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Toward Comprehension: Improving Informed Consent in Behavioral Genetic Research

Zachary Robert Batchelder
Iowa State University

Toward comprehension: Improving informed consent in behavioral genetic research

by

Zachary R Batchelder

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Major: Psychology (Counseling Psychology)

Program of Study Committee:
Norman Scott, Major Professor
Patrick Armstrong
Clark Ford
David Vogel
Nathaniel Wade

Iowa State University

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ABSTRACT

This applied experimental study examined components of informed consent documents created to enhance awareness, retention, and recall of information. It was conducted as an online study of 216 research pool participants who were considering participation in a behavioral genetic study. Following completion of the IPIP-NEO personality measure, posed as a screening procedure for participation in a study of genetic influences on personality, participants were randomly assigned to one of eight conditions (27 per condition). They were presented with one of eight experimenter-constructed informed consents with requested potential participation, during the following week, in a genetic study that involved donation of a buccal swab sample. Predicated upon a 2 x 2 x 2 between-subjects design, consent stimuli were created based on information processing theories, and they varied on three dimensions: length (short or long), structure (traditional or narrative), and comprehension check (present or absent). Following exposure to one of the consents, participants completed a free response seven-item recall questionnaire that reflected the central components of the information in the consent: risk, access to data, participation time, donation of a buccal sample, cost, and ability to withdraw from the study. Three independent raters, who were unaware of the study design or hypotheses, coded responses based on the degree of congruence between the free recall responses and information in the constructed informed consent. An overall composite comprehension score, a zero-to-seven scale, with seven indicating high comprehension, was created and constituted the primary dependent variable. Comprehension was measured directly after the informed consent presentation (by an immediate free recall measure) and one week later (by a delayed free recall measure and by a separate delayed multiple choice recognition measure) for the 54 persons who returned to participate in the proposed study. Debriefing indicated that the study was hypothetical and genetic sampling did not occur. Participant comprehension was low over all conditions and at the three measurement points. Separate 2 x 2 x 2

between-subjects ANOVAs for immediate recall, delayed recall, and delayed recognition did not reveal significant main or interaction effects. Repeated measures analysis comparing immediate with delayed recall did not show significant main effects or interactions. A mixed between-within analysis, comparing delayed recall with delayed recognition, revealed significantly higher comprehension scores in delayed recognition compared with delayed recall. However, there were no significant differences in main effects across the eight conditions in ether of the delayed measurements. The informed consent modifications tested in this study did not enhance awareness, comprehension, or recall of central elements of consent posed in this hypothetical investigation. The implications for future research, including designs and approaches for enhancing informed consent, were presented.

CHAPTER 1

INTRODUCTION

Overview

This applied psychology investigation was designed to test modifications to informed consent documents used to convey information to potential research participants who might be considering participation in a psychology behavioral genetic study. In such studies a genetic sample, often a buccal swab, is requested in order to study the relationship between the individual's genetic code and concurrent or subsequent measures of the potential participant's personality traits or behaviors. Collection, retention, storage, and dissemination of analysis of such unique person-specific information, when the person's identity is attached to the sample, is a research ethical consideration involving protection of privacy, and the potential implied concern by potential or actual research participants about unwarranted intrusion or unauthorized release of their private information. The *Ethical Principles of Psychologists and Code of Conduct* (2010), as well as required Federal IRB Research Regulations and Guidelines (Code of Federal Regulations, 45 CFR, 46:116, 2009), emphasize protecting the welfare of research participants. These sources stress and require the use of accurate, complete, and comprehensible informed consent documents to fully inform potential research participants about the nature, risk, and costs and potential benefits of participating in a study, so that an informed and voluntary decision to participate can be made.

Thus, this study focuses on the psychological aspects of informed consent in the context of requested research participant agreement to engage in a proposed behavioral genetic study involving collection of a genetic sample for which there is an actual or implied risk to privacy. The study created and systematically modified informed consent documents, guided by the theoretical lens of information processing theories, to create the independent variable stimuli used in the study's informed consent process. The purpose of these documents, and their presentation to participants by a factorial design, was

to measure the effect of variation in informed consent on research participants' recognition, recall, and retention of essential elements of a specific proposed behavioral genetic study. Selected information processing theories were used to guide the creation of independent variable stimuli and to generate hypotheses specific to recognition, recall, and retention of information, for the overall purpose of enhancing awareness and retention of informed consent information. In addition, the study builds upon prior work by Batchelder (2012) in order to determine which elements of informed consent (length, format, comprehension checks) have the greatest effect on participant comprehension of key informed consent concepts.

The subsequent sections of this chapter provide information relevant to a more complete introduction to this study and concepts and findings on which it is based. These sections appear sequentially as: Modern Ethics and Behavior Genetics, Comprehension and Informed Consent, and The Role and Influence of Information Processing Theories.

Modern Ethics and Behavioral Genetics

The study of genetics has advanced dramatically in the past several decades, and the study of how behavior is influenced by genetics, most commonly referred to as behavioral genetics, has also seen great increases in the number of studies being conducted (Leonardo & Hen, 2006). However, there are a number of unique ethical concerns relating to this area. The very nature of genetic research involves examining the unique code of an individual, as revealed through their DNA sequence, and attempting to find links between this code and elements of that individual's phenotypical or behavioral presentation. This highly personal information can be digitized and stored for extended periods of time for use across multiple research trials. Additionally, research on predictive genetic testing is increasingly common for early detection of potential pathology as well (Pelletier & Dorval, 2004). Genetic information has identifying components which are simultaneously unique to the individual but

also have key shared components across groups. These features create unique ethical dilemmas. Historically the medical field has evolved from the 'doctor knows best' model, with essentially uninformed consent to treatment. However, current emphasis is placed on patient information and autonomy, guided by the assistance of medical professionals. Despite this, modern bioethics has yet to incorporate the idea that genetic information may affect both the autonomy of an individual as well as others, and as such implications for research, testing and treatment are continuing to slowly emerge (Green, 1999).

The rapid advances in genetics-related sciences and technologies have additionally raised concerns around the re-emergence of previously extinct ethical concerns. Perhaps most notably, Petersen (1999) discussed a renewed concern among many groups of new potential for eugenics. The eugenics movement is loosely based on the Darwinian idea of 'survival of the fittest', but with the idea of 'fittest' being a societal and political construct rather than one selected by natural survival rates. At its core, the eugenics movement sought to selectively breed individuals with more 'desirable traits', though in reality this generally meant selective exclusion from breeding or even sterilizing individuals without these traits or with 'negative' traits. The earliest example occurring in America involved a plan to exchange the death penalty for many crimes with forced castration to act as both a deterrent to crime and remove the ability to reproduce individuals dubbed 'degenerates' under this proposed law. The law failed to pass the Texas state legislature where it had been proposed, but in 1910 Charles Davenport, a researcher in genetics and evolution, would found the *Eugenics Record Office*, which was dedicated to examining heredity and forming compulsory sterilization policies for individuals with a range of traits including deafness, mutism and 'feeble mindedness' (now commonly referred to as intellectual disability). This set the stage for decades of research and debate in the field of eugenics, as well as compulsory sterilization in several mental institutions (Largent, 2007). Policy on this changed

dramatically following World War II when details of experiments in eugenics directly influenced by American works in Nazi death camps came to public light, however (Kühl, 2002).

While eugenics has been effectively nonexistent in regards to policy in the United States since World War II, new genetic screening technologies are raising concerns about its resurrection. In particular, the study of the 'gay gene' has been a focus of this concern. While many LGBT rights groups have enthusiastically supported efforts to demonstrate a biological underpinning to human sexuality, legitimate concern about the potential for an ability to screen for such a gene *in utero* have been raised as well. In essence, there is concern that such a screening could allow parents with objections to non-heterosexual orientation selectively terminate such pregnancies and effectively eliminate the LGBT community through pre-emptive eugenics (Green, 1999).

Criminal justice fields are also increasingly using genetic profiling to help convict criminals and free the innocent from incarceration. This is achieved by looking at thirteen highly variable parts of the human genome, allowing a very high rate of accurate unique identification except in the case of identical twins. Genetic data is collected from all fifty states for specific felonies, such as sexual assault, with more than half of states taking genetic samples from all convicted felons and more than 20 of these states collecting samples from anyone convicted of a misdemeanor (Ossorio & Duster, 2005). This data is stored in the Combined DNA Index System (CODIS), a national federally-administrated genetic repository. Of concern with this practice is the ongoing genetic research with this data pool, which in many cases are seeking to genetically 'explain' criminality. Coupled with the disproportionate rate of felony convictions for racial minorities, this research may have serious ethical implications about justice and protection of vulnerable populations, such as the incarcerated (Ossorio & Duster, 2005). These are just a few examples of the unique challenges posed by behavioral genetics research. However, little research has been conducted to better understand how to most effectively

communicate to potential participants in behavioral genetic research their rights and potential risks, and to assess the comprehension of such information has been demonstrated to be quite poor. Extensive research on participant understanding of research protocols' informed consent documents have indicated very low rates of comprehension (Hassar & Weintraub, 1976; Kniffen, 1979; Cassileth et al., 1980; Duffy & Kabance, 1982; Riecken & Ravich, 1982; Taub & Baker, 1984; Ascheman 2009; Pederson et al., 2011).

Comprehension in Informed Consent Research

Comprehension of research informed consent documents was studied fairly vigorously in the 1970's and early 1980's, and the consistent findings were a very low level of comprehension for these documents (Hassar & Weintraub, 1976; Cassileth et al., 1980; Riecken & Ravich, 1982). Attempts were made to simplify the research informed consent documents through the use of 'readability forumlae' (Flesch, 1948; Fry, 1968; Grunder, 1978), which were designed to reduce the overall reading level of these documents. However, use of these formulae failed to create any significant differences in participants' comprehension rates (Kniffen, 1979; Duffy & Kabance, 1982; Taub & Baker, 1984) with the exception of a mild increase in comprehension in individuals over the age of 60 (Taub, Baker & Sturr, 1986).

More recent work by Ascheman (2009) aimed to investigate how participants viewed potential risks to loss of genetic privacy by suggesting that their genetic data might be shared with a variety of groups in addition to the investigators in a specific study. In this study the experimenter used research informed consent documents as a manipulation, with varying levels of risk to loss of privacy and disclosure of genetic information, with use of cued recall comprehension checks to ensure the validity of the study. In early analysis, it was found that only 14% of participants were able to recall the essential elements of consent, including potential risks from sharing personally identifiable genetic data

and amount of monetary compensation offered for participation. A more recent examination of research participant comprehension of informed consent documents demonstrated similarly low rates of comprehension, ranging between 11% and 31% comprehension across a variety of informed consent points (Pedersen et al., 2011).

Following up on Ascheman's (2009) work, Batchelder (2012) posed similar questions related to behavioral genetic research with variations in risk to loss of genetic privacy and various levels of monetary compensation for participants. However, in the latter study modification from use of standard informed consent forms was the central manipulation. Short narratives describing the same elements normally contained in informed consent documents were used in contrast to more traditional consent forms in which the information is presented in a more structured and piecemeal format. This narrative format increased comprehension of key elements of the informed consent process dramatically, with 78.8% to 80.5% comprehension of monetary payment across all conditions, 62.4% comprehension of risk in the high risk to loss of privacy condition, 84.24% comprehension of risk in the low risk to privacy condition, 43.2% comprehension of risk specifically related to the ability to gain health and life insurance if genetic privacy were compromised in the high risk condition. However, the potential elements within the short narrative informed consent document that contributed to the increased rates of comprehension were unclear, though explicit use of a comprehension check, length and format were presented as possible key components.

The Role of Information Processing Theories in Comprehension

The key elements modified in Batchelder (2012) all share the common goal of attempting to alter how the information contained in the informed consent document is processed by potential participants. This study proposes that there are two active theoretical constructs at work between the modifications to length, format and use of comprehension check warnings, namely effortful processing

and schema activation. These two key theories that which are relevant to this current proposal are described below.

Effortful processing, as originally described by Hasher & Zacks (1979), can be described as intentionally initiated information processing that requires considerable energy compared to automated processing tasks. Effortful processing results in greater retention and understanding of information compared to automatic processing. Based on these definitions, this study proposes that both length of informed consent document and an explicit statement that a comprehension check will occur following the informed consent document will both influence individuals' effortful processing and subsequent comprehension of informed consent documents. Comprehension check warnings serve as a cue to participants to give more attention to the informed consent document, thereby increasing the likelihood that they will 'intentionally pay attention' to the information being presented. Length of the document then determines how much energy will be required to maintain effortful processing, with increased length requiring more energy thus resulting in decreased likelihood of overall comprehension.

The second relevant theory to this proposal is that of *top-down* versus *bottom-up* processing. The remaining modified element, use of narrative format, is proposed to counteract top-down processing, which can be considered a form of visual schema activation. In the case of informed consent documents, the structured format is proposed to activate a visual schema, bringing to bear 'mental shortcuts' about what has been contained in previous similar-looking documents and keeping participants from fully reading the information presented. To this end, the standard informed consent format is proposed to activate *top-down processing* of the document, while the narrative format is proposed to induce *bottom-up processing* of the informed consent document. These theoretical constructs, top-down and bottom-up processing, are significant in whether or not a pre-existing schema is activated, and as such are highly relevant to this study. Bottom-up processing is described as

cognitive processing that is guided more by external information rather than prior knowledge (Bruning, Shaw & Ronning, 1999), or more simply as progressing from individual elements to the whole concept (Weiten, 2010). By contrast, top-down processing involves a primary examination of the whole stimulus before processing the individual elements that comprise that stimulus. Navon (1977) originally described this as seeing the trees before the forest (bottom-up processing) or the forest before the trees (top-down processing), and further demonstrated that global visual features precede individual features in cognitive processing.

