requires comprehension in theory, my point here is that the current practice of informed consent requires comprehension, as is illustrated by the current guidelines for informed consent in research on human subjects.

fails to inform us how to treat these people. However, this problem is not unique to consent-as-disclosure. As will become apparent in the next chapter in my explication of Manson and O'Neill's alternative informed consent account, which frames informed consent as a means of temporarily waiving certain rights so that one can undergo medical interventions, the same people who lack the requisite skills for rational autonomy also lack the requisite skills for adequately understanding the relevant information and commitments entailed in temporarily waiving certain rights. In both cases, we must turn to principles other than respect for autonomy to guide us regarding how to treat those who cannot consent.

This brings us to Manson and O'Neill's final objection to justifying informed consent by the principle of autonomy.²⁹ If the principle of respect for autonomy justifies informed consent, then informed consent should be structured so as to ensure subjects' autonomy. Yet, Manson and O'Neill insist that informed consent, in practice, does not ensure autonomy. Recall that they insist that respect for autonomy amounts to making sure that subjects have the opportunity to make any reasoned choice they wish with regards to research. In practice, a person's ability to consent is limited by current regulations that prohibit certain choices. For example, current guidelines prohibit researchers from enrolling subjects in trials that have substantial risk to them and little or no benefit.^{30,31} Moreover, these limitations are justified by principles other than

²⁹ Manson and O'Neill 2007, 71-2.

³⁰ Manson and O'Neill do not provide examples, most likely, because it is a well-known fact that informed consent guidelines limit subjects' choices. For example, see the CIOMS Guidelines 2002, GL8: Benefits and Risks of Research Participation; Belmont Report 1979, C2: The Systematic Assessment of Risks and Benefits; Universal Declaration of Bioethics and Human Rights 2005, Article 4: Benefit and Harm.

³¹ Aside from this safeguard, guidelines do not limit the option for research participants

autonomy; namely, they are justified by the principle of beneficence, or doing what is in the subjects' best interest.

In response, I disagree with Manson and O'Neill's insistence that the fact that informed consent, in practice, does not entirely ensure subjects' autonomy gives us reason to reject autonomy as the justification for informed consent. In stating that informed consent should ensure autonomy, we should set a realistic not an idealistic standard. Although I agree that the current way that informed consent is structured can be improved to better ensure autonomy, even a revised account of informed consent, such as a relational autonomy based account, is unable to attend to all of the restraints to autonomy. For example, no structuring of informed consent will be able to overcome the fact that some subjects live in areas where there is little or no healthcare. Consequently, we may need to place limits on the choices people make regarding research simply because the chances of their making an autonomous choice in such dire circumstances is questionable. Although Manson and O'Neill acknowledge this, it is unclear why they insist that it poses a problem for informed consent. As I mentioned in Chapter 1, informed consent procedures cannot be expected to remedy grave social injustices. Hence, while informed consent aims to ensure respect for autonomy to the greatest possible extent, the principle of beneficence steps in to protect subjects against currently irreparable social injustices that might impede autonomy.

from vulnerable populations to be able to participate in research. In fact, some guidelines encourage providing this option. For example, the CIOMS Ethical Guidelines, another international ethical guideline for research on human subjects, encourage research on vulnerable groups, stating, "Members of vulnerable groups also have the same entitlement to access to the benefits of investigational interventions that show promise of therapeutic benefit as persons not considered vulnerable, particularly when no superior or equivalent approaches to therapy are available (CIOMS 2002, Guideline 12)".

To summarize, Manson and O'Neill object to relying on autonomy to justify informed consent. First, they insist that doing so would justify too much and too little. Second, they argue that informed consent is not justified by autonomy, in practice, due to the fact that current informed consent guidelines place limitations on subjects' choices with regards to research participation. In response, I explained how these two objections rest on the mistaken interpretation of what it means for the principle of autonomy to justify informed consent. Contrary to Manson and O'Neill's insistence, relying on the principle of autonomy to justify informed consent does not seem problematic. Although this seems to reinforce relying on the common account of autonomy to justify informed consent, my arguments in response to Tronto's objections and in response to the problems that I argue the alternative accounts encounter highlight the need to revise our reliance on autonomy as the justification for informed consent to reflect a relational autonomy account.

7.4.2 Autonomy Fails to Adequately Attend to Social Injustices and Power Disparities

In "Consent as a Grant of Authority: A Care Ethics Reading of Informed Consent", Joan Tronto insists that relying on the principle of respect for autonomy to justify informed consent is problematic.³² According to her, it fails to attend to the ways that social injustices and disparate power can impede a subject's ability to make a self-governed choice. In other words, despite the insistence that informed consent ensures autonomous choice, Tronto argues that it fails to do so.

In order to understand what she believes are the shortcomings of justifying informed consent by the principle of autonomy, we must first understand the

³² Tronto 2009.

characteristics of informed consent that she believes arise from relying on the principle of autonomy. Tronto refers to the standard account of informed consent that is guided by the principle of respect for autonomy as consent-as-autonomy. Consent-as-autonomy frames medical decisions as a sovereign choice which patients make. As such, it treats medical decisions much like other consumer decisions that people make. Doctors disclose relevant information to patients so that they can decide whether or not to have a particular medical treatment or to participate in research. She insists that the common practice of consent-as-autonomy oftentimes amounts to a one-time occurrence, wherein practitioners disclose information and patients make a choice.

Tronto argues that consent-as-autonomy encounters two problems. First, in isolating informed consent to a one-time occurrence and considering it to be a sovereign choice that patients make, consent-as-autonomy overlooks the larger social context and the relevant injustices that impede patients' ability to provide valid consent. For example, it overlooks possible sexist or racist practices that can unjustly limit healthcare options prior to the physician presenting these options to patients.

In addition, she argues that consent-as-autonomy fails to adequately address the ways that power disparities can impede a person's ability to make a self-governed choice. Recall that consent-as-autonomy frames informed consent as a sovereign choice, which patients make, much like other consumer choices. Yet, patients are not situated like independent consumers. As a result of their illness or disease, they rely on their doctors. This dependency makes them more vulnerable to possible manipulation or coercion by doctors.

To combat possible problems of coercion that can arise from power disparities,

consent-as-autonomy uses rights as a means of empowering patients in the doctor/patient relationship. Recall that consent-as-autonomy focuses on the need for the patient to be able to make a self-governed choice regarding her medical treatment. In doing so, it frames informed consent as a right that patient's have. Tronto gives the example of New York's Patient's Bill of Rights, which lists informed consent as one of the patient's rights.³³ Corresponding to this right is the doctor's duty not to act so as to restrict patients from being able to provide informed consent. When doctors coerce patients, they fail to fulfill this duty. The patient's right to make a self-governed decision regarding her medical treatment is violated, and the patient has legal recourse against the physician. Thus, consent-as-autonomy uses informed consent to act as a "trump" card to keep the more powerful person, the doctor, from using his power to coerce a patient.

Although rights might protect patients against coercion, Tronto points out that it is not a good tool for protecting against manipulation. Cases of manipulation are much more difficult to recognize. In support of this claim, she refers to Howard Brody's work on how doctors are able to manipulate information in order to get patients to agree on a particular medical intervention.³⁴

To summarize, Tronto objects to using the principle of autonomy to justify informed consent. First, it overlooks the ways that social injustices can impede a person's ability to make a self-governed choice regarding medical treatment or research participation. Second, it is ill equipped to deal with the possibility of medical practitioners or researchers using their position of greater power to manipulate patients or subjects. Because my solution to these problems is to rely on the principle of respect for

³³ Tronto 2009, 186.

³⁴ Brody 1992.

relational autonomy, allow me first to address Tronto's argument against doing this.

Although Tronto acknowledges the benefits of relying on relational autonomy, she rejects it as a possible solution to the problems that the standard principle of autonomy encounters. She acknowledges that relational autonomy attends to the problems relating to social injustice and power disparities that can impede valid informed consent. However, she insists that an account of relational autonomy fails to provide us with the details regarding how we ought to structure informed consent to overcome these problems.³⁵

In responding to Tronto's objections, it is unclear why she insists that the specific solution to remedying these problems must be spelled out in the principle of respect for relational autonomy. An account of relational autonomy identifies the problems that can arise with regards to ensuring that people make self-governed choices. Recall from Chapter 3 that social injustices and disparate power are among the problems that relational autonomy theorists identify. Once we have identified these problems, we can construct a set of ethical conditions for attending to the problems that relational autonomy accounts identify, as I demonstrated in Chapter 6. Moreover, we can use these conditions to arrive at specific guidelines for how to structure informed consent so that it ensures respect for relational autonomy, as I explain in Chapter 10. For example, to attend to social injustices that can unjustly limit subjects' options, I propose including subjects in the pre-trial stages of research to act as a checks and balances. As a means of remedying power disparities, I propose providing vulnerable subjects with support mechanisms, such as support groups and counselors, to ensure that they are able to make

³⁵ *Ibid*, 189.

autonomous decisions regarding their research participation. Thus, contrary to Tronto's insistence, relational autonomy can provide the framework for how we ought to structure informed consent so as to ensure that subjects make self-governed choices regarding research participation.

7.5 Conclusion

In this chapter, I explained how informed consent became important in medical research and how it has come to rest on the philosophical foundation of autonomy. After doing so, I addressed objections to this common practice of justifying informed consent by the principle of respect for autonomy. The first set of objections I addressed was by Manson and O'Neill, who argued that the principle of autonomy both justifies too much and too little with regards to informed consent. In response, I argued that this is not the case. I then addressed objections by Joan Tronto, who insisted that justifying informed consent by appealing to the principle of autonomy overlooks the ways that social injustices and disparate power impede autonomy. In response, I explained how justifying informed consent by the principles of relational autonomy attends to these problems.

Having explained how we can maintain the current reliance on the principle of autonomy as justifying informed consent by revising our account of autonomy, I devote the next chapter to examining other possible solutions. Specifically, I examine proposed alternative accounts of informed consent that are directed at ensuring respect for subjects' autonomy but that insist that we need more than the principle of respect for autonomy to achieve this. In my analysis, I conclude that revising the principle of autonomy to reflect a relational autonomy account provides a better solution for ensuring that people make self-governed choices regarding their medical treatment or research participation.