As it applies to informed consent, top-down processing may be activated when a participant first sees a structured informed consent document. They may recognize it as 'another form that looks like others forms I have read before', activating their 'paperwork' schema and resulting in processing the format elements but not the individual details of the informed consent document. By removing the format elements using the narrative format, participants do not have the visual stimulus to activate top-down processing, thereby not activating a visually-mediated schema, and are forced to focus on the individual pieces, increasing the likelihood of comprehension.

Each of these elements, length, format and comprehension check warnings, are not necessary components to generate comprehension of informed consent documents. Rather, they are proposed to each increase the likelihood of accurate comprehension in participants, with a combination of all three generating the largest amount of overall comprehension. By both methodologically isolating and combining each of the proposed components, this study also aims to determine both the individual and combined effects of these modifications to effortful processing and schema activation.

Purpose of Study

This study is an applied project designed to test proposed modifications to the documents used in the informed consent process, with examination of these modifications through the theoretical lens of information processing theories. The study experimentally examines the components of the short narrative format for research informed consent previously proposed by Batchelder (2012) in order to determine which elements have the greatest effect on participant comprehension of key informed consent concepts. These elements are conceptualized using well-established information processing theories to attempt to explain why the proposed changes appear to affect participant comprehension. Further, this study is framed around behavioral genetic research to further the understanding of what methods are most effective for communicating information relevant to the informed consent process in this emerging and ethically challenging domain of behavioral genetic research. As an additional feature, this study examines comprehension of informed consent documents for behavioral genetic research immediately following the presentation of the information using cued recall measurements from previous literature (Ascheman, 2009; Pedersen et al., 2011; Batchelder 2012) as well as cued recall and recognition measurements one week after initial presentation. This approach provides additional insight regarding how well information regarding elements of informed consent is retained for behavioral genetic studies after a significant delay, which is particularly relevant as digitized genetic information may be stored and potentially used in future analyses as new technologies and methodologies emerge.

CHAPTER 2

LITERATURE REVIEW

The roots of modern Western medical and scientific ethical principles can be traced as far back as ancient Greece and Rome. Given the span of time across which modern ethical principles have developed, it is not surprising that modern research for informed consent in biomedical research is complex (Corrigan, 2003). This literature review is provides an examination of the relevant history leading to the current state of ethical principles in both behavioral and biomedical research. The review also provides a brief overview of research on informed consent and other related genetic-medical ethical concerns.

History of Biomedical Ethics

Hippocrates and the Hippocratic Oath

Modern ethical decision making as a codified element in medicine and other fields can arguably be traced as far back as the Hippocratic Oath. Written by Hippocrates or one of his students, it is widely considered to be the first standard code for physician practice (Farnell, 2004). There have been many translations of the Hippocratic Oath from its original Ionic Greek, but North's (2010) translation captures the core philosophy of this early ethical code with, "Into whatever homes I go, I will enter them for the benefit of the sick, avoiding any voluntary act of impropriety or corruption." The popularized phrase 'First do no harm' that is frequently attributed to the Hippocratic Oath does not actual occur within it. Rather, this is a modern reinterpretation. The Hippocratic Oath was traditionally taken in the name of several gods of healing, namely Apollo the physician, Asclepius the healer, Hygieia the goddess of cleanliness and sanitation, and Panacea the goddess of universal remedy. The oath served as a divine contract in addition to a more mortal one, and as such 'impropriety' and

'corruption' are left loosely defined and up to judgment by divine powers if acts that are questionable but not clearly improper are conducted.

The Hippocratic Oath extends beyond the professional practice of medicine, creating a formal structure for the education and training of future physicians who would fall under this school of thought as well. The oath mandates that the practitioner teach "without fee or contract" the healing arts to their own children, the children of their mentors, and to anyone else who swears by the Hippocratic Oath, "but to no others," thus insulating the knowledge of the healing profession of the time to only those willing to commit to these guidelines. Further still, the oath adds the expectation that medical practitioners hold to a high standard in their personal lives as well as their professional ones, stating, "in purity and according to divine law will I carry out my life and my art," as well as the first guidelines for client-doctor privilege with, "whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private," (North, 2010).

Unfortunately, a number of atrocities have been committed by medical and scientific professionals in the name of advancement of science since Hippocrates' time. In the absence of explicit ethical codes of conduct pertinent to practitioners, many harmful experiments were carried out on participants who often were forced into situations against their will. This lead to an international concern and reaction, and ultimately stimulated the creation of modern ethical codes for both research and practice.

The Nuremberg Code

A series of famous international military tribunals after the second World War took place in the city of Nuremberg, located in the southern German state of Bavaria. Aptly named the Nuremberg Trials, their primary purpose was to try and ultimately sentence Nazi war criminals.

Among the secondary trials, formally recorded as *United States of America v. Karl Brandt et al.*, was the Doctors' Trial. At question was the role those twenty-three defendants had in medical atrocities committed before and during the war against Nazi prisoners. Leading up to the war, Nazi forces identified and isolated large numbers of individuals that did not meet the 'Aryan ideal' being heralded by leaders of the Third Reich, which included Jewish people, Gypsies, political dissidents, homosexuals and the mentally ill. In most cases these individuals were transported to concentration camps where they were used for forced labor in inhumane conditions, which was justified in the eyes of those in control of the camps as they viewed the prisoners as sub-human (Shirer, 1960). A smaller number of these individuals were sent to specific sites that have modernly become known as 'death camps' whose primary purpose was the systematic elimination of prisoners either by directly killing them with methods such as toxic gasses or by working them to death. Part of this tragic process included the experimentation by medical professional members of the Nazi party on prisoners, often in search of more efficient methods of euthanasia for those that did not fit into their 'genetic ideal' model. Following liberation of these camps at the end of the war, it was discovered that these camps were actually modeled after a program for euthanizing the mentally ill and disabled that had been occurring in Germany for some time before the war (Lopez-Munoz et al., 2008).

The Doctors' Trial was the international community's effort to hold accountable the medical professionals who were responsible for or complicit with these atrocities. Twenty of the twenty-three defendants in this trial were physicians, and their charges ranged from conspiracy to commit war crimes to actual crimes against humanity. The trial concluded on August 20, 1947 and resulted in seven acquittals, ten sentences ranging from ten years to life imprisonment and seven sentences of death by hanging (Lopez-Munoz et al., 2008). While this answered the question of justice, a second question was posed in this scenario: how are such atrocities to be prevented in the future?

Dr. Leo Alexander, chief medical advisor to the Chief of Counsel for War Crimes responsible for the Nuremberg Trials, studied the German medical experiments in attempt to discover what had motivated these physicians to such acts of cruelty. He subsequently submitted six points defining what 'legitimate medical research' should be, largely contrasting the actions of the Nazi scientists, to the Counsel. Four additional points were added and subsequently adopted in conjunction with the trial verdict. These ten points came to be known as the Nuremberg Code (*Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10,* 1949), the first internationally recognized code for research ethics that would pave the way for future guidelines in research ethics (McCormack, 2005). The core concept of this document was 'voluntary consent', the idea that participants should have the right to elect what they do and do not participate in with regards to research, as well as the idea that certain information needs to be provided to participants in order for them to make an informed decision that is truly considered voluntary. While this was a massive leap forward in terms of ethical standards, this code would prove to be difficult to apply in practice.

The Declaration of Helsinki

By the 1960's, a considerable number of questions and concerns regarding the Nuremberg Code had been raised. In an attempt to address those concerns, the World Medical Association (WMA) convened 100 delegates from 32 major medical associations internationally in Helsinki, Finland with the goal of creating a new, more comprehensive set of guidelines for human research, as well to clearly distinguish the differences between therapeutic and non-therapeutic research endeavors (Corrigan, 2003). The final product of these meetings was the Declaration of Helsinki, which simultaneously reemphasized the ethical foundations of the Nuremberg Code while clarifying and relaxing some areas that had been difficult to put into actual practice. One key element of this new document was the focus on the relationship between risks and benefits in scientific endeavors. Concerns had been raised about

how participants should be informed of risks in human research they may be participating in, especially given that some studies relied then, as now, on deception of their true intent to gather accurate information; this put some studies at odds with the idea of 'fully informed consent' however, as the actual risks could not be disclosed without damaging the integrity of the work. The Declaration of Helsinki addressed this by reinforcing that participants in human research have the, "liberty to abstain from participation" as well as being, "free to withdraw his or her consent to participation at any time" (World Medical Assembly, Declaration of Helsinki, 1964; section I., item 9) while stating that in cases where *fully* informed consent would jeopardize the study then consent would not be 'absolutely necessary' in all circumstances provided that the potential benefits outweighed the potential risks. This change in particular was in response to major medical research, such as pharmaceutical trials, that rely on double-blind methodology to help control for phenomena such as placebo effects; if participants were fully informed of their status in the drug trials, the research could be fundamentally compromised by such confounds.

The Declaration of Helsinki was also the first document to make suggestions about exactly how to obtain consent from participants. Specifically, it stated that consent should be obtained in writing from all participants in a given study. While this has become the norm, it was not actually put into widespread practice until unethical experiments that were not able to prove that they had obtained informed consent, for indeed they had not, were uncovered by investigators and whistleblowers. This included several instances of experimentation on vulnerable populations such as racial minority groups and those living in poverty, which after being brought to light forced a shift in public awareness of ethical research practices and lead to the normalizing of collection of written consent in both clinical and research endeavors (Corrigan, 2003). Additionally, the Declaration of Helsinki laid early groundwork for further protections for participants at major research institutions by recommending

examination and review of any research study that involves human subjects by independent bodies, which would later take form in entities such as institutional review boards.

Since its conception, the Declaration of Helsinki has had six total revisions, occurring in 1975, 1983, 1989, 1996, 2000 and 2008. The first revision expanded and clarified a number of concerns that arose around the original document, but was then followed by only very minor adjustments to changing patterns in the world of research in the second and third revisions. This included a mandate to seek the consent of minors when possible, expanding on the notion of independent review groups for human subjects research, and guidelines for ethical considerations during drug trials that take place across multiple countries. More recent revisions have created more controversy, however, including concerns raised over the ethical implications of placebo drug trials in developing countries compared to developed countries (Nicholson, 2000) and around directives regarding the efficiency and utility of research (Stockhousen, 2000). While the sixth revision reflected a very modest modification of the fifth revision, it has received far less criticism; this may reflect that many major governing bodies did not recognize any revisions of the Declaration of Helsinki beyond the 1989 revision, including the United States Food and Drug Administration (FDA) which instead adopted its own 'Good Clinical Practice' guide (Obasogie, 2008). Similarly, the European Union cites only the 1996 revision in their Clinical Trials Directive (European Parliament and Council of the European Union, 2001), and the European Commission refers to the 2000 revision (European Commission, 2003).

Tuskegee and the Belmont Report

From 1932 to 1972, the United States Public Health Service conducted a lengthy clinical study on several hundred rural Black farmers in Macon County, Alabama. Referred to as the Tuskegee Syphilis Experiment, this study followed the developmental course of the disease syphilis in the participants in the study over an extended period of time and included a multitude of deaths from the

disease as well as transmission to sexual partners and offspring born with congenital syphilis. Participants were also denied treatment that was available to other members of the community, and most disturbingly were denied information and access to treatments for this disease, which included penicillin as of 1940 (Center for Disease Control, 2013). Following details of the study being shared by whistleblowers, the study ended in 1972 and set the stage for the National Research Act of 1974, which included the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The task of this commission was twofold: first, to reassess the ethical principles that were being used to guide human subjects research in both behavioral and biomedical fields, and second, to develop procedures and guidelines for adherence to these ethical principles. The committee took four years to prepare what ultimately became the Belmont Report (1979). This document provided broad interpretations of ethical principles for both common and unique circumstances, which in turn set the standard under which many legal and professional ethical codes and codes of conduct were later developed. Three broad ethics principles were also set forth, which themselves played a strong role in the development of current bioethics and professional codes, including the APA Ethical Principles (2002).

Beneficence

The principle of beneficence is broadly defined as focusing efforts on 'doing good'. In practice this involves moving science toward positive change. The unspoken converse of this principle as outlined in the Belmont Report is that researchers and practitioners should also attempt to avoid or minimize harm. As the nature of much of research, particularly biomedical research, often involves putting human subjects in situations of potential harm with new treatments that promise a potential benefit as well, this can be a tricky dichotomy to navigate. Traditionally this has been navigated by vigorous risk assessment in the process of proposing a study, which focuses researchers on attempting

to find ways to maximize potential gains against minimizing potential risks. This concept becomes further complicated with researcher that may involve some risk to participants with no direct benefits for them immediately, but a potential long-term benefit for society as a whole. In nearly all studies participants are put in some kind of risk, including potential for distress even just by participating, so the question of beneficence must be navigated frequently by nearly all researchers working with human subjects.

Respect for Persons

The principle of respect for persons primarily refers to autonomy of persons, namely their ability to make informed choices regarding their participation or lack thereof in research endeavors. This principle is designed to allow individuals to act in their own best interest, though it is further specified that this is exclusive of any interest to harm others. It also provides additional protections for individuals that may not be able to make fully informed autonomous decisions such as in cases of immaturity, decreased cognitive ability or intellectual disability, or incarceration. The principle does allow for the collection of consent for individuals in these circumstances, but expresses considerations that should be taken in these special cases to maintain these individuals' rights and dignity. The principle as a whole aims to force consideration of individual freedoms and rights regarding potential participation in research endeavors.