Chapter 8: Addressing Alternative Solutions

In the previous chapter, I argued that relational autonomy provides us with an account of informed consent that overcomes the problems with the standard or traditional autonomy account as justifying informed consent. To further illustrate the benefits of relying on relational autonomy, I analyze the feasibility of other possible solutions to structuring informed consent so that it is still aimed at ensuring that people make self-governed choices regarding medical treatment and research participation but does not rely on the traditional principle of autonomy to accomplish this. Because it is beyond the scope of this dissertation to examine all alternative accounts, I have chosen to present a brief analysis of alternative accounts of informed consent as a means of indicating how a relational account of informed consent fares better than some of the proposed alternatives. Due to the limited scope of my analysis, I am not claiming that an account of informed consent that is guided by a relational autonomy account is best; instead, I am arguing that it is preferable.

To arrive at this conclusion, I examine and reject informed consent accounts by Manson, O'Neill, and Tronto.¹ After pointing out insurmountable problems with their accounts, I explain how an account of informed consent that is based on respect for relational autonomy overcomes these problems, giving us good reason to favor this account.

8.1 Consent-as-Waiver

Recall, from Chapter 7, that Manson and O'Neill insist that the way that informed consent has been structured to rely on respect for autonomy fails to ensure that people

¹ Manson and O'Neill 2007; Tronto 2009.

make self-governed choices regarding their medical care or research participation. Also recall that their reason for arguing against relying on the principle of respect for autonomy is that they believe that this principle is equated with respecting rational choice. According to them, the emphasis on rational choice justifies too much by allowing an individual to make a risky choice, so long as he has reflected on his reasons for making the choice. They also insist that it justifies too little, since not many people will meet the standard of being able to rationally reflect on their choices. Consequently, they conclude that the way that informed consent has been structured so as to respect the principle of autonomy actually fails to ensure that people make self-governed decisions.

As a better way of accomplishing this goal, Manson and O'Neill insist on broadening the focus of informed consent beyond simple choice to focus on consent as a communicative process. They argue that attending to the ways that consent as a communication process affect a person's ability to provide valid consent is a better solution for ensuring autonomous choice.^{2,3}

As with my explanation of their interpretation of the standard account of informed consent that is justified by the principle of autonomy, I begin by explaining the model of communication that underlies Manson and O'Neill's alternative account of informed consent, a model that they call the agency model.⁴ The agency model highlights the ways

² Mason and O'Neill 2007, 26-7.

³ Although Manson and O'Neill insist that consent-as-waiver better ensures respect for subjects' self-governed choices, their focus on consent as waiving rights narrows the scope of consent to those choices that deal with medical interventions or research trials that would violate a person's rights had she not temporarily waived them. Thus, they believe that consent-as-waiver has a more limited scope than the standard account of informed consent, or consent-as-disclosure (Manson and O'Neill 2007, 78).

⁴ *Ibid*, 50.

in which communication requires the agency of all those involved. Unlike the conduit-container model that they insisted underlies the common account of informed consent, or consent-as-disclosure, the agency model does not think of patients and subjects solely as recipients of information. Instead, the agency model recognizes that patients and subjects exercise agency by doing such things as asking clarification questions and sharing relevant information.⁵

According to Manson and O'Neill, highlighting the agency of all those involved in communication broadens the focus of informed consent to attend to the epistemic and ethical norms that impact how successful the communication process is. In general, epistemic norms deal with ensuring that participants understand and engage in the information being shared.⁶ Although Manson and O'Neill argue that some of the relevant epistemic norms that come into play will be specific to the context of a particular communication, they also insist that there are epistemic norms to which almost all successful communication must adhere. For example, participants should communicate information that is intelligible. In addition, they should share only information that is relevant. Providing too much information for a particular context is unnecessary and can overwhelm people's comprehension. In order to determine what constitutes intelligible and relevant information, participants must be familiar with each other's background knowledge. Doing so enables the participants to determine what others are capable of understanding and what others might already know, so as to avoid unnecessary repetition. Successful communication also requires more than sharing intelligible and relevant information. Participants must feel confident that the person who is sharing information

⁵ *Ibid*, 61-2.

⁶ *Ibid*, 62; 84-90.

is communicating the information in an honest way, which Manson and O'Neill refer to as truthfulness. Also, it must be the case that the material itself is the true. Together, these universal epistemic norms, intelligibility, relevance, adequate accuracy, truth and truthfulness, assist in successful communication.⁷

In addition to epistemic norms, Manson and O'Neill insist that ethical norms also come into play in successful communication.⁸ Simply put, ethical norms deal with commitments and obligations that relate to our communications. These obligations might arise out of a particular communication between two people.⁹ For example, a student and I might talk about meeting to discuss coursework. The result of this communication might be that both of us take on the commitment to meet at a particular place and time.

In addition to ethical obligations that stem from a particular communication between people, there are universal obligations that direct the communication process.¹⁰ For example, persons are prohibited from using duress, manipulation, and coercion in their communications with others. Thus, while I am communicating with a student about the possibility of meeting to discuss coursework, I cannot coerce or manipulate her to say that she will meet with me during office hours.

⁷ *Ibid*, 64.

⁸ Because many of the relevant norms for communication can be both epistemic and ethical, Manson and O'Neil are not particularly concerned with classifying which norms are ethical and which are epistemic (2007, 92). However, they indicate that epistemic norms will deal primarily with understanding, while ethical norms deal with commitments and obligations regarding actions.

⁹ Manson and O'Neill 2007, 90.

¹⁰ *Ibid*, 92.

Manson and O'Neill use the agency model of communication to frame their revised account of informed consent, which they call consent-as-waiver.¹¹ Consent-as-waiver focuses on the role of consent as a waiver by which people temporarily waive rights that would otherwise be violated by research or medical treatments. When a research subject or patient exercises consent-as-waiver, they confer a special right to researchers and medical practitioners to perform actions that would otherwise be unacceptable.

According to Manson and O'Neill, shifting the focus to consent as a waiver broadens the scope of how we think about informed consent so that we can attend to the multiple relationships that bear on consent, and not just on the need to disclose information. Consent-as-waiver highlights the graveness of temporarily lifting certain prohibitions. The fact that informed consent entails lifting certain prohibitions illustrates the need to ensure that consent results from good communication.¹² To promote successful communication, consent-as-waiver incorporates the attention to epistemic norms that the agency model of communication highlights. Thus, for example, it emphasizes the need for all those involved to be trustworthy in their communication. A person should not deceptively present facts about a particular intervention, as this decreases the believability of such claims and impedes overall understanding. In addition, recall that epistemic norms also mandate that the information that participants share is truthful, intelligible and relevant. Part of determining what constitutes relevant information will depend on the particulars of the situation. The aim is to provide an adequate but not overwhelming amount of information by which one can determine

¹¹ *Ibid*, 72.

¹² *Ibid*.

whether to provide consent-as-waiver. Thus, contrary to what they insist is the goal of consent-as-disclosure of providing all information about an intervention, consent-as-waiver aims to provide adequately accurate information for the given context. For example, researchers might discuss possible risks, benefits, and compensation. They might also generally describe any interventions so that the subject understands the extent to which they are temporarily waiving certain rights and the cost and possible benefits of doing so.

In addition to paying attention to epistemic norms, consent-as-waiver also attends to ethical norms that come into play.¹³ In consenting to temporarily waive certain rights, patients and subjects are committed to viewing as acceptable actions that would otherwise be wrongful without consent, such as invasive treatments. In doing so, they agree not to seek legal recourse when these actions are carried out. Those who seek consent commit themselves to fulfilling the actions under consideration if and only if they have obtained the requisite consent to do so. In this way, consent-as-waiver operates within broader ethical norms that are at play within the medical profession. These include prohibitions against coercion, force, manipulation, and fraud. A requisite of consent-as-waiver is that those who consent realize that they are providing consent and are not being forced to waive their rights.

8.2 Problems with Consent-as-Waiver

Despite Manson and O'Neill's insistence that consent-as-waiver adequately ensures that people make self-governed choices in the medical and research context, this revised account of informed consent fails to do so. The reason is that consent-as-waiver

¹³ *Ibid*, 90-94.

fails to adequately attend to the ways that social structures impede autonomy. Recall, from Chapter 3, that social structures can limit people's autonomy by disparate power, unjustly limited options, internalized oppression, and not fully developed skills for autonomy. Although consent-as-waiver attends to some of these problems, it fails to attend to all of them.

Among the problems arising from social structures, consent-as-waiver specifically addresses disparate power. In being guided by the agency model of communication, consent-as-waiver is directed towards remedying power disparities that would impede subjects' ability to be active participants in the communication process regarding informed consent. Additionally, epistemic norms, such as those that ensure that subjects comprehend the information they receive so that they can actively participate by asking questions, serve to put subjects on a more equal footing as researchers.

While consent-as-waiver acknowledges the problem of disparate power, it may appear that it fails to recognize the problem of unjustly limited options. Manson and O'Neill do not specifically discuss unjustly limited options, which makes it seem as if consent-as-waiver fails to address this problem. However, recall that they insist that broader ethical norms can bear on the communication process wherein subjects decide whether to participate in a research trial. In the case of unjustly limited options that act as coercive offers, it appears that two broader ethical norms combine to attend to this problem.¹⁴ The universal ethical norm that it is wrong to unfairly limit a person's choices

¹⁴ For an explanation of how unjustly limited options amount to coercive offers, refer to Chapter 7 and Moodley 2002. For arguments regarding necessary conditions for being a coercive offer, see Wilkinson and Moore 1997; Wertheimer 1999; Brody 2003; Faden and Beauchamp 1986. For arguments that illustrate how the problem of unjustly limited options fulfills these requirements, see Pogge 2002; Sample 2003.

attends to the problem of unjustly limited options in general. When these options act as coercive offers, they violate the universal ethical norm that coercion is wrong. Understood in this way, it appears that consent-as-waiver is equipped to deal with the ways that unjustly limited options impede autonomy.

Although consent-as-waiver attends to unjustly limited options and disparate power, it attends to only some of the ways that not fully developed autonomy skills can impede a person's ability to make a self-governed choice regarding her research participation. Recall that self-assertion and self-worth are some of the requisite autonomy skills that those from vulnerable groups might not have fully developed due to their socialization. Consent-as-waiver is equipped to deal with problems relating to lack of self-assertion but not lack of self-worth. In emphasizing the need for subjects to be able to exercise their agency in the communication process, consent-as-waiver is directed towards ensuring that subjects are self-assertive. However, it does not address decreased self-worth. Neither the emphasis on agency nor the need to adhere to epistemic and ethical norms deals with how decreased self-worth might lead people to underestimate their needs in deciding to waive their rights.

This is closely connected to the concern that oppressive socialization can lead to problems of internalized oppression. Notably, consent-as-waiver does not attend to the way in which a person's decision to temporarily waive her rights might stem from mistaken oppressive beliefs. For example, a research subject might actively participate in the communication process, asking clarification questions about the intelligible and relevant information that the researcher shares. She might also feel that the researcher is trustworthy and that the material he presents is true. She understands the obligations that

arise from the consent process. However, she may choose to participate in a trial that is not in her best interest because she knows that her family wants her to and, due to her gender socialization, she has internalized the mistaken belief that others' desires necessarily trump her own.

To summarize, we have good reason to reject Manson and O'Neill's proposed alternative account of informed consent, consent-as-waiver. As I have explained, it is not equipped to deal with some of the ways that people's ability to make a self-governed choice regarding medical treatment or research participation can be impeded. Consent-as-waiver is ill-equipped to address not fully developed autonomy skills. Although it is directed towards ensuring self-assertion, it is not structured to be able to attend to ensuring self-worth. In addition, consent-as-waiver cannot attend to the ways that internalized oppression impedes autonomy.

8.3 How Consent-as-Relational-Autonomy Overcomes These Problems

While consent-as-waiver is unequipped to attend to internalized oppression and not fully developed autonomy skills, relational autonomy is specifically directed towards these problems. Recall that relational autonomy focuses on the ways in which relationships enhance or impede autonomy. In doing so, it recognizes the ways that oppressive socialization can result in internal restraints to autonomy. These include internalizing oppressive beliefs and not fully developing necessary skills for autonomy, such as self-assertion and self-worth. In Chapter 6, I indicated how a relational account of autonomy might inform a set of ethical conditions for ensuring respect for autonomy. As will become apparent in Chapter 10, these conditions can guide us in structuring informed consent, or consent-as-relational-autonomy, so that it attends to the problems of

internalized oppression and not fully developed autonomy skills. Because consent-as-relational-autonomy attends to these problems and Manson and O'Neill's consent-as-waiver does not, we have good reason to prefer an account of informed consent that is justified and guided by respect for relational autonomy.

8.4 Consent-as-Authority-and-Trust

As a better alternative to consent-as-autonomy, Tronto argues for what she calls consent-as-authority-and-trust, or what I will refer to as consent-as-authority. Instead of resting informed consent on the principle of autonomy, she calls for framing consent as necessarily relying on authority. This draws on the role of authority that the medical practitioner has. In doing so, it shifts the focus of consent from mere agreement to focusing on the relationship between the practitioner and patient. Consent becomes an issue of the patient granting the practitioner the authority to provide medical services.

In focusing on consent as the patient granting the doctor authority, Tronto insists that consent-as-authority attends to the ways that social injustices and disparate power impede a person's ability to make self-governed choices regarding medical care and research participation. First, in focusing on the relationship between the doctor and the patient, consent-as-authority highlights the responsibility that the physician has to look out for the patient's best interest. Because a necessary condition to granting this authority is that the patient must trust the doctor, Tronto insists that the doctor will be motivated to be beneficent as a means of ensuring this trust. Additionally, the requirement of trust also brings the principle of justice into consideration. A patient's trust in her doctor not only relies on the patient trusting that the physician will do what is in her best interest. It also depends on the patient trusting the healthcare system in which the doctor operates. In

focusing on the need for patients to trust the healthcare system in which their physicians operate, consent-as-authority attends to the problem of how social injustices negatively affect the patient's trust. When social injustices decrease the patient's ability to trust her physician, then the patient is unable to grant authority. Because consent amounts to granting authority, consent-as-authority must attend to how social injustices impede the patient's ability to provide consent.

8.5 Problems with Consent-as-Authority-and-Trust

Despite the initial appeal of Tronto's proposal, there appear to be two problems with consent-as-authority. The first problem relates to the main component of her proposal, the patient's trust in medical practitioners and the healthcare system in which they operate. The second deals with her insistence that granting authority incorporates the principle of justice.

A problem arises when we consider the role of trust in Tronto's proposal. Recall that much of what is entailed in the patient granting authority to the medical practitioner is the patient's trust in the practitioner. Yet, too much trust can actually impede the consent process. To illustrate, recall the example from Chapter 6 regarding how a federal law regarding educating handicapped children failed in practice. The Education for All Handicapped Children Act included provisions for getting parents of handicapped children to engage in dialogue with educators as a means of gleaning what is in the children's best interest. In many schools where parents began engaging in this dialogue, their trust in the educators began to increase. The result was that many ended up relying solely on the educators' analysis and opting out the opportunity to provide valuable input. This ends up defeating the goal of determining what is in the children's best interest.

Without the parents' input regarding aspects of the children's lives, educators were less able to accurately determine what is in the children's best interest.

Similar problems arise in many situations where the less powerful person in a relationship turns her decision over to the more powerful person, trusting that the more powerful person will do the right thing. Some of these cases are like the handicapped children case in that people opt out of providing information about third parties because they trust the more powerful person in the relationship. For example, parents may opt out of providing coaches, counselors, or teachers with valuable input regarding what may be in their young child's best interest. In other cases, people may opt out of providing information about themselves because they trust that the more powerful party is better able to determine what is in their best interest. For example, patients might defer to their doctors regarding medical treatment.

We can see how similar problems would result in the research setting. Of course, some level of trust is necessary due to differences in medical knowledge and the degree to which subjects may be reliant on clinical researchers to provide care. However, if this trust becomes so great that subjects no longer engage in on-going dialogue with researchers, it can impede the consent process. For example, without this communication, researchers will be unclear as to the extent to which subjects actually understand the information researchers disclose throughout the dynamic research process.

This reliance on trust also illustrates problems with attending to issues of justice. Recall that Tronto insists that consent-as-authority highlights the need to attend to social injustices since it is necessary for patients to trust the healthcare system in order to grant authority to their doctors. While this may be true, it is also the case that too much trust

can overshadow, and in many cases, further perpetuate, problems arising from social injustices. To understand why this is, recall that there are two primary problems resulting from differences in race, class, gender, and disability – those arising from oppressive socialization and those resulting from external restraints. Focusing on the need to trust healthcare systems, or in our case, medical research in general, sheds light on external restraints such as unjustly limited healthcare resources. However, it does not attend to the problems that can arise from oppressive socialization which impede subjects' ability to provide consent. This is due to the fact that Tronto is relying on a narrower scope of social justice, one that is limited to external restraints. As such, she does not recognize nor attend to the internal restraints that can arise from social structures.

To summarize, I believe that there are two primary problems with Tronto's consent-as-authority. First, her reliance on trust leads to concerns that too much trust can impede subjects' ability to provide consent and may add to the power disparity between researchers and subjects. And second, her focus on a narrow definition of social justice overlooks the internal restraints to being able to provide valid consent that arise from differences in race, class, gender, and disability between researchers and subjects.

8.6 How Consent-as-Relational-Autonomy Overcomes These Problems

Fortunately, there is a better solution. As I have previously explained, I propose revising the current account of autonomy that underlies informed consent guidelines to reflect a relational account. Recall in Chapter 6 I explained how, contrary to Tronto's insistence, a relational account of autonomy can guide us in how to structure informed consent so that it ensures that subjects make self-governed choices regarding research participation. The principle of respect for relational autonomy identifies the things that

impede autonomous decision-making, such as internalized oppression, not fully developed autonomy skills, unjustly limited options, and disparate power. From this list, we can construct a set of ethical conditions that specifically attend to these problems (Chapter 6). This set of ethical conditions then can guide us in how to structure the informed consent process in the research setting (Chapter 10).

Because consent-as-relational-autonomy overcomes the problems that Tronto's consent-as-authority encounters, we have good reason to prefer consent-as-relational-autonomy. Not only does consent-as-relational autonomy identify and provide guidance for ensuring people's consent, but I believe it is a better solution than Tronto's consent-as-authority. Recall that one of purported benefits of Tronto's account is that it acknowledges power differences between doctors and patients. To attend to this problem, Tronto relies on trust. Yet, recall that I explained how this reliance on trust could result in subjects deciding not to provide their input in the informed consent process and, instead, preferring to turn their decisions over to the researcher. When this occurs, trust can magnify the power differences between subjects and researchers by giving researchers even more power, which they could use to manipulate or coerce subjects.

While consent-as-relational-autonomy also recognizes the problems that arise from power differences, it does not hinge on the problematic condition of trust that consent-as-authority does. In my account of how relational autonomy can inform guidelines for informed consent in research, for example, I propose providing various support mechanisms for subjects in order to enable them to identify and address the disparate power between themselves and researchers. Rather than risk further perpetuating the power differences that might occur from a reliance on trust, support aims

to empower subjects, attempting to close the power gap and enable them to better exercise their autonomy.

Consent-as-relational-autonomy also provides a better alternative because only it attends to internal restraints that arise from social structures. Recall that I explained how Tronto's account fails to address problems relating to oppressive socialization. A further benefit of consent-as-relational-autonomy is that it highlights the need to address these problems. Due to the insurmountable problems that consent-as-authority encounters and the benefits derived from consent-as-relational-autonomy, we have good reason to revise the consent-as-autonomy model instead of shifting to Tronto's consent-as-authority.

8.7 Conclusion

In this chapter, I strengthened my arguments in support of relying on relational autonomy to justify informed consent by explaining why we should prefer it to other proposed solutions. In doing so, I pointed out problems with Manson, O'Neill, and Tronto's alternative accounts of informed consent and explained how an account of autonomy that is justified by relational autonomy overcomes these problems. Although I have not provided a thorough defense of relying on relational autonomy as the philosophical foundation for informed consent in this chapter, I have presented several good reasons for wanting to maintain the important relationship between autonomy and informed consent and for insisting that the best account of autonomy for doing this is a relational one.

Chapter 9: Current Informed Consent Guidelines

In this chapter, I address the current international informed consent guidelines. I explain the extent to which each attends to the problems regarding social structures that I pointed out in Chapter 3 and how the extent to which they accomplish this illustrates the type of account of autonomy that informs each. While some of the guidelines rely on a traditional autonomy account, some of the more progressive ones rely on a relational account. However, even the most progressive guidelines require revisions in order to better promote subjects' autonomous decision-making in the research context.

Because I am concerned with how current policy guides researchers' conduct in obtaining informed consent, I address guidelines that carry some force, whether this is as the master document that guides other guidelines (i.e., Declaration of Helsinki) or as an enforceable guideline (i.e., The Federal Code of Regulations). Also, in addressing the guidelines, I attend to the most recent version of each, which includes the amendments and comments that were a response to ethical problems that became more apparent over time.