Justice

The final and perhaps most abstract principle is that of justice. While this has traditionally been a difficult concept to define in a broad sense, the Belmont Report focuses the concept of justice on the distribution of costs and benefits. The report suggests five dimensions for consideration of this balance:

"1. To each person an equal share.

2. To each person according to individual need.

3. To each person according to individual effort.

4. To each person according to societal contribution.

5. To each person according to merit (individual ability)." (The Belmont Report, 1979, Volume I, Chapter 6, Page 6).

These considerations are reflected in both distribution of benefits of research as well as potential burdens and risks. The historical context and relation of the development of this report to the Tuskegee syphilis study highlights these points further, and make clear the concept that this principle is designed as a protection for potentially vulnerable populations, such as welfare patients, racial and ethnic minorities, and individuals who may be institutionalized, in order to keep them from bearing an undue amount of the burden and risk for research because of the potential ease of access or manipulability of these populations (United States Department of Health and Human Services, 2014).

Due to the overarching nature of justice as it applies to research, it has been one of the major focal points in the development of structural and foundational changes in how research is conducted. One of the primary examples of this can be seen in the emergence of entities such as institutional review boards, which are designed to safeguard human subjects through a rigorous process of review and risk assessment for studies conducted within their purview. The three principles laid out in the Belmont Report taken as a whole have served as a starting point for the development of ethical guidelines and best practices for a large number of professional and academic groups, including the ethics code endorsed by the American Psychological Association as explored later in the next section.

Ethics in Modern Psychological Research

The American Psychological Association (APA) continued the tradition of the three principles set forth by the Belmont Report (1979) but expanded on these principles, added two new principles, and created specific ethical guidelines for both research and practice in the field of psychology. The most current revision is the *Ethical Principles of Psychologists and Code of Conduct* (2010). The spirit of the three original ethical principles enshrined in the Belmont Report are reflected in the APA's principles of beneficence and nonmaleficence, justice, and respect for peoples' rights and dignity, which closely mirror the original three principles but add the some significant clarification. Nonmaleficence makes explicit the originally implied idea that not only must researchers seek to do go, they should also seek to minimize harm. Justice is essentially unchanged conceptually, though because of its nature as a social construct its interpretation may be considered to have changed over time. Respect for peoples' rights and dignity specifies, beyond the Belmont Report's concern for individual rights, that not only must participants in research and clinical practice have their rights carefully preserved, but that they also have a fundamental right to not be degraded or have their sense of self and dignity damaged or threatened by means of participation in these activities. The APA ethics code also adds two new principles for consideration: integrity as well as fidelity and responsibility.

These new principles raise significant consideration for the informed consent process in particular, with a focus on ethical awareness of professional and social responsibilities and promotion of accuracy and honesty in both research and clinical endeavors (American Psychological Association, 2010). Studies that use deception are in particular scrutinized under these new principles, which can be defined as studies in which it is impossible to fully inform participants of what may occur during research without compromising central aims of the research. While the very idea of a deception study appears to conflict with both the principles of integrity and respect for peoples' rights and dignity, the

APA ethics code addresses this conflict directly in section 8.07 of the 2010 ethics code by stating, "(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective non-deceptive alternative procedures are not feasible." This places the burden of proving that deception is the only methodology to validly collect data in a given research endeavor squarely on the shoulders of the individuals conducting the research, in addition to needing to demonstrate the potential benefit that the research is hoping to promote. The code further specifies that in order to rectify the deception and fully inform the participant afterward, all aspects of the study should be revealed to participants following the deception and they must then be given an opportunity to withdraw their consent to have their data used for the study (American Psychological Association, 2010, Sections 8.07 and 8.08).

Modern Federal Genetic Ethics Legislation

While many professional organizations such as the American Psychological Association have taken steps to enshrine their own ethics policies and standards, the federal government has also taken steps to help prevent ethics abuses for all researchers. One of the main bodies responsible for the investigation of alleged abuses and for recommending legislation to prevent such abuses is the National Bioethics Advisory Commission (NBAC). This commission was established by former president Bill Clinton in 1994 and was charged with investigation into several alleged abuses during the time, many of which centered around the emerging research field of genetics. Their work resulted in the passage of a law, cited as Annas, Glantz & Roche (1996), entitled The Genetic Privacy Act of 1996, which was designed to establish clear legal ownership over genetic samples that had been or would be contributed to research endeavors to the individuals that donated the samples. The Genetic Privacy Act also requires researchers to obtain specific consent from participants to collect, store, and analyze genetic

data, as well as explicit consent before disseminating any samples beyond the original research project. The primary difficulty that this legislation ran into, despite being well intended, was that it did not have the means to actually enforce these guidelines. More recently, the Genetic Information Nondiscrimination Act (GINA) of 2008 reinforced several of the major tenets of the Genetic Privacy Act, but also prohibits the use of genetic information in employment and health insurance determinations, and has both a mandate and resources to enforce this. It does, however, leave open loopholes regarding life insurance and long-term disability insurance eligibility determinations with genetic data. The most recent addition to these protections comes under the 2010 Affordable Care Act, which prevents health insurance carriers from discriminating against individuals with pre-existing conditions when obtaining health insurance. While GINA also prevented health insurers from discriminating on the basis of genetic information, the Affordable Care Act goes one step further by preventing discrimination against 'manifest' genetic diseases that could be discriminated against by health insurers under GINA. This meant that genetic diseases that were having an impact on an individual's health at the time of application for coverage could be used to determine eligibility, as opposed to a genetic marker for an increased for some form of disease or disorder (Saraka, DeBergh & Staman, 2011).

Federal Informed Consent Guidelines

The approval and regulation of studies involving human subjects, particularly if the study or the institution it is being conducted at receives any federal funding, is regulated primarily by the United States Department of Health and Human Services. In particular, the Code of Federal Regulations, Title 45 (Public Welfare), Part 46 (Protection of Human Subjects) details how institutional review boards should be structured, criteria for membership on these boards, how these boards should review research

proposals, and a comprehensive list of what is *required* in the informed consent process (45 CFR 46:116). The core of the informed consent process requirements begins by stating:

> "Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence," (Code of Federal Regulations, 45 CFR, 46:116, 2009).

The code goes on to describe what specific elements must be present in an informed consent document. Section 116a(1) identifies the need to state that the study involves research, an explanation of the purposes of the research, the expected duration of involvement for the participant, a description of the procedures to be followed during the study and explicit identification of any procedures which are experimental. Sections 116a(2) through 116a(4) involve information regarding possible risks and discomforts to the subject as well as potential benefits to both the subject and others. Disclosure of alternative procedures or treatments, confidentiality of records and recourse for adverse events if the study involves more than minimal risk are covered under sections 116a(4) through 116a(6). Finally, sections 116a(7) and 116a(8) cover requirements for contact information for the principal

investigator(s) and groups responsible for subject's rights, as well as statements that participation is voluntary and consent may be withdrawn at any time without loss or penalty of benefits to which the subject is otherwise entitled. Sections following these deal with specifically vulnerable populations, such as pregnant women and children.

Comprehension in Informed Consent

Given the specificity and breadth of the above federal guidelines, the question of whether or not participants are able to understand this information has been raised repeatedly, especially given that the onus is on researchers themselves to demonstrate that they are appropriately informing potential participants to the risks and benefits of participation in research. In an attempt to quantify the readability of informed consent documents, several 'readability' formulas were proposed to measure the difficulty of language in such documents. The most famous and frequently used examples of these, as outlined by Grunder (1978), are the Flesch (1948) and Fry (1968) formulas. Both formulae use variations of counting words per sentence, sentences per 100 words, and syllables per 100 words, with different criterion for scoring the actual reading difficulty. While these formulae were used extensively to study readability of informed consent documents (Gray et al., 1978; Riecken & Ravich, 1982; Handelsman et al., 1986; Ogloff & Otto, 1991), the actual utility of these formulae for comprehension of informed consent has been called into serious question.

Several early studies examined the assumption that improved readability increases comprehension. Among the earliest was Coleman's (1962) study that used the Flesch readability formula to compare documents with average sentence lengths of either 38.6 words or 15.4 words, but found only marginally significant differences in comprehension of the documents between these two dramatically different levels of readability. Siegel, Lautman & Burkett (1974) used the same formula and adjusted consent documents down in 3.5 grade level increments, but again found only marginally

significant improvements in comprehension in one of three experimental trials. Even adjusting documents so that the readability formula indicated that the document's difficulty was four grade levels below what participants were rated as showed no significant improvements in comprehension (Kniffen, 1979).

A major criticism of these early studies, however, was that they consistently had fairly small groups participating in the experiments. Duffy & Kabance (1982) addressed this criticism and took this a step further by conducting a series of five experiments that varied documents in difficulty from an 11^{th} grade reading level to as low as a 5.5^{th} grade reading level. Each of the five experiments had between 50 and 230 participants, a substantial increase over previous studies, and like the previous studies found no effects on comprehension in four of the five conditions, and only marginally significant improvements in comprehension in the most extreme comparison condition, and then only when examining participants' responses to a multiple-choice questionnaire about the documents but *not* in the case of responding to open-ended questions about the document. Memory for informed consent documents in general also appears to be quite poor (Hassar & Weintraub, 1976; Cassileth et al., 1980; Riecken & Ravich, 1982) and the use of readability formulae also do not appear to improve memory for this information (Taub & Baker, 1984) except in individuals over the age of 60 (Taub, Baker & Sturr, 1986).

Experimental examination of comprehension in informed consent has seen far less research in the past twenty years than in the twenty that preceded it, but more recent work has demonstrated that comprehension is still an elusive, and increasingly critical, element of the informed consent process (Ascheman, 2009; Pedersen et al., 2011; Batchelder, 2012). More recent work on the informed consent process and the potential pitfalls of low levels of comprehension and document readability have focused in more specific areas, such as informed consent in psychotherapy (Handelsman & Martin,

1992; Wagner, 1998; Walfish & Ducey, 2007) and more recently how the informed consent process plays into the emerging field of integrated primary care (Hudgins et al., 2013). Despite years of such research, comprehension of informed consent documents continues to be a significant difficulty and an area of substantial ethical concern.

Relevant Psychological Theories

Effortful vs. Automatic Processing

The idea of automatic processing has existed for nearly as long as the field of psychology, with references in foundational works such as James' (1890) *The principles of psychology* and Wundt's (1903) *Grundzüge der physiologischen Psychologie* [Principles of physiological psychology]. Since these early works, the idea that much of what is processed by the human mind occurs in an 'automatic' fashion has been widely discussed (Moors & De Houwer, 2006), though the converse idea that some stimuli must then be processed in an 'effortful' manner did not receive much attention until the seminal work of Hasher & Zacks (1979). These researchers defined *automatic processing* as, "Operations that drain minimal energy from our limited-capacity attentional mechanism," and *effortful processing* as, "require[ing] considerable capacity and so interfere with other cognitive activities also requiring capacity. They are initiated intentionally and show benefits from practice," (Hasher & Zacks, 1979, pg. 356). More recently, theorists have broken these concepts down further, again focusing on defining automatic processing and contrasting those subsequent concepts against the idea of an effortful process. Moors & De Houwer (2006) describe automatic processes as being made up of the presence of features including unintentionality, uncontrolled or uncontrollable processing, goal independent or non-goal oriented processing, autonomy, purely stimulus driven, unconscious, efficient and fast.

By way of contrast then, effortful processes may be considered those that have elements of intentionality, control in what is being processed and when, goal-driven orientation, processing that

goes beyond the immediate stimulus, conscious awareness of what is being process, lower efficiency and decreased speed (Moors & De Houwer, 2006). While many of these sound, at face value, to be less useful and by nature less efficient, there are benefits to effortful processing as well. While the process is slower and less efficient, it increases the amount of mental energy being spent on a given stimulus (Hasher & Zacks, 1979). For purposes of this research, this increased time and energy is described to be a feature sufficient, but not always necessary, for increasing comprehension of a stimulus being effortfully examined, in this case informed consent documents. This effect on comprehension has been demonstrated, though historically this has been in fields such as learning-disabilities (Ackerman, Anhalt, Dykman & Holcomb, 1986) and most recently this research has occurred largely in the field of geropsychology (Naveh-Benjamin, Shing, Kilb, Werkle-Bergner & Lindenberger, 2009; Naveh-Benjamin, 2012).

Bottom-up and Top-down Processing

The concepts of bottom-up and top-down processing go by several different names based on the domain of the researcher discussing the concepts (Navon, 2003). For the purpose of this literature review, the primary work from the area of cognitive psychology that will be used as a starting point is Navon's (1977) work examining whether participants more immediately recognize *global* features of a stimulus (top-down activation) or *local*, or smaller and more specific components that make up the whole picture (bottom-up activation). In this early work, participants were asked to verbally identify single letters on paper; the large (global-level) letters presented were composed of a series of arranged smaller letters (local-level), with a different letter comprising the local level than the global level, though only one letter was used at the local level (i.e. a large capital letter 'I' composed of a series of capital letter 'P's). The series of experiments conducted by Navon (1977) demonstrated no interference from the smaller stimuli at the local level when identifying the larger letter, but significant

interference from the global-level stimulus when trying to identify the smaller stimuli. To remove the effects of reading, he also conducted a similar experiment using geometric shapes with similar results.