I do not address what is regarded as the originating document concerning ethical conduct in research on human subjects, the Nuremberg Code (1949).¹ The Code consists of ten ethical guidelines that were derived from doctors' testimony during the Nuremberg Trials, in which Nazi doctors were tried for war crimes pertaining to the atrocities that they performed in the name of medical experimentation on Nazi concentration camp prisoners. Two of these guidelines deal with informed consent, mandating that subjects make a voluntary and informed decision to participate in research (Point 1) and granting

¹ *Nuremberg Code* 1949.

subjects the right to withdraw from the research (Point 9). This document never gained legal force and was never implemented into American or German law.² However, it served as the impetus for the Declaration of Helsinki, which I address.

In addressing the current guidelines on informed consent in international research on human subjects, I present these in chronological order. In doing so, one might anticipate a progression from guidelines that rely on vague traditional accounts to those that reflect more precise relational ones, which would indicate a gradual improvement. As will become apparent, this is not the case. For example, the CIOMS Guidelines, which were most recently revised in 2002, came before the UNESCO Declaration, which was enacted in 2005.³ Yet, the latter rely on a traditional account and the former reflect a relational one. As I explain, even the CIOMS Guidelines, which address the impact of social structures on subjects' informed consent much more than the other guidelines, still requires revisions in order to better ensure subjects' informed consent in research.

9.1 Declaration of Helsinki

The Declaration of Helsinki provides international guidelines for research on human subjects. Although not legally binding, the Declaration provides the groundwork for many of the later international guidelines. The International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993) states, “The Declaration of Helsinki... is the fundamental document in the field of ethics in biomedical research and

² Nuremberg Code: Background 2009.

³ Some might argue that the reason for this is due to the fact that the different guidelines stem from different organizations and, in some cases, attend to certain research funded by particular agencies. However, as I explained in Chapter 3, the problems regarding social structures to which only relational accounts adequately attend can arise in all research on human subjects. Consequently, they need to be addressed, regardless of who is conducting the research.

has considerable influence on the formulation of international, regional and national legislation and codes of conduct”.⁴ In addition, the International Guidelines for Ethical Review of Epidemiological Studies (CIOMS), the Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products (CIOMS), and the Guidance Document on Ethical Considerations in HIV Preventive Vaccine Research (UNAIDS) cite the Declaration as the basic reference for ethical guidance on human research.⁵ Since its initial formulation in 1964 (Helsinki, Finland), the Declaration has been amended five times and clarified twice, each in response to unethical aspects of particular international research studies.⁶ Today, the Declaration of Helsinki continues to be one of the primary guidelines for ethical decision-making in research.⁷

9.1.1 Informed Consent

Among the amendments and clarifications, the only amendment to informed consent appears in Paragraph 31, which clarifies the type of information that researchers must share with current and prospective participants. Researchers’ obligation to obtain informed consent from subjects is included in the ethical guidelines spelled out in Paragraph 22:

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

⁴ Council for International Organizations of Medical Sciences (CIOMS), 1993.

⁵ World Medical Association, “Chapter 4: The Declaration of Helsinki”.

⁶ Amendments were made in 1975, 1983, 1989, 1996, and 2000. Clarifications were made to Paragraph 29 in 2002 and to Paragraph 30 in 2004.

⁷ Crawley and Hoet 1998.

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.⁸

Not all research subjects are able to exercise autonomous choice. To address problems of consent that can arise in these cases, the Declaration has special provisions for children, severely mentally disabled individuals, and persons in comas or emergency situations.⁹ Although there are interesting ethical issues that arise regarding non-autonomous subjects, I have narrowed my focus to those who have the capacity to make informed decisions regarding their participation in research.

9.1.2 How the Declaration Reflects a Traditional Account of Autonomy

As Paragraph 22 illustrates, the Declaration frames informed consent through the liberal framework of a contract in which researchers provide information and subjects provide consent. In addition, it fails to mention the possible inclusion of community. These characteristics point to the fact that the Declaration rests on a traditional account of autonomy. As I explained in Chapter 4, this type of account fails to adequately attend to the ways in which social structures, such as race, class, and gender, can impede a subjects' ability to provide informed consent.

In failing to attend to possible community involvement, the Declaration permits harms that it should not permit. First, it fails to recognize and, thus, respect, that some individuals value community to the extent that they would want community to be

⁸ World Medical Association 2004.

⁹ *Ibid*, Paragraphs 8, 24-26.

included in the informed consent process.¹⁰ Second, without mentioning community involvement, these guidelines are unable to attend to the further concern that social structures, such as race, class, and gender as these are expressed through the community interaction with subjects can impede subjects' ability to provide informed consent.

In response, one might find the vagueness of the Declaration appealing, as this seems to make these guidelines more flexible with regard to particular cultural applications. Although the Declaration does not mention community, it also doesn't explicitly prohibit community involvement. The individual remains free to determine to what extent to draw on her community when making important decisions.

However, leaving the possibility of community involvement open like this is not a good solution. In failing to spell out the specifics of how to obtain informed consent when communities are involved, international guidelines that were constructed to protect subjects' autonomy ironically put many subjects in danger of having their individual human rights violated. Failure to implement specific safeguards for protecting subjects once communities become involved in the informed consent process increases the vulnerability of those who oftentimes already comprise the more vulnerable members of their communities. This danger is even more pronounced given that women, some of the most vulnerable persons within many societies, also tend to be the most likely candidates for international research. For example, pregnant women are the only possible research population for testing drugs for preventing fetal AIDS transmission.

¹⁰ Notably, it is not enough to include community in the pre-trial stage of designing a research study. For those who value community in the way that the *Akan* do, community is so much a part of the value of the person that one would want community involved in all stages of the research process.

9.2 The Belmont Report

You may recall from Chapter 7 that the 1979 Belmont Report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in an attempt to spell out the ethical principles for research on human subjects and the particular ethical guidelines that these principles inform. The moral force of the Report is its use as a common reference by internal review boards (IRBs) that review research trials that are either conducted by or funded by the United States Department of Health and Human Services. In addition, both the Code of Federal Regulations (otherwise known as the Common Rule) and the Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health incorporate many of the principles from the Belmont Report. According to the NIH Guidelines, “The NIH embraces The Belmont Report and holds IRP (Intramural Research Program) investigators responsible for conducting their research activities in keeping with its principles and guidelines”.¹¹

9.2.1 Informed Consent

In addressing informed consent, the Belmont Report states that there is “widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness”.¹² Notably, the Report acknowledges some of the ways in which social structures can result in disparate power between researchers and subjects. In regard to vulnerable populations, the Report warns:

¹¹ NIH 2004, 6.

¹² Department of Health, Education and Welfare. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979, Part C:1.

Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate *as a result of their illness or socioeconomic condition*.¹³

In doing so, the Belmont Report acknowledges that the social structures of disability and class can result in subjects having far less power than researchers to the extent that they become easier prey for manipulation.

9.2.2 How the Report Reflects a Traditional Account of Autonomy

Although the Belmont Report acknowledges some of the ways in which social structures impede autonomy, it reflects a traditional account rather than a relational one. Recall from Chapter 4 that I explained how a traditional account, in attending to coercion, might acknowledge the ways that racism, sexism, and so forth result in unjustly limited options or disparate power. However, also recall that I explained how reliance on the atomistic account of the individual resulted in their overlooking the ways that oppressive socialization also can affect a person's ability to provide consent. While the Report recognizes the external restraints arising from social structures, it overlooks internal restraints, or restraints that result from oppressive socialization. In addition, it fails to acknowledge the importance that some subjects place on community. Nowhere in the Belmont Report are there ethical guidelines for addressing the possible involvement of community in informed consent.

¹³ *Ibid*, Part C:3.

9.3 CIOMS Ethical Guidelines

The Council for International Organizations of Medical Sciences (CIOMS) first presented the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* in 1982. Since then, the document has been amended twice, in 1993 and in 2002.¹⁴ The CIOMS is comprised of a group of over 70 international biomedical science organizations put together by the World Health Organization and the United Nations Educational, Scientific and Cultural Organization. The purpose of the guidelines is to provide a set of universally applicable ethical guidelines for research on human subjects. Three philosophical principles direct these ethical guidelines: respect for persons, which includes both respect for autonomy and respect for those who lack the requisite requirements for autonomy; the principle of beneficence, which requires medical professionals to maximize benefits and minimize harm; and the principle of justice, which primarily deals with “the equitable distribution of both the burdens and the benefits of participation in research”.¹⁵

As I will explain, the guidelines pertaining to informed consent reflect a relational account of autonomy. Not only do they address problems with consent due to vulnerabilities arising from race, less education, poor economic conditions, and severe illness, but they also attend to the ways in which oppressive socialization can impede subjects’ autonomy. Despite their thoroughness, however, the CIOMS Guidelines fail to adequately promote respect for autonomy in informed consent in research on human subjects.

¹⁴ CIOMS 2002.

¹⁵ *Ibid*, 10, General Ethical Principles.

In what follows, I analyze the CIOMS Guidelines as they relate to informed consent and respect for autonomy. I then illustrate the ways in which they reflect a relational account of autonomy. I end my discussion by providing some examples that illustrate ways in which the CIOMS Guidelines do not adequately promote respect for relational autonomy. In Chapter 10, I provide a lengthier discussion of the shortcomings of the CIOMS Guidelines. I also explain the specific changes that we should make so as to best promote subjects' autonomy as it relates to informed consent in research on human subjects.

9.3.1 Informed Consent

Several provisions in the CIOMS Ethical Guidelines attend to many of the ways in which social structures can impede informed consent. First, the CIOMS Guidelines overcome the problem of relying on a liberal framing of informed consent. Recall from Chapter 5 that one of the problems that I argued results from social structures in the international research context is the liberal framing of informed consent as a one-time contractual exchange of information for consent. This framing leads to problems with ensuring autonomy. In structuring informed consent as a contract, the liberal framework mistakenly assumes that researchers and subjects are on equal footing with regards to power in the relationship. As a result, the liberal framing of informed consent fails to attend to the ways that disparate power can impede subjects' ability to make an autonomous decision. Recall that one of the problems that could result from disparate

power is that subjects might refrain from making certain choices if they believed, even mistakenly, that this might cause researchers to terminate their care.¹⁶

In framing informed consent as an on-going process in which researchers facilitate greater subject participation, the CIOMS Guidelines provide tools for attending to mistaken beliefs that might impede valid consent. Guideline 4: Individual Informed Consent states:

Obtaining informed consent is a process that is begun when initial contact is made with a prospective subject and continues throughout the course of the study. By informing the prospective subjects, by repetition and explanation, by answering their questions as they arise, and by ensuring that each individual understands each procedure, investigators elicit their informed consent and in so doing manifest respect for their dignity and autonomy.¹⁷

Encouraging researchers to have an on-going dialogue with subjects throughout the research trial, encouraging subjects to ask questions, and ensuring their comprehension are all tools that can help to address any mistaken beliefs subjects might have about researchers withdrawing care if they make a particular choice.

Other problems that arise from social structures that the CIOMS Guidelines addresses are those that occur when subjects are vulnerable. Guideline 13: Research Involving Vulnerable Persons defines vulnerable persons as those who are unable to protect their own interests. This inability can arise from “insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests”. Among those who are vulnerable, the CIOMS Guidelines list those in subordinate positions within a professional setting (i.e. nurses, hospital personnel, and medical

¹⁶ Notably, this is more problematic in cases of therapeutic research, where part of the research protocol specifically includes medical care.

¹⁷ *Ibid*, 20, Guideline 4.

students), the elderly, those in nursing homes, poor people, ethnic and racial minority groups, those unfamiliar with modern medicine, and those who suffer from severe illness or diseases.^{18,19} According to Guideline 13, researchers who wish to include vulnerable persons as research subjects must make sure that there is an equitable distribution of the risks and benefits involved in the research, meaning that vulnerable persons should not bear risks by participating in research that will benefit others more than themselves.

In addressing vulnerable research subjects, the CIOMS Guidelines also address specific vulnerable populations, including women. In doing so, the Guidelines acknowledge problems that can arise from oppressive socialization. Because researchers have excluded women in the past due to concerns over their becoming pregnant, the CIOMS Guidelines encourage the involvement of women in research. In doing so, the Guidelines point out additional ethical concerns that can arise when women are research subjects:

Although this general presumption favours the inclusion of women in research, it must be acknowledged that in some parts of the world women are vulnerable to neglect or harm in research because of their social conditioning to submit to authority, to ask no questions, and to tolerate pain and suffering. When women in such situations are potential subjects in research, investigators need to exercise special care in the informed consent process to promote that they have adequate time and a proper environment in which to make decisions on the basis of clearly given information.²⁰

Thus, the Guidelines recognize that oppressive socialization, or what they refer to as social conditioning, can impede women's ability to provide informed consent.

¹⁸ *Ibid*, 42, Guideline 13.

¹⁹ In addition to Guideline 13, the CIOMS Guidelines attend to more specific vulnerable populations, such as children (GL14), the mentally disabled (GL15), women (GL16), and, even more specifically, pregnant women (GL17).

²⁰ CIOMS 2002, 48, Guideline 16.

In addition to attending to the specific ways that social structures can impede autonomy in research on human subjects, the CIOMS Guidelines make room for the possible involvement of community in informed consent. For example, the Guidelines assert that researchers must respect cultural differences, including the practice of obtaining consent from community leaders to conduct research on community members. At the same time, however, they also include the safeguard that community leaders' consent should never replace individual informed consent regarding research participation.²¹

To summarize, then, the CIOMS Guidelines that relate to autonomy and informed consent attend to many of the specific problems that arise in international research on human subjects. As I have explained, these include reframing consent as an on-going and more participatory process between researchers and subjects; acknowledging how differences in race, class, professional rank, and gender lead to disparate power between researchers and subjects; and recognizing that oppressive socialization can impede a subject's ability to provide valid consent. In addition, the Guidelines include provisions that acknowledge the value that some subjects may place on community involvement.

9.3.2 How the Guidelines Reflect a Relational Account of Autonomy

In comparison to the other guidelines we have discussed thus far, the CIOMS Ethical Guidelines reflect a relational account of autonomy. To illustrate, consider the difference between the Belmont Report, which reflects a traditional account of autonomy, and the CIOMS Guidelines. Recall that the Belmont Report attended to some of the problems arising from external restraints but overlooked the possible role of community

²¹ *Ibid*, Guideline 4.

in informed consent and the problems that arise from oppressive socialization. This is not surprising given my explanation in Chapter 4 regarding how traditional accounts recognize problems relating to external restraints but not those relating to oppressive socialization. Also, recall that traditional accounts fail to attend adequately to the importance that many place on community.

In contrast, the CIOMS Guidelines recognize that oppressive socialization can impede autonomy. Recall that the Guidelines acknowledge that gender socialization can impede a woman's ability to provide valid consent. In addition, these guidelines also include provisions that recognize the value that some place on community. Because only relational accounts of autonomy attend to these issues, the CIOMS Guidelines reflect a relational account, as opposed to a traditional one.

9.3.3 Why the Guidelines Fail to Respect Relational Autonomy

Although the CIOMS Guidelines seem to be informed by a relational account of autonomy, further provisions are needed to address the ethical issues raised by the Guidelines. Because I will attend to these in Chapter 10, I here provide a few examples to illustrate that even the most progressive international informed consent guideline for research on human subjects needs to be revised in order to adequately promote respect for relational autonomy. For example, although the CIOMS espouses a more participatory research process, potential subjects are not involved in the formulating stages of research protocol. As we saw in Chapter 5, this leads to problems regarding unjustly limited options that come into play in the framing of the research trial. Also, despite its admirable recognition that gender socialization can impede autonomy, the Guidelines do not provide guidance for how to remedy this problem.

9.4 Code of Federal Regulations

The Code of Federal Regulations is the result of work that began by the United States Department of Health, Education and Welfare (HEW) in 1979. It took two years to comprise the Code, during which time HEW was renamed the Department of Health and Human Services (DHHS). The Code is comprised of fifty sections that deal with various areas that are subject to Federal regulation. Among these fifty, Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects (45 CFR 46) provides rules and regulations for research on human subjects.²²

Initially, 45 CFR 46, otherwise known as the Common Rule, only applied to research that was funded by the DHHS. In June 1991, however, it was expanded to include all research involving human subjects that is conducted or funded by any federal agency. The most recent revision of 45 CFR 46 was in 2009.

Because the Common Rule is administrative law, researchers must abide by its rules and regulations in order to get Federal approval for conducting research or receiving Federal funding. For example, the Common Rule is the primary document that the Deputy Director of Intramural Research (DDIR) uses to determine whether the requisite ethical requirements have been met in research conducted or funded by the National Institutes of Health.²³

²² DHHS 2009.

²³ *Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health* (NIH 2004: fifth printing, 7). Because the NIH Guidelines defer to the Common Rule as providing the ethical guidelines for research on human subjects, I do not address separately the NIH document.

9.4.1 Informed Consent

In 45 CFR 46, subsections 116 and 117 deal specifically with informed consent. Section 116 presents general guidelines for obtaining informed consent. As is common in all of the international guidelines for research on human subjects, Section 116 requires that researchers obtain the informed consent of subjects prior to enrolling them in a research trial. Researchers must also inform subjects that they have the right to withdraw from research. This section also includes provisions regarding the kind of information that researchers should disclose, such as the risks, benefits, compensation, and the purpose and duration of the trial. Section 117 provides specific guidelines for documenting that informed consent has been obtained. This amounts to a written document verifying that the requirements from Section 116 have been met.

In addition to devoting two sections specifically to informed consent, the Common Rule acknowledges that vulnerabilities can impede consent. Rather than spelling out the possible problems arising from vulnerabilities, it assigns the task of identifying and attending to these problems to members of an Institutional Review Board (IRB). According to Section 111: Criteria for IRB Approval of Research:

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.²⁴

Thus, IRB members must make sure that research involving vulnerable populations includes safeguards against coercion and manipulation so as to better promote valid consent.

²⁴ DHHS 2009, Section 111, 3(b).

The Common Rule also contains provisions directed towards certain vulnerable populations, namely, children, prisoners, and pregnant women.²⁵ According to these guidelines, researchers can only enlist subjects from these vulnerable populations for research in which the benefits to the subjects outweigh the risks. In addition, when subjects from these vulnerable populations have the requisite comprehension skills, researchers are required to ensure that subjects understand what they are consenting to when they agree to participate in a research trial. While the Common Rule provides for IRB oversight and contains guidelines pertaining to some vulnerable populations, it does not acknowledge problems that might occur when subjects are more vulnerable due to economic or education differences. Nor does it spell out which specific safeguards should be implemented to remedy these problems.

9.4.2 An Indeterminate Account of Autonomy

This vagueness makes it difficult to determine which account of autonomy the Common Rule reflects. Recall that the guidelines that pertain to the vulnerable populations of prisoners, children, and pregnant women do not specifically attend to the ways that vulnerability can impede autonomy. Instead, they focus on the need to balance risks and benefits to subjects and the need for subjects to comprehend information pertaining to their research participation. As a result, such problems as how gender socialization might impede a pregnant woman's ability to provide consent due to internal restraints of not fully developing self-assertion skills or internalizing oppressive beliefs that her desires being unimportant are not addressed.

²⁵ DHHS 2009, Subpart B: Pregnant Women; Subpart C: Prisoners; Subpart D: Children.

Of course, it may be that the IRB can fulfill the role of identifying how vulnerability impedes consent. Recall that the Common Rule leaves it up to the IRB to determine what problems might arise and whether the appropriate safeguards have been included in research. Admittedly, there is a possibility that IRB members might identify the various ways that social structures impede consent. In an attempt to ensure that the IRB will correctly identify restraints to autonomy arising from the multitude of vulnerabilities present in the research context and suggest appropriate safeguards, the Common Rule requires that IRB members include men and women, people from differing races and ethnicities, and a professional who is familiar with the specific vulnerabilities that come into play in the particular research trial.²⁶

Despite these inclusions, however, it is questionable whether a professional is able to adequately identify the ways in which external and internal restraints can impede consent. Just as researchers oftentimes drastically differ from patients due to the former being members of the privileged gender, class, ethnicity, and ability within society (Chapter 5), similarly professionals oftentimes do not share many of the characteristics of research subjects. Without adequate input from subjects, professionals are unlikely to adequately discern the external and, especially, the internal restraints subjects might encounter.²⁷ Thus, even if we were to grant the questionable conclusion that the Common Rule reflects a relational account of autonomy, it is important to note that it does not ensure that subjects make self-governed decisions regarding their participation in research.

²⁶ *Ibid*, Section 107 (a) & (b).

²⁷ As the Handler case in Chapter 6 illustrated, differences in social positioning between professionals and others can impede autonomy.