Following this early work, Navon (1983) proposed the idea of *global addressability*, which states that global features are more likely to activate visual schemata faster than local features, which was supported by a series of other experiments on visual stimulus recognition (Breitmeyer, 1975; Henning, Hertz & Broadbent, 1975; Hughes, 1986). This concept suggests that the brain may be wired to examine larger global cues first for similarity to existing schemata, which is arguably a more efficient process (Navon, 2003). Neuropsychological research has more recently begun to demonstrate that the identification of global versus local features, or top-down versus bottom-up processing of stimuli, appears to be handled by two largely separate, lateralized neurological functions as well (Fink, Marshall, Halligan, Frith, Frackowiak & Dolan, 1997; Evans, Shedden, Hevenor & Hahn, 2000). A substantial body of literature has supported the idea that top-down processing is a more efficient measure that appears to try to occur before examination of local features, or bottom-up processing, which can actually interfere with the processing of local stimuli (Navon, 1977; Navon 1983; Treiman, 2001; Navon, 2003; Woltin, Corneille & Yzerbyt, 2012).

Assessment of Memory

Until the 1960's, memory was generally considered to be a single process (Tulving, 2001). Over five decades of extensive research into this area has dramatically shifted our understanding of human memory, recognizing many facets that serve different functions at different times (Eichenbaum & Cohen, 2001). Previous studies looking at comprehension in informed consent documents primarily examined immediate cued recall (Hassar & Weintraub, 1976; Cassileth et al., 1980; Duffy & Kabance, 1982; Riecken & Ravich, 1982; Ascheman, 2009; Batchelder, 2012), which is quite appropriate given the need to immediately understand informed consent information before deciding whether or not to

participate in a given research project. The examination of comprehension in these conditions is a direct assessment of explicit memory, described as a conscious, intentional recollection of the past (Mulligan, 2008). While cued recall plays an important role in memory, there is evidence to suggest that it is neurologically different from recognition memory.

Perhaps most notably, a great deal of research differentiating the concepts of recognition and recall memory originated with the study of patient HM, first discussed by Scoville and Milner (1957). HM suffered from epileptic seizures, and in an attempt to alleviate these underwent a bilateral removal of his medial temporal lobes. This resulted in dramatic impairment in his episodic memory functioning, notably a near complete loss of his ability to complete free recall memory tasks and severe impairment to his ability to complete cued recall tasks. However, as demonstrated in HM and other research subjects (Manns et al., 2003), the ability to recognize recently learned stimuli and differentiate them from new stimuli was substantially stronger than their ability to recall learned stimuli, though their performance was still weaker in this area than the general population. While there is a great deal of debate regarding the specific areas of the brain responsible for recall and recognition memory (Manns et al., 2003; Yonelinas et al., 2005), there is broad agreement that these are two fairly distinct forms of memory, which has resulted in notable changes in memory assessment as well, such as the inclusion of recognition measures in the third revision and onward of the Wechsler Memory Scales (Wechsler, 2009).

Behavioral genetics studies raise new concerns that merit new types of measurement; with the ability to digitize genetic information and store it indefinitely for potential analysis at later times as new techniques emerge, the ethical landscape around this particular topic may become more difficult if participants in such studies are unable to access other longer-term forms of explicit memory as it pertains to their rights and responsibilities with their genetic information in each study. Therefore, this

study will examine not only immediate cued recall of informed consent comprehension using various formats, but also delayed cued recall and delayed recognition relating to comprehension in these conditions as well.

Recall

Recall memory can be divided into two subtypes: free recall and cued recall. The primary distinguishing feature of both of these subtypes is the focus on remembering previously presented information without having the information presented again (Stern & Hasselmo, 2008). Free recall refers to remembering previously presented stimuli, such as a list of words, without any addition structure or cues. For example, if someone were presented with a list of ten words, five naming different pieces of furniture and five naming types of fruit, a free recall task might ask the individual simply to repeat all of the items that were on the previously presented list without any other prompts. Cued recall, by contrast, presents some structure to responding by giving an individual cues regarding precisely *how* to structure their responding. Using the above example, cued recall questions might ask the individual to first name all the pieces of furniture from the previous list they could remember, followed by asking them to name all the fruit names from the previous list they can remember. In either case, the original list is not being presented or in any way directly referenced when the individual has to try to remember what they had previously been exposed to. As there are several unique subcomponents of the informed consent process, cued recall is generally selected when assessing comprehension to help differentiate what specific pieces are or are not being comprehended.

Recognition

While recall is a powerful method for assessing learning and memory, recognition serves a similar purpose in examining whether or not information was encoded into memory while using far fewer resources. While both assessments of explicit memory require that information be encoded,

stored and retrieved from memory, recognition only requires that previously learned stimuli be distinguished from novel stimuli (Stern & Hasselmo, 2008). This process was further broken down by Atkinson and Juola (1974), who suggested that recognition actually has two components, a rapid familiarity process to determine if a stimulus has been seen before and a secondary search process to retrieve more detailed information if the stimulus is recognized as one that has been previously seen. Tulving (1983) expanded on this for long-term recognition memory by suggesting two separate recognition components termed 'recollection' and 'familiarity'. Recollection is described as the ability to identify that information has been seen before without any necessarily greater detail than that, while familiarity refers to the ability to retrieve specific contextual details for the information. Stern and Hasselmo (2008) explain this in the context of passing someone on the street, with recollection leading to the ability to identify that someone you may pass is someone you have met previously but not necessarily being able to remember where you have seen them before or details such as their name, whereas familiarity would include details such as the person's name, context in which you are acquainted to them, last time you spoke with this individual, and so on. To build from the example used in the recall section above, a recognition test for the ten item list of fruits and furniture might be similar to a multiple-choice test, with one correct answer represented by one of the previously encountered stimuli (i.e. 'apple') and several new distractor stimuli (i.e. tomato, pineapple, bench) that were not in the previous list. In such cases, either recollection or familiarity will lead to a correct answer provided that distractors are appropriately identified as novel.

Narrative Informed Consent

While the use of narrative format is common practice in the discussion and critical analysis of many ethical issues in psychology (Koocher & Keith-Speigel, 2008), the use of narrative format for the facilitation of informed consent has not been explored in the current literature. In this case, a narrative

format informed consent is described as a brief descriptive statement that evokes the core concepts of what is being described, in this case the nature of a study, risks, benefits and costs as normally described in the structured informed consent process. While there is no extant literature to support the use of this as a proven method for improving comprehension in the informed consent process, the work by Batchelder (2012) demonstrated a dramatic spike in comprehension using this format when adapting similar research materials used in Ascheman's (2009) thesis work.

Ascheman (2009) sought to follow up on Bentley & Thacker's (2004) study examining concerns about genetic privacy, but modified the aim to consider how monetary compensation might shift undergraduate students' concerns about their genetic privacy. The study began with a 140-item personality questionnaire that was stated to be the primary measure of the study, but in reality this served as a distractor that was followed by an 'invitation' to a second study. The informed consent document for the second study was the primary manipulation, with participants receiving either an invitation to a highly risky study in which their genetic data, if they chose to share it, would be accessible to many individuals across a number of disciplines including health and life insurance agencies, or low risk in which their data would be well-protected and accessible only to the researchers. Additionally, they were offered either a very small ($10) or large ($100) monetary incentive if their genetic information was accepted into a genetic repository, though the repositories were fictitious, so no money was ever paid to participants.

One of the critical problems that arose in the analysis of this data, however, was extremely low rates of comprehension on a brief open-ended writing tasks designed to check whether or not participants actual understood, or even read, the informed consent document. After final analysis, only 14% of participants were considered to have comprehended the document they read. This finding was similar to previous estimates of between 11% and 31% comprehension rates (Pederson et al., 2011).

However, this finding compromised other analyses, so Batchelder (2012) sought to follow up on this by improving comprehension using a new short-narrative format that described identical elements of the standard informed consent document from Ascheman's (2009) work, but in a less structured narrative format. Comprehension rates jumped to between 78.8% and 80.5% for level of compensation offered, 62.4% comprehension of the high level of risk condition, 84.24% comprehension of the low level of risk condition, and 43.2% of the specifically stated risk to potential to get insurance in the high risk condition. This spike in comprehension was proposed to have been due to some combination of four possible factors: length of the document, use of the short-narrative format, novelty of the format, and use of a personalized message highlighting the individual's contribution to the study when inviting participants to review the informed consent document. The proposed study aims to follow up on these questions in order to determine which of them, or which combination, may be most responsible for the dramatic increases in informed consent seen in the previous study, as well as which elements may result in a better ability to recall and/or recognize key elements of the informed consent document.

Unique Features of this Study

In Batchelder's (2012) thesis study, high levels of comprehension were demonstrated using primarily immediate recall measures regarding both risks and benefits for participating in a fictitious behavioral genetics study. This study experimentally examines the features and possible feature combinations used in the short-narrative format informed consent manipulations to causally determine which features or feature combinations have significant effects on participants' comprehension of the study. The features are the structure (standard or short-narrative), the length (either standard or shortened), and either the presence or absence of a statement identifying the use of a comprehension check immediately following the informed consent document. The study was conducted as a 2(structure) x2(comprehension check warning) x2(length) between-subjects factorial design with each

of the above features serving as a binary factor, either present or absent in each given cell (see Figure 1, page 34). This study is unique in that it manipulates new elements of an informed consent that has already shown very high rates of comprehension, whereas other studies have used well-established criteria such as word count and readability formulae (Ogloff & Otto, 1991; Pedersen et al., 2011). Further, this study examines these modifications guided by application of established psychological theoretical constructs, namely visual schema activation and effortful processing.

Examination of long-term retention across manipulations to the informed consent process is a unique feature of this study. By examining both recall of information related to the manipulated informed consent documents, as well as the ability to recognize correct information from the consent manipulation one week from the original presentation, this study develops understanding of which modifications to informed consent documents produce both the best immediate and long-term information retention outcomes. In the case of behavioral genetic studies, which may store data for long periods of time but also offer individuals other rights such as the ability to have their data removed at any time, increased long-term retention of information pertinent to rights and risks may have substantial benefits to participants.

An additional unique feature of this study is the emphasis on informed consent in behavioral genetic studies. While this focus does limit generalizability of the findings for informed consent in other research or clinical areas, there has been a substantial increase in research in behavioral genetics (Leonardo & Hen, 2006) and the delicate nature of behavioral genetic research and its potential impact both on participants and non-participants that may share elements of the same genetic make-up cannot be ignored (Burgess, Laberge, & Knoppers, 1998). The decreased generalizability outside this area is offset by the potential benefit to greatly improve comprehension during the informed consent process in this domain. As very little research has been done in the area of informed consent for behavioral

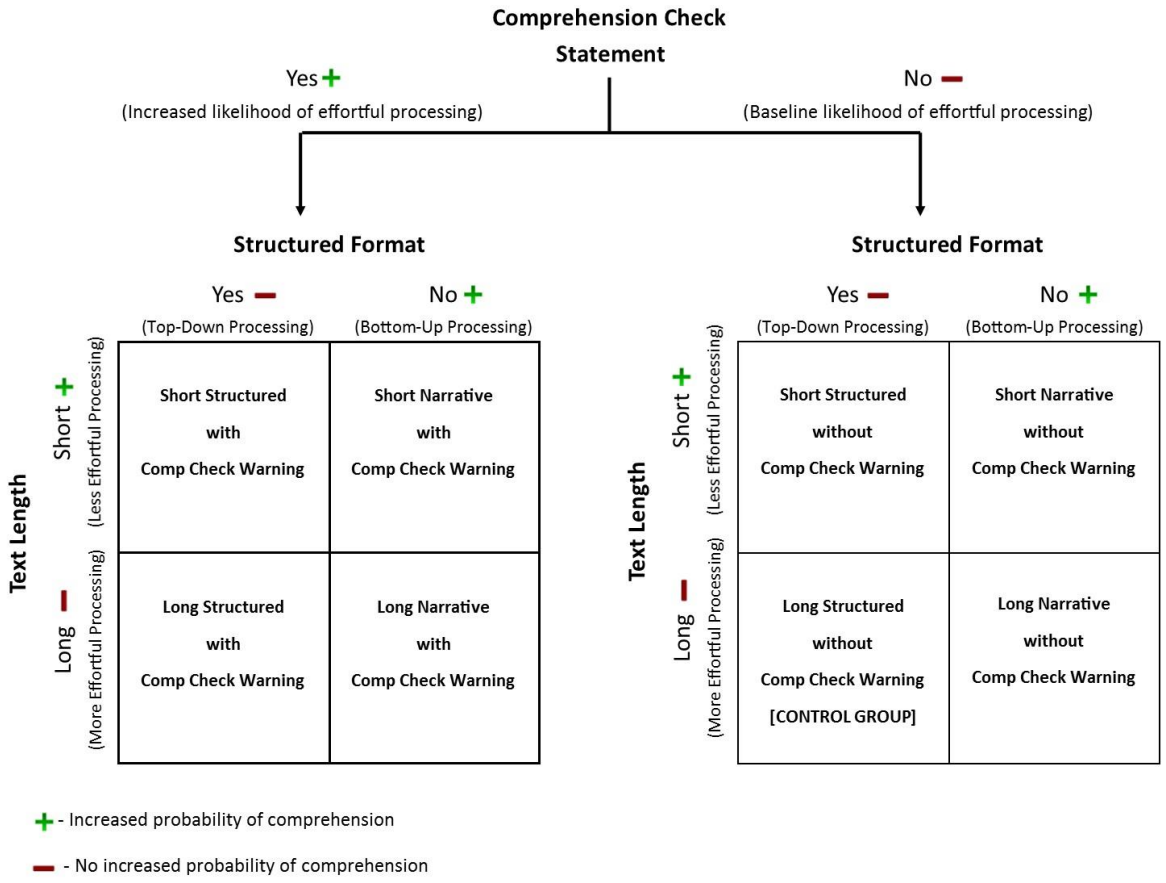


Figure 1: Treatment Conditions

genetics, focusing elements of this study specific to this domain has an opportunity to make a unique contribution to the current body of research. In addition the study has the potential to better inform researchers, clinicians and institutional review boards about the most useful elements to incorporate into the informed consent process for behavioral genetic research or even genetic counseling.