9.5 UNESCO Declaration

In October 2005, the United Nations Educational, Scientific and Cultural Organization (UNESCO) enacted the Universal Declaration on Bioethics and Human Rights. UNESCO originated in 1945, bringing together people in the fields of education, science, culture and communication with the goal of finding a universal approach to addressing ethical issues in these areas. As of October 2009, UNESCO consisted of one hundred ninety-three member states and six associate members.²⁸

The main purpose of the Universal Declaration is to act as a tool to guide States in constructing ethical guidelines for the treatment of human beings in biomedical contexts. In addition to guiding countries in constructing their own guidelines, the Universal Declaration also serves to “guide the actions of individuals, groups, communities, institutions and corporations, public and private”. The scope of the guidelines is broad; the guidelines are intended as general principles that can be universally applied to a variety of bioethical contexts, including medicine and research (Articles 3 through 17). In order to maintain universal appeal, the explanation of the application of these principles in bioethical contexts is vague, consisting of four short articles (18-21). Nonetheless, given that it is an international guideline that applies to bioethical contexts, including research on human subjects, it is important to examine.

Among the general principles that the Universal Declaration lists, the following are relevant to my concerns regarding research on human subjects: consent (Article 6), respect for human vulnerability and personal integrity (Article 8), equality, justice and equity (Article 10), non-discrimination and non-stigmatization (Article 11), and respect

²⁸ UNESCO 2009, 1.

for cultural diversity and pluralism (Article 12). Among the articles directed at the application of the principles, Article 18, which relates to decision-making, is relevant to my interest in informed consent as it relates to research on human subjects. In what follows, I describe each of these articles. After doing so, I explain why the vagueness of the articles makes it difficult to determine which account of autonomy underlies them.

9.5.1 Ethical Principles and Their Application

Not surprisingly, the Universal Declaration addresses the issue of informed consent. According to Article 6: Consent, researchers must obtain subjects' informed consent to participate in a research trial. To do so, researchers must provide an adequate amount of information that potential subjects can understand in order to make an informed choice. They must also inform subjects of their right to withdraw from the research at any time. In cases in which research is conducted on a group or community, researchers must get the consent of those involved in the research trial. In addition, when required by a particular society's practices, researchers may need to get the consent of community leaders. Like other guidelines that have this provision (i.e., the CIOMS Guidelines), the Universal Declaration also includes the safeguard that community leaders' consent cannot trump the research subject's consent.

In addition to provisions relating to the obligation to obtain consent, the Universal Declaration attends to the issue of vulnerability. Article 8 reads:

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.²⁹

²⁹ UNESCO 2005, 5, Article 8.

Because the Universal Declaration's scope is admittedly broad, Article 8 does not define what constitutes a "special vulnerability". Instead, it acknowledges that medical professionals should be attentive to vulnerabilities and attempt to protect and respect vulnerable individuals and groups.

Articles 10 and 11 are applicable to problems that arise from racism, sexism, and so forth. Article 10: Equality, Justice, and Equity asserts that all people should be treated "justly and equitably", while Article 11: Non-discrimination and Non-stigmatization requires medical professionals not to discriminate or stigmatize individuals or groups. Again, the principles are intentionally broad, indicating general ethical requirements for how medical professionals must treat people.

At this point, some might object that the UNESCO guidelines are too vague to be useful. For example, Article 10 (in its entirety) reads: "The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably."³⁰ Thus, it appears that Article 10 defines treating subjects justly and equitably as treating them with human dignity and respecting their rights. Yet, this does not tell us what is specifically entailed in respecting someone's human dignity, nor does it tell us what rights might be applicable in the context of informed consent and research. I will have more to say about the problems that arise from these vague principles at the end of this section.

Because my focus is on international research, the final general principle that applies to our context is Article 12: Respect for Cultural Diversity and Pluralism. It

³⁰ UNESCO 2005.

emphasizes the need to respect cultural diversity but never at the expense of respecting individual rights.

After spelling out the general ethical principles for bioethical contexts, the Universal Declaration includes more specific guidelines meant to illustrate how the general principles are to be applied. Among the four applied principles, Article 18: Decision-making and Addressing Bioethical Issues is relevant to our concerns. Article 18 consists of three provisions. The first provision attends to the information that medical professionals must provide in order for patients or subjects to make decisions regarding their medical care or research participation. Professionals need to convey truthful and optimal information. In addition, they need to be transparent by divulging any conflicts of interest they may have. The second and third provisions deal with the communication between medical professionals and patients/subjects. Not only should those participating in medical treatment or research be involved in an on-going dialogue, but society also should be able to participate. According to Article 18: Part 3, “opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted”.³¹

9.5.2 An Indeterminate Account of Autonomy

As I explained, the principles that comprise the Universal Declaration are intentionally vague. This is due to the fact that the guidelines have a broad, universal appeal intended for all bioethical contexts. The result of such vague guidelines is that it is unclear which account of autonomy is reflected. For example, it appears that the

³¹ *Ibid.* Notably, the Article does not specify what constitutes a relevant opinion nor whose opinions are relevant.

Universal Declaration attends to the problem of external restraints arising from racism, sexism, etc. Recall that Article 10 indicates the need to exercise justice and equity. We might interpret this as attending to concerns regarding unjustly limited options due to racism, sexism, etc. In addition, Article 11 further emphasizes the need to avoid discrimination and stigmatization, which also applies to avoiding racism, sexism, etc. Because both traditional and relational accounts acknowledge problems relating to external restraints arising from social structures, it is difficult to determine which account informs the guidelines. What we need is to identify whether any articles address problems arising from oppressive socialization in order to answer this question.

The only article that might relate to this problem is Article 8, which deals with the need to protect and respect vulnerable people. However, it is unclear what constitutes “vulnerable”. Does vulnerable mean having less power as a result of racism, sexism, and so forth? If so, then Article 8 attends to problems arising from social structures that deal with external restraints, a problem that both accounts of autonomy address. Or does vulnerable refer to problems arising from internalized oppression or not fully developed autonomy skills that result from oppressive socialization? If so, then the Universal Declaration reflects a relational account.

Regardless of which interpretation one chooses, the vagueness of the articles is problematic. Even if we interpreted the Universal Declaration as broadly attending to a relational account of autonomy, it lacks the specificity for taking respect for relational autonomy seriously. For example, although it acknowledges the need to recognize vulnerabilities, the Universal Declaration does not provide guidance regarding how this can negatively impact subjects’ ability to consent and what safeguards must be

implemented to resolve these problems. Also, although Article 18 highlights the importance of making research a more participatory process by encouraging on-going and open dialogue between medical professionals and society throughout the research trial, it fails to attend to problems that can arise due to differences in race, class, and gender between participants and how this impedes autonomy.

In response, one might insist that the guidelines are intentionally vague so as to be universally applicable in all bioethical contexts. However, as I explained in Chapter 4 in my analysis of Beauchamp and Childress' principles, the problems arising from oppressive socialization and external restraints and how these impede subjects' autonomy are universally applicable. As a result, promoting respect for a relational account of autonomy requires attending to the general internal and external restraints that stem from social structures. In other words, it should spell out the need to attend to unjustly limited options and disparate power (external restraints), as well as internalized oppression and not fully developed autonomy skills (internal restraints).

9.6 Summary of Current Guidelines

In this chapter, I argued that none of the current guidelines for informed consent in international research on human subjects adequately promotes respect for a relational account of autonomy. As I explained in Chapters 3 and 5, adequate respect for a relational account requires: (1) attending to the ways that external restraints and oppressive socialization arising from social structures can impede autonomy, and (2) recognizing the value that some place on community to the extent that they wish for it to be involved in informed consent and providing guidance regarding how to accomplish this while promoting subjects' autonomy.

In analyzing the current guidelines, I addressed the following: the Declaration of Helsinki, the Belmont Report, the CIOMS Guidelines, the Common Rule, and the Universal Declaration of Bioethics and Human Rights. Because the Declaration of Helsinki and the Belmont Report fail to attend to how internal restraints impede autonomy, I concluded that these reflected a traditional account of autonomy. Due to the ambiguity of the provisions in the Universal Declaration and the Common Rule, it was unclear which account of autonomy these reflected. However, even if we interpreted these as resting on a relational account of autonomy, I explained how the ambiguity in these guidelines fails to promote respect for a relational account of autonomy. Lastly, I explained how the CIOMS Guidelines reflected a relational account.

Despite the commendable progressiveness of the CIOMS Guidelines, I indicated that further revisions are necessary in order to better ensure respect for a relational account of autonomy. In the next chapter, I explain the specific provisions that must be implemented to better promote this respect, using the CIOMS Guidelines as a template for illustrating these changes.

Chapter 10: Revisions to Informed Consent Guidelines

I have been insisting that the philosophical foundation for informed consent in international research on human subjects must rest on a relational account of autonomy since only a relational account both recognizes the importance of community and adequately attends to the ways in which social structures impede subjects' autonomy. In Chapter 6, I argued for a list of minimally sufficient ethical conditions for promoting respect for relational autonomy. In this chapter, I propose guidelines for informed consent that reflect these ethical conditions.

Recall from Chapter 6 that I arrived at the following list of five minimally sufficient ethical conditions for respecting relational autonomy in international research on human subjects: critical reflection, support mechanisms, participation, external monitoring, and a safeguard for prioritizing subjects' consent. Because the need to prioritize subjects' consent necessarily comes into play in discussing the majority of the other conditions, I present this specific safeguard as it might appear within the various guidelines that deal with the other conditions. This leaves us with four main ethical conditions: critical reflection, support mechanisms, participation, and external monitoring.

In what follows, I address each of the four ethical conditions in turn. I begin each section by briefly reminding the reader why the particular condition is important. I then explain how the condition can be translated into a particular ethical guideline for research on human subjects. Finally, to illustrate how the proposed guideline could be integrated into current policy, I map it onto what I have argued is the most progressive international ethical guideline for research on human subjects, the CIOMS Ethical Guidelines.

10.1 Requiring Critical Reflection

Recall that critical reflection is a universal condition of all accounts of autonomy. In Chapter 6, I explained the importance of having subjects, community members, and researchers reflect critically on their values, beliefs, and choices. Critical reflection can help subjects and community members identify mistaken oppressive beliefs. It also can help community members and researchers identify any racist or sexist beliefs they may have that inform their actions or decisions, which might impede subjects' autonomy.

Guidelines for Critical Reflection

In Chapter 6, I concluded that international guidelines for informed consent in research on human subjects must include a provision that requires researchers, subjects, and community to reflect critically on their beliefs, values, and choices. Researchers should reflect critically on the extent to which possible mistaken beliefs might inform the research trial and their treatment of subjects. Subjects should attempt to identify mistaken beliefs that bear on their decision to participate in research. And community members should reflect critically on mistaken beliefs that they may have internalized that bear on their decisions, as well as identify harmful stereotypes that affect the way they interact with subjects in the research process. To facilitate critical reflection, a guideline that requires critical reflection would provide examples of some of the questions that people should ask themselves in order to identify these mistaken beliefs.