The elements of the informed consent document from Batchelder (2012) that are hypothesized by this study to have had a positive effect on comprehension also involve relatively direct and accessible changes to the informed consent process. A decrease in length or use of a narrative format both have the benefit of decreased reading time with increased comprehension for participants. These

elements in particular are consistent with research by Sachs et al. (2003) that demonstrated that even fully functional, healthy adults may not have the capacity to fully understand informed consent documents at their current length and complexity. While one condition in this study highlights the presence of a comprehension check, participants' responses to the comprehension check was not used to screen individuals and determine their eligibility for the study, which is consistent with current informed consent procedures.

Statement of Purpose

The purpose of this study was to experimentally examine the components of the informed consent manipulation used in Batchelder (2012) to determine which of these components or combinations thereof have an effect on participants' comprehension of informed consent documents. By determining which elements contributed to the increased comprehension demonstrated in the previous study, the aim of this research is to improve understanding of how informed consent documents are understood by participants through the lens of established psychological theories of information processing, as well as to help refine future informed consent documents and further improve the potential welfare of research participants. These findings help to better emphasize participants' right to self-determination for participation in a study by enhancing understanding of the procedures, risks and benefits of each unique study. In particular this study aims to directly improve the consent process for behavioral genetic research. This is especially important as use of genetic samples from a single participant may have far wider-reaching impact on individuals who also share elements of the participant's genetic make-up but did not consent to any kind of research. These studies raise the potential of intrusion into privacy that could also have wide ranging impacts on that individual or even an entire class of individuals. Further, this study examines what changes to informed consent documents for behavioral genetics studies improve long-term retention of relevant

information and how this may be affected by different forms (top-down versus bottom-up processing) and degrees (effortful versus non-effortful) of information processing. This is an especially important implication of behavioral genetic research as some participant samples used in these studies may be stored for a number of years. By helping improve comprehension overall, it is the goal of this research to improve participants' ability to exercise their right to choose what research to actively engage in and to better understand both individual effects of the research as well as potential broader implications of a given research endeavor.

Main Hypotheses

These hypotheses are delineated by independent variables (structure, presence or absence of comprehension check warning and length), with each independent variable hypothesis including the three dependent variable measurement points: Immediate *Recall* Comprehension, Delayed *Recall* Comprehension, and finally Delayed *Recognition* Comprehension.

Hypothesis 1 (Figure 2) – (Structure) Improvement with Bottom-Up Processing:

- 1a – At the *immediate recall* measurement, the short-narrative condition will have a higher rate of overall comprehension than the standard format condition.
- 1b – At the *delayed recall* measurement, the short-narrative condition will have a higher rate of overall comprehension than the standard format condition.
- 1c – At the *delayed recognition* measurement, the short-narrative condition will have a higher rate of overall comprehension than the standard format condition.

Hypothesis 2 (Figure 3) – (Presence/Absence of Comp. Check Warning) Improvement with Effortful Processing:

- 2a – At the *immediate recall* measurement, the comprehension check warning condition will have a higher rate of overall comprehension than the no warning condition.
- 2b – At the *delayed recall* measurement, the comprehension check warning condition will have a higher rate of overall comprehension than the no warning condition.
- 2c – At the *delayed recognition* measurement, the comprehension check warning condition will have a higher rate of overall comprehension than the no warning condition.

Hypothesis 3 (Figure 4) – (Length) Improvement with Decreased Length:

- 3a – At the *immediate recall* measurement, the decreased length condition will have a higher rate of overall comprehension than the standard length condition.
- 3b – At the *delayed recall* measurement, the decreased length condition will have a higher rate of overall comprehension than the standard length condition.
- 3c – At the *delayed recognition* measurement, the decreased length condition will have a higher rate of overall comprehension than the standard length condition.

Hypothesis 4 – Interaction effects:

- 4a – At the *immediate recall* measurement, there will be a significant positive (increase in comprehension) three-way interaction between decreased length, short-vignette format and presence of a comprehension check warning.

- 4b – At the *delayed recall* measurement, there will be a significant positive (increase in comprehension) three-way interaction between decreased length, short-vignette format and presence of a comprehension check warning.
- 4c – At the *delayed recognition* measurement there will be a significant positive (increase in comprehension) three-way interaction between decreased length, short-vignette format and presence of a comprehension check warning.

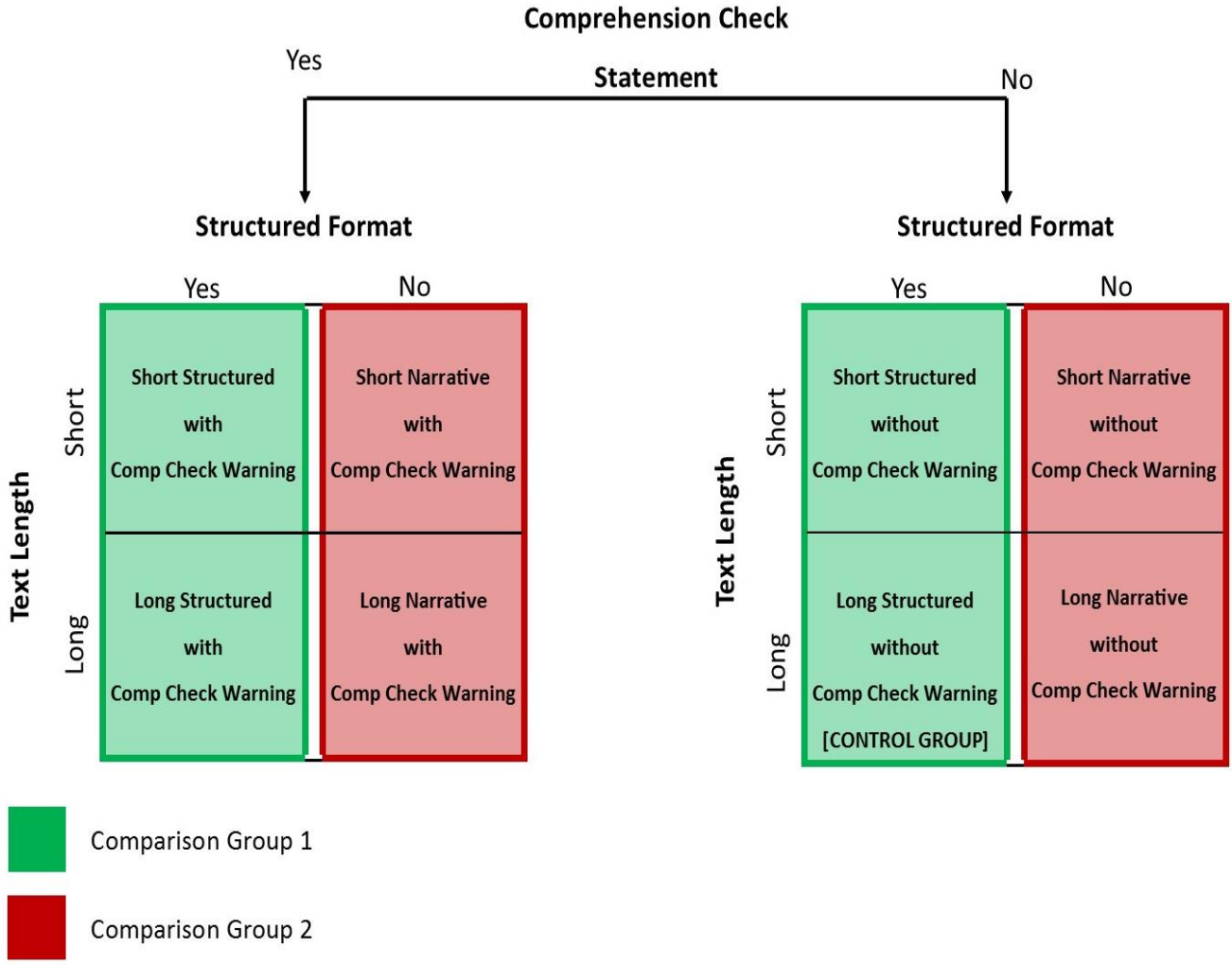


Figure 2: Hypothesis 1 (Structure) Contrast Plan

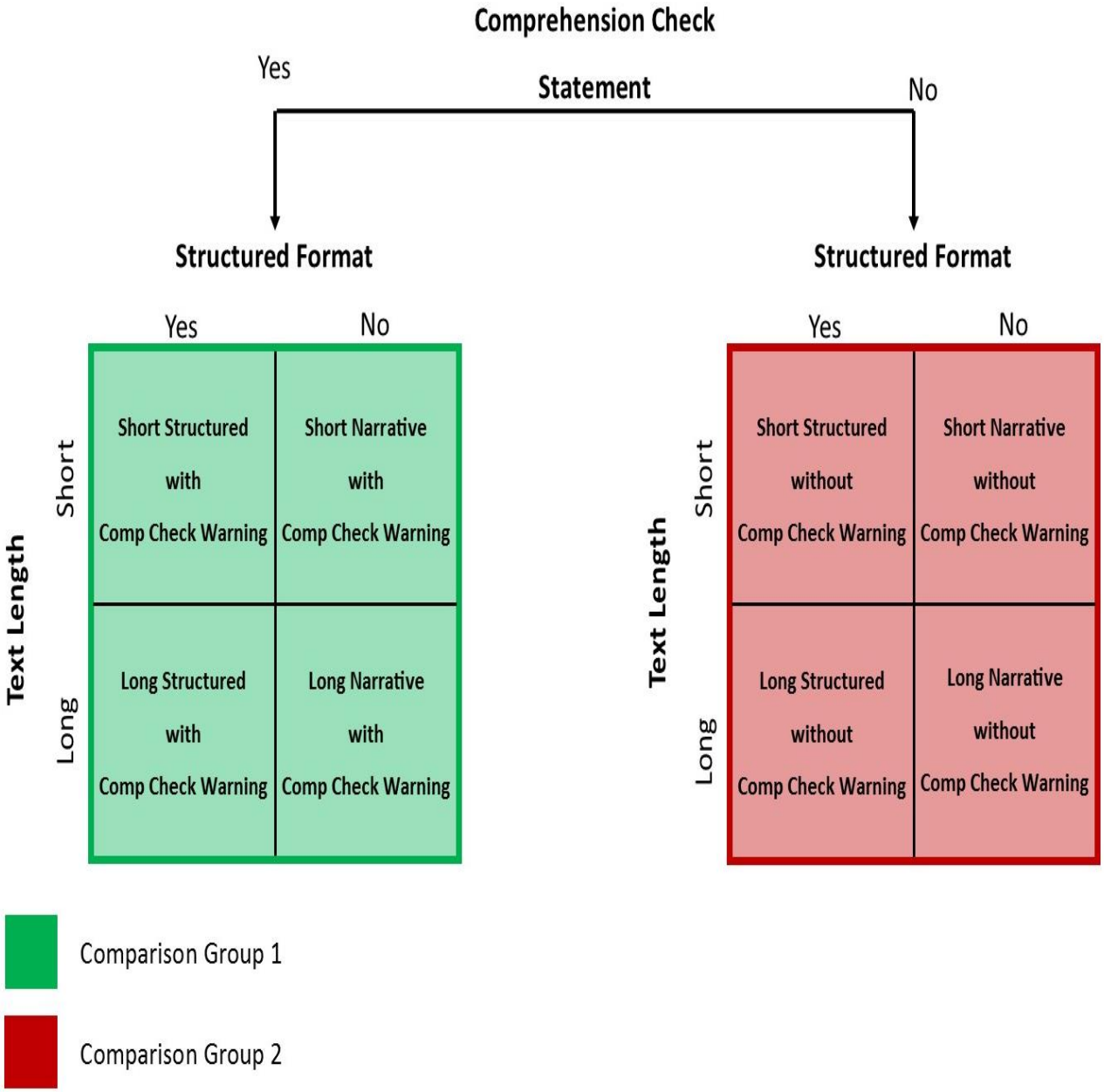


Figure 3: Hypothesis 2 (Comprehension Check Warning) Contrast Plan

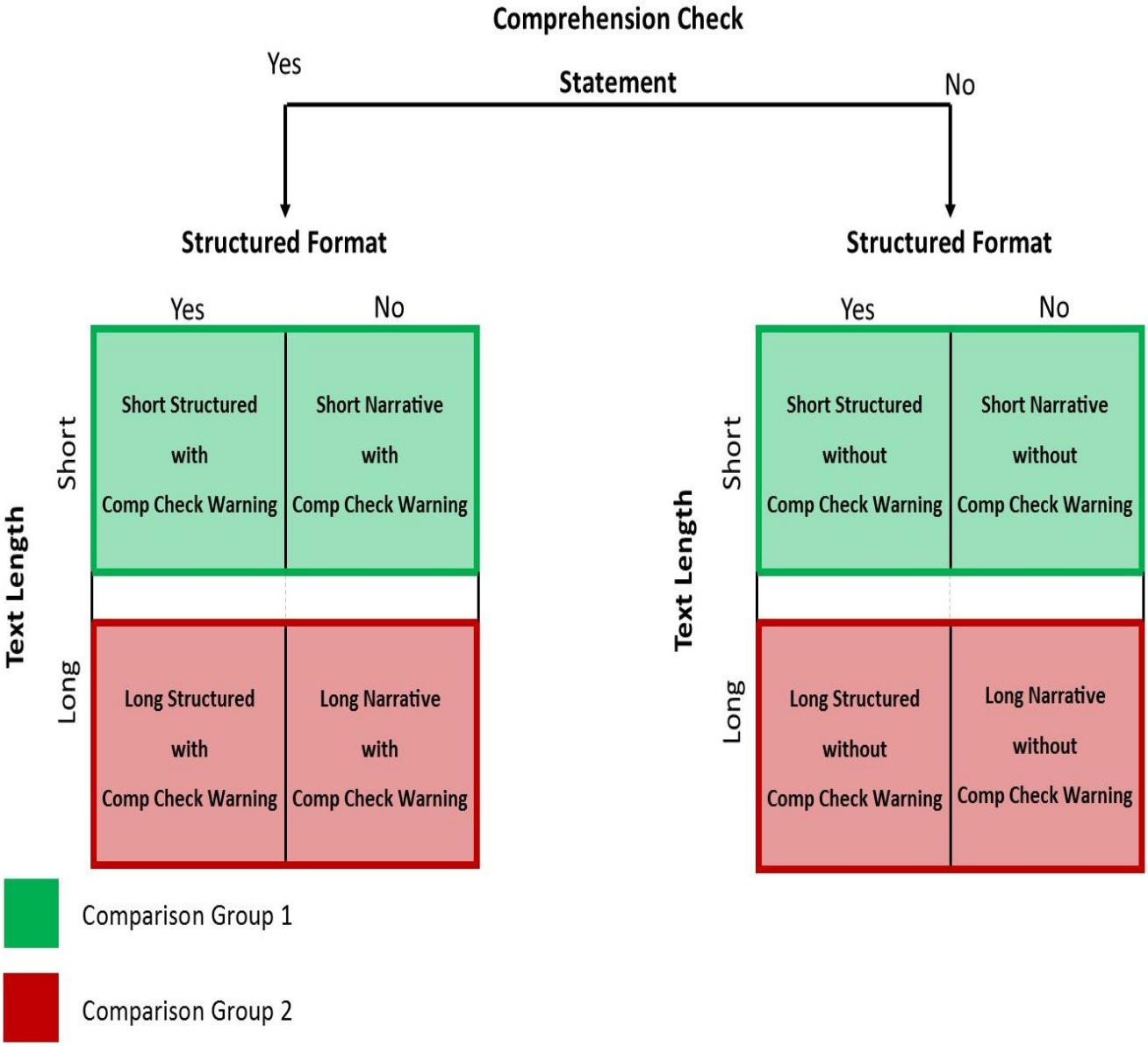


Figure 4: Hypothesis 3 (Length) Contrast Plan

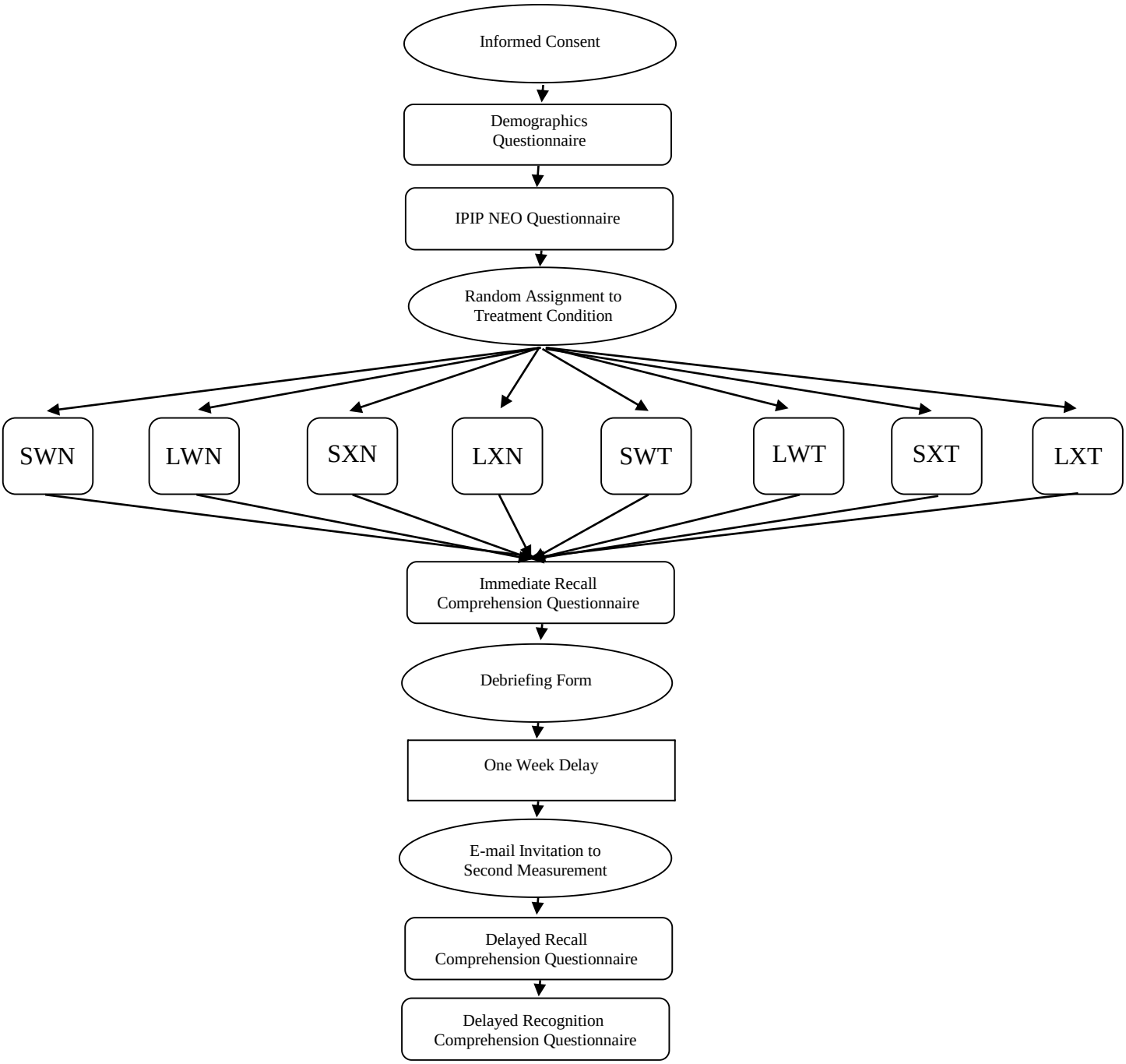
CHAPTER 3

METHOD

Design

The independent variable in this study is an informed consent document that was manipulated across multiple dimensions. The study uses a 2(structure) x2(comprehension check warning) x2(length) factorial between-subjects design for a total of eight treatment conditions, described in Figure 1 (page 34). The order of presentation of components of this study is outlined in Figure 5 (page 43). The study involves a minor deception: participants are told that they are completing a personality screening for potential participation in a behavioral genetic study with a follow-up questionnaire to completed seven days after this. However, the actual intent of the study is to investigate participants' comprehension of the informed consent document presented after they are told that they have been accepted for participation in the fictitious behavioral genetic study. Contrary to what they were led to believe initially, participants did not engage in any behavioral genetic study; that is, they did not participate in a buccal swab or collection of any genetic data. All participants were exposed to only one treatment condition. The control condition is considered to be the condition using standard informed consent procedures that is consistent with the current informed consent documents in format and length, as well as no indication of a comprehension check following the document. The control informed consent outlines a fictitious behavioral genetics study. All other treatment informed consent documents were based off of this control document and used identical language when possible.

The seven remaining treatment conditions based on the control informed consent document have combinations of the control elements and modified elements, including length of the document, format (use of short narrative), and a use of a statement informing participants that there will be a comprehension check at the end of the document. Length was modified by reducing the total



Treatment Condition Key - S = Short | W = Warning | N = Narrative
L = Long | X = No Warning | T = Structured

Figure 5: Study Flowchart

number of words in the document while maintaining identical formatting to the control condition and keeping technical language identical when possible. Modification of the format involved the removal of formatting and separation of informed consent elements to create a narrative describing the study in a single paragraph. The comprehension check condition added a statement that after the informed consent document there will be a few brief questions to ensure participants understand the informed consent document. Three conditions have one modification [length (Appendix B), format (Appendix C) or comprehension check warning (Appendix D)], three conditions have a combination of two modifications [length x format (Appendix E); length x comp check warning (Appendix F); format x comp check warning (Appendix G)], and one treatment condition has a combination of all modifications (Appendix H).

The dependent variable in this study is participant comprehension. This was assessed along seven dimensions of comprehension of the informed consent document: risk, compensation, time required, procedures, cost, ability to leave study, and confidentiality. Each of these domains was assessed using a single cued recall question, such as 'What are the risks of this study?' for the risk domain, which participants will give written responses to (see Appendix I for the complete question set and participant responses that would indicate comprehension). After data collection, three independent graduate student raters who are not associated with the study coded each participant's response to the cued recall questions, scoring zero for responses that do not demonstrate comprehension in each domain and one for responses that demonstrate comprehension of the informed consent document's details in each domain. Scores were summed for each participant to create a zero-to-seven total comprehension scale for use in statistical analyses. A score of seven would indicate comprehension on all assessed measures of the stimulus informed consent document. Scoring of each item for final

analysis was based upon agreement of either comprehension or non-comprehension by at least two of the three independent raters.

This aspect of the participant comprehension variable was assessed twice for each participant; once immediately following presentation of the manipulation informed consent document and once again seven days after the first presentation. The second assessment of comprehension was not preceded by a repeat presentation of the manipulation informed consent document, as the purpose of the second assessment was to measure long-term retention of information rather than short-term comprehension. Additionally, following the second assessment of participants' ability to recall relevant informed consent information, comprehension was assessed a second time using the same set of questions but with multiple-choice options (a correct answer and three distractors) in order to measure recognition of the manipulation informed consent information after a long delay.

Participants

Based on the power analysis using the *GPower3* program, this study aimed to collect at least 192 participants, 24 in each of the eight treatment conditions, in order to achieve a power of at least .80 and a significance level of .05. This sample size was considered sufficient to detect medium main and interaction effects (d = 0.51, as defined by Cohen, 1988). A medium effect for purposes of this study would be considered a roughly 50% comprehension rate, compared to the literature-based standard comprehension rate of between 11% and 31% (Pedersen et al., 2011). A total of 216 participants took part in this study, divided equally among the eight conditions for a total of 27 participants in each condition. All participants were students enrolled in introductory level psychology or communications studies courses at a single large Midwestern university. Participants enrolled in the study through the psychology department's online research system, the SONA system, and received experimental study credit in their introductory psychology or communications studies courses. All potential participants

are given the option to complete studies for credit in these courses or to complete brief writing assignments as an alternative.

The 216 participants that took part in the first part of the study (Table 1, page 47) analyzing immediate recall of informed consent information were majority female (59.7% female, 39.4% male, and 1% identifying as transgender or other), and majority under 22 (84.3% ages 18-20, 11.6% ages 21-22, 2.3% ages 23-24, and 1.9% 25 or older). Breakdown of education levels of participants was 46.3% freshmen, 28.2% sophomores, 16.7% juniors and 8.8% seniors. Self-identified ethnicity was predominantly Caucasian/European American (73.1%), but with larger than anticipated numbers of Black/African American (6.0%), Hispanic/Latino/a (6.5%), Asian/Asian American (9.3%) and Multiracial (3.7%) participants, as well as three participants identifying as 'Other' (1.4%).

The second measurement to assess both delayed recall and delayed recognition had a substantial attrition rate of 75%, with only 54 respondents completing the second questionnaire. This group looked demographically similar to the first group, with 70.4% females, 27.8% males, and 1.9% identifying as 'Other' for sex. School classification for this group was 42.6% freshmen, 24.1% sophomores, 27.8% juniors and 5.6% seniors. Age was similar to the first group as well (88.9% ages 18-20, 7.4% ages 21-22, 1.9% ages 23-24, and 1.9% 25 or older). This group also identified as majority Caucasian/European American (79.6%), but also with a larger than anticipated minority ethnicity response, with 3.7% Black/African American, 7.4% Hispanic/Latino/a, 5.6% Asian/Asian American, and one respondent each identifying as Multiracial (1.9%) and Other (1.9%). Table 1 shows comparisons of the demographics between groups at the two measurement points. No significant differences between the two groups were observed in any demographic variables.