Bringing these points together, we arrive at the following guideline for requiring critical reflection:

All those involved in the research process are required to reflect critically on their beliefs, values, and choices to determine the extent to which they may be relying on mistaken beliefs. Especially harmful are beliefs that

mistakenly undervalue an individual based on race, ethnicity, disability, illness, class, educational level, sexuality, or gender. To best ensure that people have the opportunity to reflect critically, they should be allotted a reasonable amount of time in which to critically evaluate their beliefs and values prior to making a decision.

Researchers are required to exercise critical reflection to avoid relying on harmful mistaken beliefs about subjects and community in formulating the research protocol and in interacting with subjects and community. Specifically, researchers should reflect critically on whether their judgment of subjects' and community members' competency rests on mistaken beliefs that members of certain populations lack the requisite skills for understanding information about the research trial based on such irrelevant features as gender, race, ethnicity, sexuality, and class. They should ask themselves a similar question with regards to determining what constitutes relevant and adequate information for the purpose of obtaining informed consent.

Research subjects, especially those from oppressed groups within society, are required to reflect on whether they are internalizing oppressive beliefs that, in turn, inform their decisions regarding research participation. For example, in determining whether to participate in a research trial, do they mistakenly believe that their interests carry little moral weight compared to others' interests?

When community members are involved in the informed consent process, they should reflect critically on mistaken beliefs that they may have internalized that bear on their decisions, as well as identify harmful stereotypes that affect how they treat others in the community and the research subject. For example, community members should attempt to identify any mistaken stereotypes they may have about the more vulnerable people in the community and the ways that these influence how they interact with them in the informed consent process. Do they not value input from members of oppressed groups within the community? At the same time, vulnerable members of the community should ask themselves such questions as whether they mistakenly undervalue their interests compared to others' interests.

Notably, the CIOMS Ethical Guidelines do not attend to the need for researchers and subjects to reflect critically on their values and beliefs and the ways in which these might affect the informed consent process. To attend to this, then, we would need to implement the previously proposed guideline in its entirety.

Because, as we saw in Chapter 6, critical reflection alone is not sufficient for promoting autonomy, this amendment should be followed by a clause that explains how support mechanisms can help with critical reflection. With this in mind, I now turn to the ethical condition of support mechanisms and how we can translate this into an ethical guideline for informed consent in international research on human subjects.

10.2 Providing Support Mechanisms

In discussing the ethical condition of support mechanisms in Chapter 6, I explained that this condition addresses two general concerns. First, support groups and counselors can enhance subjects' critical reflection by helping them identify mistaken internalized oppressive beliefs. In doing so, the ethical condition of support mechanisms attends both to critical reflection and to one of the problems relating to social structures, the problem of internalized oppression. The condition also addresses another problem that results from social structures, the problem of oppressive socialization causing subjects to not fully develop some of the skills for autonomy. Counselors and support groups can assist subjects in more fully developing some of these skills, such as self-assertion, self-trust, and self-worth.

How to Structure Support Mechanisms

Since the primary goal of support groups is to help subjects identify internalized oppressive beliefs and to more fully develop their autonomy skills, we should determine how to structure these groups in order to accomplish this goal. One proposal is to have support groups comprised solely of members of the same vulnerable population, such as a support group comprised of women from the community. However, this proposal is problematic. Although it is by no means a certainty that all women suffer from

internalized oppression, it is likely that participants will share internalized oppressive beliefs and underdeveloped autonomy skills. In cases in which all support group members share similar oppressive beliefs and underdeveloped autonomy skills, it will be extremely difficult for them to identify and remedy these problems.

An alternative solution is to have professionals facilitate the support groups. Because professionals are specifically trained in identifying internalized oppression and in facilitating the development of autonomy skills, they can assist participants in accomplishing these goals. Once we rely on professionals to facilitate support groups, we introduce concerns about disparate power and its negative impact on subjects' autonomy. Since this problem also arises in implementing the next ethical condition, participation, I forgo discussing this problem until the next section.

Guidelines for Support Mechanisms

With the preceding arguments in mind, it appears that the best way to structure the support mechanism is to have professionals facilitate support groups that consist of members from the vulnerable population. So as to respect their autonomy, participants should never be coerced to join support groups. Rather, they should be provided the option of doing so, along with an explanation of how it is in their best interest to choose to participate.¹

Having argued that we should provide subjects with an option to participate in support groups, a guideline relating to support mechanisms would read as follows:

¹ Recall from Chapter 6 that the problem with forcing subjects from vulnerable populations to participate in support groups is that this further perpetuates their oppression. It reinforces the mistaken belief that all members of a certain group lack the necessary skills for making an autonomous decision.

As a result of social conditioning, members of vulnerable populations are especially prone to problems of internalizing oppressive beliefs and in not having fully developed some of the necessary skills for autonomy, such as self-trust and self-assertiveness. Internalized oppression occurs when members of vulnerable populations internalize oppressive societal beliefs about members of the population and allow these beliefs to inform their decisions, which results in further perpetuating their oppression.

To better promote their valid informed consent, subjects from vulnerable populations should be provided the opportunity to participate in support groups aimed at identifying internalized oppressive beliefs and assisting in more fully developing autonomy skills. Such support groups are to be offered as an option and are not mandatory.

Support groups should be facilitated by professionals who have the requisite skills for identifying and remedying problems relating to internalized oppression and underdeveloped autonomy skills. Although professionals are assigned the task of assisting subjects, subjects remain the primary risk-bearers of research. As such, their consent takes precedence. In no case shall the consent of a professional override the subject's consent.

Despite being the most progressive international ethical guideline for informed consent in research on human subjects, the CIOMS Guidelines do not insist that researchers provide subjects with the opportunity to participate in a support group. This is not to say that the Guidelines do not acknowledge that oppressive socialization can impede subjects' autonomy. You may recall that Guideline 16: Women as Research Subjects acknowledges that some women's autonomy may be impeded as a result of their social conditioning. However, rather than providing support mechanisms, the Guideline recommends:

When women in such situations are potential subjects in research, investigators need to exercise special care in the informed consent process to promote that they have adequate time and a proper environment in which to make decisions on the basis of clearly given information.²

² CIOMS 2002, Guideline 16.

Although they do not specifically spell out what constitutes a proper environment, it appears that they have in mind an environment in which women are free to reflect on their choices. In other words, their solution for remedying problems that arise from social conditioning is to provide women more time and space to be able to reflect critically on their choices.

Yet, as I have been arguing, critical reflection alone is not sufficient. Many of the ways that social conditioning impedes autonomy have become internalized. Being granted enough time and space to reflect on one's choices does not ensure that one will be able to identify internalized oppressive beliefs or nurture underdeveloped autonomy skills. Consequently, guidelines directed towards remedying these problems must include support mechanisms for assisting subjects from vulnerable populations who suffer from oppressive socialization. Because the CIOMS Guidelines do not contain a clause for providing support mechanisms, we must implement my proposed guideline in its entirety.

10.3 Fostering Participation

Recall from Chapter 6 that the reason for involving subjects and community in various stages of the research process is to attend to problems arising from social structures that relate to external restraints. First, involving them in the formulation stage of research attends to unjustly limited options. Involving the pool of potential subjects and, when relevant, community, in the formulation stages of research enables them to identify unjustly limited options that result from racism, sexism, and so forth. Second, in being able to participate in the formulation stage of research, the pool of potential subjects can help researchers better identify subjects' best interests. And finally, extending participation throughout the research trial helps to maintain more of a balance

of power between researchers, subjects, and community, thereby addressing the problem of disparate power between them.

Guidelines for Participation

A guideline that reflects the need to involve subjects and community in the various stages of research process would require researchers to include subjects in the formulation stage and research trial stage. In addition, when the subject wishes for community to become involved or when the research directly affects members of the community, researchers also should include community in these stages.

Currently, the CIOMS Guidelines include a provision for having subjects participate in an on-going dialogue with researchers that begins in the early stages of the research. Recall from the previous chapter that the following recommendation is included in Guideline 4: Individual Informed Consent:

Obtaining informed consent is a process that is begun when initial contact is made with a prospective subject and continues throughout the course of the study. By informing the prospective subjects, by repetition and explanation, by answering their questions as they arise, and by promoting that each individual understands each procedure, investigators elicit their informed consent and in so doing manifest respect for their dignity and autonomy.³

Notably, this guideline is geared specifically towards having subjects ask questions and researchers provide information in order to promote that subjects understand various aspects of the research, such as the risks, benefits, compensation, and procedures.

Although it is certainly important in order to promote subjects' valid informed consent, I have argued that there are additional aspects of research that also bear on the subjects' ability to provide valid consent. For example, recall from Chapter 6 that, by the

³ *Ibid*, Guideline 4.

time researchers approach prospective subjects, they have already formulated the research protocol. The concern becomes that the options that researchers offer subjects may be unjustly limited as a result of racism or sexism. Including subjects in the pre-trial stages of research, during which time researchers determine the compensation and, in cases of therapeutic research, available treatments, enables subjects to help identify unjustly limited options. Given the disparities of wealth, education, class, ability, etc., involving subjects in the pre-trial stages of research also helps researchers better identify subjects' interests. Hence, it is necessary to add to the CIOMS Guidelines an additional provision that calls for including subjects in the pre-trial stage of research:

In addition to engaging in an on-going dialogue with subjects during the research trial, researchers should obtain prospective subjects' input during the pre-trial stages, a time at which researchers determine the compensation and care which subjects will receive. Doing so helps researchers to better identify unjustly limited options that might arise due to subjects' race, ethnicity, gender, socio-economic class, education, or illness. This also assists researchers in better understanding subjects' best interests.

In addition to including subjects in the pre-trial and trial stages of research, I argued that there are times when researchers also should include community. In cases in which the subject wishes the community to be involved or in cases in which the research has a direct impact on the community at large, community should be included. To address community involvement, we should add the following to the preceding proposed guideline:

Besides having subjects participate in the pre-trial and trial stages of research, there are times when researchers also should include community. These include: (1) instances when the research subject or prospective research subject wants community to be included in the informed consent process due to the value he or she places on community; and (2) instances when the community at large will be directly affected by a research trial.

Adding these proposed guidelines to Guideline 4 in the current CIOMS Guidelines would better promote respect for subjects' autonomy in research on human subjects.