Table 1

Demographics by Measurement Point

		Measurement Point		Difference		
		Immediate	Delayed	χ^2	df	sig.
	Overall N	216	54			
Sex				7.151	3	0.67
	Male	85 (39.4%)	15 (27.8%)			
	Female	129 (59.7%)	38 (70.4%)			
	TG/Other	2 (1%)	1 (1.9%)			
Age				1.33	3	0.722
	18-20	182 (84.3%)	48 (88.9%)			
	21-22	25 (11.6%)	4 (0.9%)			
	23-24	5 (2.3%)	1 (1.9%)			
	25+	4 (1.9%)	1 (1.9%)			
School Classification				6.849	3	0.77
	Freshman	100 (46.3%)	23 (42.6%)			
	Sophomore	61 (28.2%)	13 (24.1%)			
	Junior	36 (16.7%)	15 (27.8%)			
	Senior	19 (8.8%)	3 (5.6%)			
Ethnicity				2.994	5	0.701
	Caucasian	158 (73.1%)	43 (79.6%)			
	Black	13 (6.0%)	2 (3.7%)			
	Hispanic/Latino/a	14 (6.5%)	4 (7.4%)			
	Asian/Asian American	20 (9.3%)	3 (5.6%			
	Multiracial	8 (3.7%)	1 (1.9%)			

Independent and Dependent Variables and Measures

The independent variables in this study are format (structured or narrative), length [standard (approximately 754 words) or shortened (approximately 539 words)] and comprehension check warning (absent or included). The control condition used formatting and wording similar to other informed consent documents reviewed from a large Midwestern university and have no warning of a comprehension check following the document (Appendix A). The two options within the length variable kept either identical length and wording as the control document or use of a substantially reduced the length of the document by more briefly summarizing key points relevant to the informed consent process. The formatting variable either used standard headers from informed consent documents (Introduction, Description of Procedures, Risks, Benefits, Costs and Compensation, Participant Rights, Confidentiality, Questions or Problems) or simply removed these formatting elements and instead used a narrative format to present the same information. The comprehension check warning variable either had a brief statement at the top of the document stating that there would be a comprehension check following the presentation of the informed consent document or simply did not have this variation from the control document.

The dependent variable in this study is participant comprehension of the manipulation informed consent documents. This was measured across seven basic criteria related to the informed consent process using short cued-recall questions (Appendix I). The seven criteria are risk (‘What are the risks associated with this study?’), compensation (‘How much would you be paid to participate in this study?’), time required (‘How long should this study take to participate in?’), procedures (‘What will you do / what will happen in the study if you choose to participate?’), cost (‘What, if any, are the costs to you for participating in this study?’), ability to leave study (‘If you choose to participate, when can you withdraw from the study?’), and confidentiality (‘Who will have access to information gathered by

this study?'). Each of these seven items were be rated by three independent raters who are not familiar with the purpose of this study using criteria for correct answers developed *a priori* by the researcher (Appendix I). Raters completed the scoring across the course of one week; each of the three raters were located in geographically separate areas, with two raters on pre-doctoral internship outside the institution this study was completed at and one rater working as a research assistant at this institution but naïve to the research hypotheses. Raters were instructed to give scores of zero for responses that did not demonstrate comprehension of the presented material from the manipulation consent documents, while scores of one were instructed to be given for responses that demonstrate comprehension. Rater scores for each participant were compiled into a zero-to-three scale for each of the seven comprehension items. Scores of two of more, which indicated that at least two raters considered the response to have indicated comprehension, were recomputed the SPSS statistics package as scores of one for that participant, while summed rater scores below two were recomputed as zeroes, indicating non-comprehension. Raters showed a high degree of inter-rater reliability ($\kappa = .88$). Following this, comprehension scores were summed for each participant, resulting in a single comprehension scale item ranging from zero to seven points, with higher scores indicating higher levels of comprehension of the presented material.

The above procedure for measuring comprehension was also repeated seven days after the initial presentation, though the treatment informed consent document was not be presented again. Participants first completed the same cued-recall activity with the questions in a different order from the original presentation to avoid unintentional memory cues (Appendix J). Following this they were presented with the same questions, but this time in a multiple-choice format including the correct answer and three distractors to assess long-term recognition memory for the information (Appendix K). To prevent possible answer contamination in the recognition portion, items were be presented one at a

time without the ability to change previous answers. As with the previous comprehension measure, outside rater scores were used to create composite scores ranging from zero to three, with scores of two or above being recomputed as scores of one to indicate comprehension and scores less than two as zeroes to indicate non-comprehension. Scores were then summed to create a zero-to-seven point scale identical to the one used in the first measurement.

Other Measures

Five-factor model of personality. As both part of the deception relating and for purposes of future analyses with this data set, the International Personality Item Pool version of the NEO Personality Inventory Revised (IPIP-NEO) was included (Appendix L). The NEO-IP-R was developed by Coast & McCrae (1992) using factor analysis to identify the five personality domains of Extroversion, Agreeableness, Conscientiousness, Neuroticism and Openness to Experience. The original NEO-IP-R additional breaks each of these five factors into six sub-scales for each domain, totaling thirty sub-domains.

The IPIP-NEO was developed by Goldberg (1999, 2006) using a similar factor analysis process that was used to develop the NEO-IP-R. The goal of the development of this new version was to create a publicly available personality measure with a smaller item pool that has strong correlations to the full NEO-IP-R. Correlations between these two measures average 0.77, though this increases to 0.90 when correcting for unreliability attenuation. The IPIP-NEO is available in long- and short-form versions, with the long-form maintaining all thirty sub-domains originally assessed by the NEO-IP-R. For the purpose of this study, the 50-item short form of the IPIP-NEO has been selected (Appendix L). Normative sampling has been completed with over 20,000 individuals and internal reliability for all five major personality domains range from 0.77 to 0.86 (see Appendix M).

Given that the delayed measurement had only one-quarter of participants return, the IPIP-NEO

was examined both for the full group of participants from the first measurement, as well as the second group that comprised a subset of the first. This examination was used to both examine the traits of participants overall, as well as to see if there were any significant differences among those that chose to participate in the second part of the study compared to the overall characteristics of the first group. All measures were found to be highly similar between both the larger first group and the much smaller second group. Neuroticism in the full group had a mean of 2.8 (*sd* = 0.74) and a mean of 2.84 (*sd* = 0.77) in the second group. Extroversion had a mean of 3.27 (*sd* = 0.68) in the full group and 3.28 (*sd* = 0.65) in the second group. Openness to New Experiences had a mean of 3.59 (*sd* = 0.61) in the full group and 3.46 (*sd* = 0.65) in the second group. Agreeableness had a mean of 3.72 (*sd* = 0.57) in the full group and 3.88 (*sd* = 0.41) in the second group. Finally, Conscientiousness had a mean of 3.43 (*sd* = 0.62) in the full group and 3.65 (*sd* = 0.65) in the second group. Correlation between NEO variables (Table 2) was consistent with those seen in Batchelder (2012) with overall internal consistency, coefficient alpha, of -.188.

Table 3 below shows a comparison between these two measurements, which demonstrated no significant differences between the participants as a whole and participants who chose to complete the second part of the study. Neuroticism, extroversion and openness to new experiences did not show any significant difference between participants who only completed the immediate recall portion and those who completed both the immediate and delayed portions of the study. Agreeableness and conscientiousness, however, show statistically significant differences between these two groups, with higher mean scores in both of these measures among participants who completed both portions of the study. This appears highly consistent with the fact that these are the participants who *did* return to the study, which would suggest they are both more agreeable to participation in the study generally, as well

as increased attention to detail and organization that would assist in attending to the reminders to complete the second part of the study a week after initial participation.

Table 2

NEO-IPIP Correlations

Variable	1	2	3	4	5
1 Neuoriticism	—				
2 Extroversion	-.362**	—			
3 Openness	.098	.122	—		
4 Agreeableness	-.402**	.229**	.176*	—	
5 Conscientiousness	-.351**	.194**	-.060	.213**	—

Note: N = 213; three participants declined to complete the NEO-IPIP measure but completed all other measures; * = $p < .05$, ** = $p \leq .01$

Table 3

Comparison of NEO Scores by Measurement Point

	Immediate Recall		Delayed Recall		Difference	
	Mean	SD	Mean	SD	*t*	sig.
Neuroticism	2.8	0.74	2.74	0.77	0.147	0.883
Extroversion	3.27	0.68	3.28	0.65	-0.041	0.967
Openness	3.59	0.61	3.46	0.65	1.033	0.303
Agreeableness	3.72	0.52	3.88	0.41	-2.755	0.006
Conscientiousness	3.43	0.62	3.65	0.65	-2.575	0.011

Procedure

This study and all materials were reviewed and approved by the Iowa State University Institutional Review Board before any data were collected (IRB Approval #15-124, approved 3/26/2015, Appendix S).

The study followed the procedure outlined in the study flowchart seen in Figure 5 (page 43). Potential participants were be recruited through the university's SONA online research system (see SONA Posting Form, Appendix N). Those who elected to participate in the study were directed to the Qualtrics-hosted survey, beginning with informed consent document for participation in this study (Appendix O). The informed consent presented in Appendix O is the general standard informed consent for participation in this study, as contrasted with the eight experimenter created consent forms (Appendices A through H) that constitute the eight independent variable stimuli used in this study. Participant names were collected through the SONA system, and no individual names were linked to data so that no participants could be directly associated with any of their data. Participants first read an informed consent document approved by the university's Institutional Review Board, in which they were informed that their participation is entirely voluntary and they were free to withdraw from the study at any time without penalty (see Informed Consent, Appendix O). The consent provided a deceptive description of the study (selected elements of purpose are omitted) in which potential participants were informed that this study was a screening to identify individuals with certain personality profiles for potential invitation to a later behavioral genetic study, as well as a follow-up survey seven days after their initial screening. After reading the informed consent the potential participant was asked to indicate “yes” or “no” to providing their online consent, stating also that by providing consent they attest that they had read the informed consent and understood what was being asked of them.

After completing the informed consent procedure, participants who did not give consent were redirected to a page debriefing them and thanking them for their time. Those that gave consent were redirected to the primary survey for this experiment on a separate webpage. Participants then responded to a demographics questionnaire (Appendix P) including a question asking them to enter a unique four-digit code, such as the last four digits of their personal phone number, with a reminder that this code would be needed to link their data together with the second measurement in seven days. This was then followed by the IPIP-NEO measure. Participants were then randomly assigned to one of eight possible treatment orders using the Qualtrics random assignment tool, which determined which manipulation consent document they are presented. Participants were then asked to carefully read the manipulation consent document they had been randomly assigned to that described the fictitious future study regarding personality and behavioral genetics. After having an opportunity to read this document, participants were asked to complete seven cued-recall questions regarding elements of the document they were presented with (Appendix I).

After completing the recall questionnaire, participants were directed to a debriefing form (Appendix Q) designed to explain the true nature of the study and the actual research interests. Participants were then shown a two page brochure regarding genetic testing, privacy protections, and informed consent (Appendix R). Participants were informed that they would receive a follow-up e-mail with a link to the second part of the study in seven days, then were redirected to the SONA homepage.

After seven days, participants received a link in their e-mail to the second part of the study, beginning by asking them to re-enter their unique four-digit code to match their previous responses to this section's responses. Participants then completed the second set of comprehension questions, which included the same cued-recall comprehension questions in a different order, followed by the same set

of questions but with multiple-choice options that include a correct answer and three distractors, presented one at a time without the ability to change previous answers to prevent answer contamination from information gained in successive cues from recognition elements.

CHAPTER 4

RESULTS

Preliminary Analyses

Data Cleaning

Throughout the data collection process, data were regularly analyzed through the Qualtrics survey software to identify surveys in which participants declined during the informed consent process (after which they would not be able to access the rest of the survey) or surveys in which participants merely clicked through the survey pages without answering any items. These items were routinely removed once per week during data collection to maintain an equal distribution of participants with valid data across all eight conditions. Once data collection surpassed the required number for statistical power, data were exported and examined in the SPSS 23 statistical package to eliminate any duplicate responding by participants who opened the survey more than once from the SONA research tool. During this process, 21 duplicate responses were identified; the duplicate points were removed and the collection totals for each of the conditions in the Qualtrics random assignment tool were manually modified to reflect these changes and preserve equal distribution of participants across conditions. Data collection resumed until power had been satisfied and for two weeks following this, finally resulting in 216 valid responses distributed equally across the eight conditions (27 participants in each condition).

Tests for Normality and Homoscedasticity

All three dependent variable measures were examined to determine if they met the necessary assumptions for carrying out analysis of variance testing. Levine's test of homogeneity of variance demonstrated no significant heterogeneity in the variances of any of the dependent variable measures at any compensation levels (Table 4). The dependent variables additionally did not demonstrate any

significant non-normality (Table 5). As normality and homoscedasticity appeared to fall within acceptable ranges for all dependent variables, planned analyses using analysis of variance and planned contrasts were maintained.

Table 4

Test for Homogeneity of Variances

Variable	F	df1	df2	sig.
Immediate Recall Comprehension	0.738	7	46	0.641
Delayed Recall Comprehension	2.164	7	46	0.055
Delayed Recognition Comprehension	1.259	7	46	0.292

Table 5

Tests for Normality

Variable	N	Skewness (SE)	Kurtosis (SE)
Immediate Recall Comprehension	216	-.252 (0.166)	-.825 (.330)
Delayed Recall Comprehension	54	-.300 (.325)	.231 (.639)
Delayed Recognition Comprehension	54	-.074 (.325)	-1.259 (.639)

Descriptive Statistics

Comprehension of Informed Consent Components

Overall Comprehension – Comprehension was measured as a sum of seven scores for each participant based on binary scoring of their comprehension of each subdomain of the informed consent document. The potential range for this measure is zero (no comprehension) to seven (comprehension of all elements). Table 6 (page 57) and Figure 6 (page 61) examines the descriptive statistics of the overall comprehension measure in each condition and at each measurement time point.