How to Structure Participation

In requiring the research process to be more inclusive, ethical guidelines should provide general guidance regarding how to structure participation. Once we include community, we must spell out when a subject's input should trump the community's input and vice versa. The following guideline indicates how to structure participation with regards to prioritizing subjects' or community's input:

Including community in the consent process raises questions regarding how much weight to place on community input. The answer to this question depends on the degree to which the community will be affected by the research.

Because medical interventions that are part of many research trials directly affect the subject, the subject continues to be the greatest risk-bearer in research. For this reason, community input can never override a research subject's choice regarding his or her research participation.

In decisions that have a greater impact on the community than they do the research subject, community input should outweigh the subject's input. For example, community input should collectively outweigh a subject's input regarding benefit sharing, or the way in which researchers make any treatments they have discovered in the trial available to the community at large.⁴

⁴ Some might be concerned that problems would arise if one subject wanted community to be involved and another did not. If the decision dealt with an aspect of research that affected the community at large, such as benefit-sharing, then community has a right to be involved in the pre-trial stage of planning that deals with this aspect, regardless whether a particular subject disagrees. If, in contrast, the decision has to do with an aspect of research that has a greater impact on the subject, such as whether to participate in a research trial, each subject gets to choose whether they want community involved. The subject that does not want community involved can choose on her own, while the one who wants community involved can ask for community input.

Notably, the previous guideline includes the safeguard of prioritizing the subject's choice in decisions where subjects bear the greatest risk, such as choosing to participate in research. However, this safeguard alone is insufficient for promoting that the subject has made an informed and self-governed choice. Namely, it fails to attend to problems regarding how subjects' consent can be impeded by oppressive socialization in the form of internalized oppression and not fully developed autonomy skills.

In an attempt to attend to this problem, some non-governmental organizations (NGOs) have appointed professionals to assist vulnerable subjects in participating in the research process. Professionals facilitate what they call consciousness-raising workshops for women from less developed countries. These workshops are aimed at accomplishing two goals: (1) helping women identify and analyze systems of oppression within their culture; and (2) involving them in decisions regarding aspects of the research process.⁵

Notably, the way that the NGO workshops are formulated illustrates how support mechanisms can assist with participation. By involving women in the decision-making process that deals with research, the workshops are directed at making the research process more democratic. At the same time, NGOs recognize the problems that arise from oppressive socialization that can impede subjects' ability to provide valid consent. As a result, they supplement participation with what I have referred to as a support mechanism. Recall that support mechanisms are aimed at having professionals assist subjects from vulnerable populations in identifying internalized oppressive beliefs and more fully developing certain autonomy skills. The NGO approach to having

⁵ Eckenwiler 2000, 293-4.

professionals help women identify and analyze systems of oppression within their community represents this sort of support mechanism.

Yet, just as I pointed out in Chapter 6, the combination of participation and providing a support mechanism still fails to promote subjects' autonomy as it relates to informed consent. In the case of the NGO workshops, for example, power disparities occurred between the staff and the women. For example, staff members "determine the categories for analysis, who the target groups are, and who will produce the knowledge that both comes to and emerges from the discussion".⁶

What we can learn from this example is that, if we are to have professionals facilitate, we must attend to possible power disparities that can occur between them and the group members. This is where the ethical condition of having an external review board comes into play. Because I have yet to discuss the external review board, I postpone presenting a guideline that spells out how to address this problem until after discussing the external review condition.

10.4 External Monitoring of the Research Process

In introducing the ethical condition of having an external monitoring board, I presented it as a means of attending to problems that can arise with participation. In Chapter 6, I explained how an external monitoring board could better promote a democratic research process by gauging and encouraging participation and by helping participants work through conflict.

In the previous section, I indicated how the support mechanism and participation work together. Similar to the NGO workshops, a professional can assist subjects in

⁶ *Ibid*, 294.

identifying internalized oppression and nurturing underdeveloped autonomy skills. Assisting subjects with such autonomy skills as self-assertion better promotes their ability to provide input. It may also be the case that subjects want the professional to speak on their behalf.

As a checks and balances against the disparate power between professionals and subjects, an external monitoring board would monitor whether subjects are able to provide valuable input in the research process and, when applicable, the accuracy with which professionals speak for subjects. When community is involved, they could also monitor the balance of input between members and make sure that subjects' consent is prioritized in decisions that deal directly with their involvement in research.

Currently, the CIOMS Guidelines include provisions for an ethical review committee, which is a form of external review.⁷ Researchers must submit a proposal to the review committee for approval prior to conducting research. The committee is comprised of people who are not part of the research team and who are not in a position to benefit, in a financial or material way, from the results of the research. In addition to the necessary requirement of reviewing research prior to its being conducted, the CIOMS Guidelines state, "The ethical review committee should conduct further reviews *as necessary* in the course of the research, including monitoring of the progress of the study".⁸ Because nothing in the Guidelines spells out what conditions call for a necessary review during the course of the research, it appears that the committee is to determine this.

⁷ CIOMS 2002, Guideline 2.

⁸ *Ibid.*

Because the CIOMS Guidelines already include a provision for an external review committee to monitor the progress of a research protocol, the duties that I have insisted belong to an external monitoring board can be incorporated into the duties for the external review committee. Because these duties come into play once we insist on making the research process more democratic, I present guidelines that reflect both how to structure participation and the additional responsibilities of the external review committee:

Whenever subjects, and, when applicable, community, become involved in the pre-trial and trial stages of research, the concern arises that subjects from vulnerable populations may be less likely to provide their input due to power differences between them, community members, and researchers.

Professionals who facilitate the support groups should be available to assist subjects. Research subjects' ability to provide input can be increased by assisting them in more fully developing such autonomy skills as self-assertiveness, when applicable. Subjects may choose to have professionals speak on their behalf. When this occurs, the professional's role is to act as an intermediary between researchers and subjects, and, when applicable, community. As such, they must be careful to only convey the subjects' input.

It is necessary for an external review committee to monitor the progress of the democratic process that occurs during the pre-trial and trial stages of research. The committee should not include members of the research team nor support group professionals. In addition, members of the committee must not be in a position to gain, either financially or materially, from the benefits of the research.

In monitoring the democratic process, the external review committee should monitor whether subjects are able to provide valuable input in the research process and, when applicable, the accuracy with which professionals speak for subjects. When community is involved, they should monitor the balance of input between members. The committee must always promote that the subject's consent is prioritized in decisions that deal directly with his or her involvement in research.

In the CIOMS Guidelines, the previous guidelines would be added to the guidelines for support mechanisms and participation. Translating and incorporating these conditions

into guidelines, along with the safeguard to prioritize subjects' consent, would better promote that the decisions that subjects make with regards to research participation are self-governed ones.

10.5 Conclusion

In this dissertation, I have argued that we need to revise the current philosophical foundation for international informed consent guidelines for research on human subjects. With more and more research being conducted on subjects from less developed countries, it is of the utmost importance that these guidelines be globally applicable. Yet, as I have argued, the current philosophical foundation of respect for autonomy and the guidelines it informs fail to address the importance that many subjects from less developed countries place on community. Based on this importance, many desire for community to become involved in the informed consent process. Once this occurs, researchers have even more reason to recognize and attend to the ways in which social structures, or differences in race, class, gender, or illness, can impede subjects' autonomy. To adequately attend to these problems, I have argued that we need to revise the current foundation to reflect a relational account of autonomy.

In support of this conclusion, I began by comparing the three general accounts of autonomy that appear in the philosophical literature, the traditional, communitarian, and feminist accounts (Chapters 2, 3 and 4). In doing so, I explained why we should prefer a relational account of autonomy. An account of autonomy should address the ways in which social structures impede people's autonomy. Social structures result in such problems as internalized oppression, not fully developed autonomy skills, disparate

power, and unjustly limited options. Only a relational account of autonomy adequately attends to these problems.

In Chapter 5, I strengthened our reasons for preferring a relational account of autonomy by illustrating how this account better promotes autonomy in the context of international research on human subjects. First, I explained how a relational account of autonomy best respects the importance that subjects from less developed countries place on community. To illustrate, I focused on the Akan from Africa, who hold an account of the person in which the value of the person rests, to a large extent, on community. Second, I provided examples of how social structures impede subjects' autonomy in research on human subjects, focusing on those from less developed countries. This gave us even more reason to prefer an account of autonomy that attends adequately to problems arising from social structures.

In order to understand how revising the philosophical foundation for informed consent guidelines might be reflected in policy, I devoted a chapter (Chapter 6) to arriving at a list of minimally sufficient ethical conditions for respecting relational autonomy. After exploring suggestions that others have made in the philosophical literature, I concluded that a combination of most of the previously proposed conditions were still insufficient. In addition to encouraging critical reflection, providing support mechanisms, and participation, I argued that we need an external monitoring board and a safeguard for prioritizing subjects' consent.

Having focused primarily on autonomy in the first few chapters, I shifted gears to address informed consent. In Chapter 7, I began by discussing the relationship between autonomy and informed consent, explaining how informed consent within the research

context has come to rely on the philosophical foundation of respect for autonomy. Because part of the role of being the philosophical foundation for informed consent is that the principle of autonomy justifies informed consent, I responded to objections against having autonomy justify consent, arguing that a relational account of autonomy overcomes the problems that plague the common account of autonomy. As a means of strengthening my arguments in support of relying on the principle of autonomy as justifying informed consent, I explained how relying on a relational account of autonomy provides a better solution than recently proposed alternatives to overcoming the problems that plague the current reliance on the standard account (Chapter 8).

I then broadened my focus to attend to current guidelines for informed consent in international research on human subjects and examined on which account of autonomy each relied (Chapter 9). I concluded that two of the guidelines, the Universal Declaration on Bioethics and Human Rights and the Federal Code of Regulations (or Common Rule), were too ambiguous to be able to determine. Among the remaining guidelines, I argued that the Declaration of Helsinki and the Belmont Report reflected the traditional account of autonomy, while the CIOMS Ethical Guidelines reflected a relational account. Although the CIOMS Guidelines rest on a relational account of autonomy, I explained why further revisions to the specific guidelines were necessary in order to ensure respect for relational autonomy in the context of international research on human subjects.

In this chapter (Chapter 10), I demonstrated how the list of ethical conditions I comprised in Chapter 6 could be turned into specific guidelines for guiding researchers in promoting respect for relational autonomy in the research setting. After proposing these

guidelines, I explained how we might incorporate them into what I argued was the most progressive informed consent guidelines, the CIOMS Guidelines.

In closing, I hope that I have left the reader convinced of the need to have current informed consent guidelines for international research on human subjects reflect respect for relational autonomy. Doing so will enable these guidelines to be more globally applicable in accomplishing the goal to which they are directed.

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