Table 6

Descriptive Statistics by Measurement Time and Condition

	Immediate Recall			Delayed Recall			Delayed Recognition		
Condition	*n*	*M*	SD	*n*	*M*	SD	*n*	*M*	SD
LxRxNW	27	1.81	1.388	8	2.13	1.356	8	3.75	1.669
SxRxNW	27	2.41	1.394	5	1.83	1.329	5	4.6	0.894
LxUxNW	27	2.3	1.636	6	2.17	0.753	6	4.33	1.862
LxRxCW	27	2.59	1.421	6	2.67	1.751	6	5.33	1.366
SxUxNW	27	2.41	1.309	11	2.73	1.009	11	4.55	1.214
SxRxCW	27	2.56	1.281	6	1.83	1.329	6	4.33	1.862
LxUxCW	27	2.52	1.312	7	2.71	0.756	7	4.29	1.496
SxUxCW	27	2.15	1.322	5	3.2	0.837	5	4.4	1.517

L = Long, S = Short; R = Structured, U = Unstructured;

CW = Comprehension Check Warning, NW = No Warning

Compensation – In the immediate recall measurement across all conditions, 73.1% of participants (N = 158) were able to correctly identify that they would not receive any monetary compensation for their participation but would receive one research credit toward their introductory-level psychology course. The remaining 26.9% (N = 58) either did not correctly identify that would receive credit or did not answer. In the delayed recall task 77.5% of participants (N = 55) were able to correctly identify the compensation they would receive, and 97.2% (N = 69) were able to recognize this as the correct answer from four multiple-choice options.

Access to Data – Participants across all conditions were only able to correctly identify core elements of who would have access to their genetic information 2.8% of the time in immediate recall (N = 6), compared to 97.2% (N = 210) that could not identify the fictional national repository that would have access to their genetic information, or even that there was a repository or large-scale group of any kind that may have access to this information. No participants were able to identify this in the delayed recall task (N = 71), and only 8.5% (N = 6) were able to pick the correct response from four multiple-choice answers, well below what would be estimated to be achieved if participants were even blindly guessing.

Risk – Only 3.2% (N = 7) of participants across all conditions at immediate recall were able to identify both that there was the possibility of a mild allergic reaction to buccal swabbing and the potential for their genetic information to be linked to their identity resulting in potential loss of ability to obtain life insurance or possible use of their genetic data in criminal investigations. A single participant (1.7%) in the delayed recall portion correctly identified these risks, though 42.3% (N = 30) were able to identify the risks from among four multiple-choice answers.

Time Needed to Participate – No participants in any condition at either recall point, immediate or delayed, correctly recalled that the study would take 50 minutes or less to complete. An examination of this portion of the data shows that participants tended to respond that it would take either 30 minutes or less (the current standard for a single research credit in non-fictional studies) or 60 minutes or less. However, in the delayed recognition task 59.2% of participants (N = 42) were able to correctly identify the amount of time needed to participate in the fictional study. It should be noted that none of the multiple-choice options included either 60 or 30 minutes as part of the answer.

Procedure – Across all conditions, 37.5% of participants (N = 81) were able to identify the core procedure of the fictional study at immediate recall, namely a buccal (cheek) swabbing. This decreased to 25.4% (N = 18) at the delayed recall measurement, though 42.3% (N = 30) were able to identify the procedure from among multiple-choice answers.

Cost to Participate – At immediate recall, 66.7% of participants (N = 144) were able to correctly identify that there was no cost to them to participate in the fictional study. A comparable 74.6% of participants (N = 53) were able to identify that there would be no costs to them at the delayed recall measurement. The vast majority of participants were able to correctly identify this from four multiple-choice answers (97.2%, N = 69).

Ability to Withdraw from Study – Participants correctly identified their ability to withdraw from the study at any time 50.9% of the time (N = 110) at immediate recall. At the delayed recall measurement, this proportionally increased slightly to 66.2% (N = 47), with a further increase to 78.9% (N = 56) able to identify the correct answer from four multiple-choice answers.

Consent to Participate in Buccal Swabbing

Consent to be contacted to participate in a buccal (cheek) swab for the fictional study presented to participants was asked following the presentation of the manipulated informed consent document. Across all conditions, 74.5% of participants (N = 161) agreed to be contacted to set up a time to complete the buccal swabbing, while 25.5% (N = 55) declined to be contacted. Among the eight conditions (Table 7), the condition with the highest rate of agreement to participate was in the *long, unstructured, no comprehension-check warning* condition, with 23 participants consenting and four declining. By contrast, the lowest agreement rate was in the *short, unstructured, no comprehension-check warning* condition, with 17 consenting and 10 declining. No significant differences in consent for buccal swabbing was observed between the eight conditions ($F(1,26) = .259$, $p = 0.611$).

Table 7

Consent for Buccal Swab by Condition

Condition	Consented	Declined	Total
LxRxNW	20	7	27
SxRxNW	20	7	27
LxUxNW	23	4	27
LxRxCW	20	7	27
SxUxNW	17	10	27
SxRxCW	22	5	27
LxUxCW	21	6	27
SxUxCW	18	9	27

L = Long, S = Short; R = Structured, U = Unstructured;

CW = Comprehension Check Warning, NW = No Warning

Modified Comprehension

As comprehension for several items was lower than was is typically expected based on previous literature (Pedersen et al., 2011), a second composite comprehension measure was calculated with all measures that exceeded 10% comprehension (Figure 7, page 62). This included *compensation*, *procedure*, *cost to participate*, and *ability to withdraw from study*. The purpose of this measure is as a secondary dependent variable for additional analysis in the same manner as the primary comprehension composite is analyzed to help determine if any effects of the manipulation informed consent documents can be detected with fewer components contributing to comprehension. While not designed to replace the primary analyses, this measure is hoped to be useful in determining possible future directions for study if primary analyses are non-significant. This measure was calculated only for the immediate recall measurement point. This resulted in an overall mean of 2.28 and a standard deviation of 1.322.

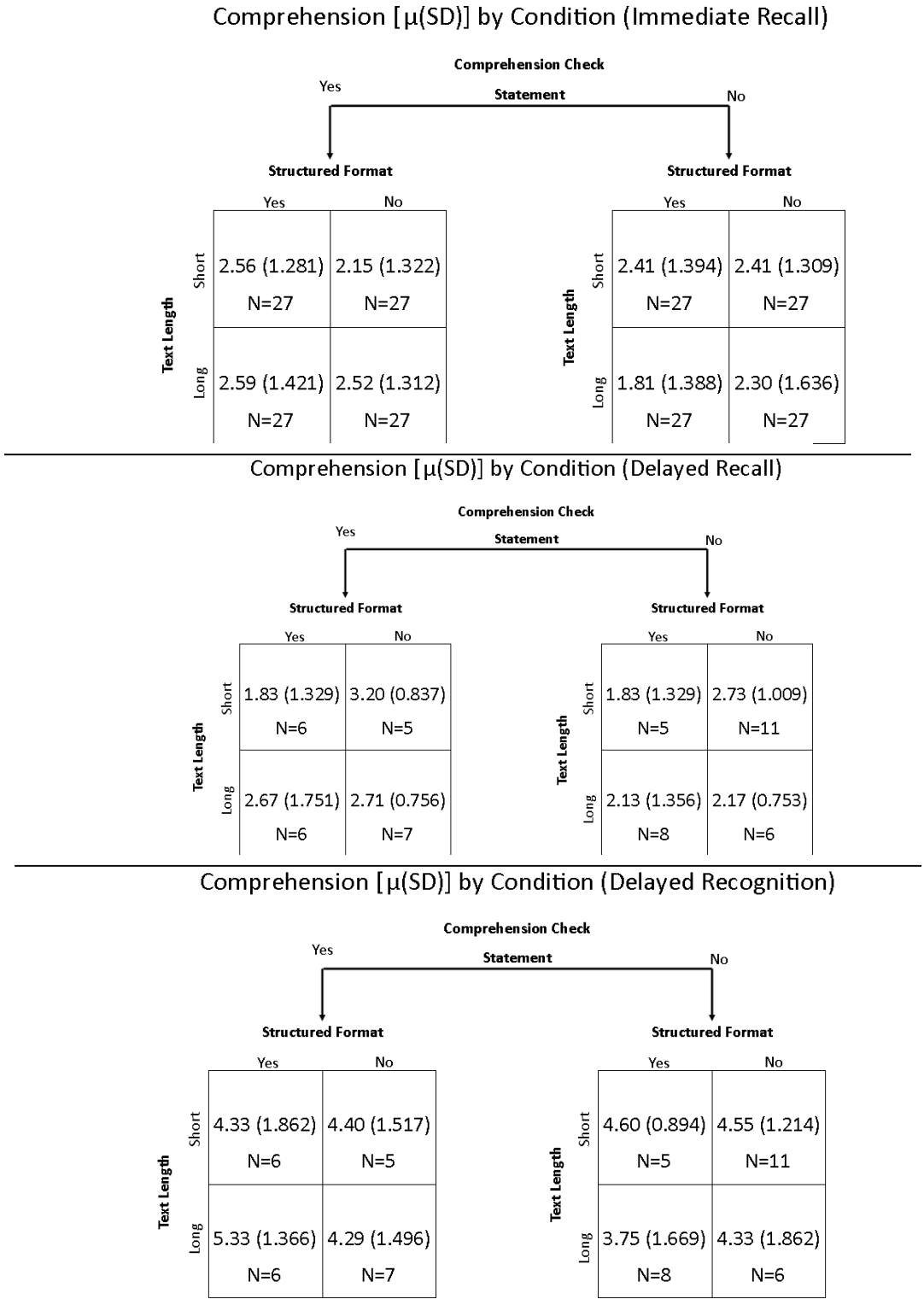


Figure 6: Comprehsion by Condition Across Measurements

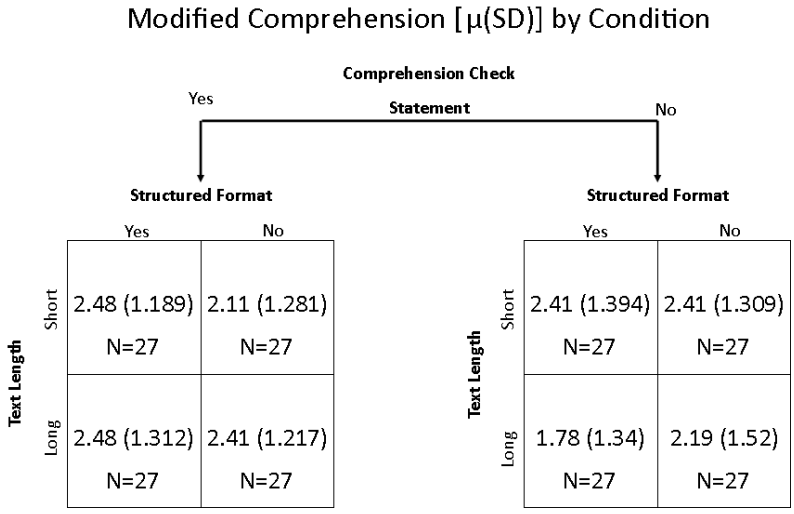


Figure 7: Modified Comprehension by Condition for Immediate Recall

Analysis Strategy

To determine what, if any, main effects and/or interaction effects were present across each of the three measurement points, 2x2x2 ANOVAs were run to establish the presence or absence of any effects. If any effects were present, analysis would proceed to separate planned-contrast ANOVAs for each of the three dependent variables at each of the three measurements as shown in figures 2, 3 and 4. If no statistically significant main or interaction effects were detected in the preliminary analysis, the 2x2x2 ANOVAs for each measurement point would be run using the modified comprehension composite (see page 60), rather than the total composite, with corresponding planned-contrast ANOVAs if main and/or interaction effects are detected. A repeated-measures ANOVA was completed using the immediate recall and delayed recall measurements to determine if there is a significant difference among any of the dependent variables at these two measurement points. The delayed recognition measurement is not appropriate to include in this analysis as the methodology for measurement differs substantially and would not yield meaningful information in such an analysis, so a

2x3 mixed between-within ANOVA will be run to determine if any main or interaction effects have significant influence on the difference between participants' delayed recall and delayed recognition.

Hypotheses 1-4 Omnibus ANOVAs

Initial 2x2x2 ANOVAs were run using data from each of the three measurement points (immediate recall, delayed recall and delayed recognition) to examine all possible main effects for length, structure and comprehension-check warning across the eight manipulation conditions, which included analyses for interaction effects between length and structure, length and comprehension-check warning, structure and comprehension-check warning, and a three-way interaction between length, structure and comprehension-check warning.

Immediate Recall

In the immediate recall condition (Table 8), there were no significant findings of main effects for length ($F(1, 208) = .154$, $p = .695$), structure ($F(1, 208) = .000$, $p = 1.000$), or comprehension check warning ($F(1, 208) = 2.667$, $p = .240$). No significant interaction effects were observed for length*structure ($F(1, 208) = 1.165$, $p = .282$), length*warning ($F(1, 208) = 2.166$, $p = .143$), structure*warning ($F(1, 208) = 1.627$, $p = .204$), or length*structure*warning ($F(1, 208) = .039$, $p = .845$).

Given the high degree of statistical improbability associated with the main effect of structure having a mean-squared of zero, the data were examined to rule out any possible errors in the analysis or the data set. No errors in data coding were observed, and subsequent analyses yielded identical results. Closer examination of the descriptive statistics for the structured and unstructured groups shows that they do indeed have identical numbers of participants (N = 108) and both have means of 2.34 with

standard deviations of 1.389. While statistically improbable, it does appear that there was literally no difference between these groups.

Table 8

Analysis of Variance Results for Main and Interaction Effects at Immediate Recall

Variable	df	MS	F	sig.
Main Effect of Length (L)	1	0.296	0.154	0.695
Main Effect of Structure (S)	1	0	0	1
Main Effect of Warning (W)	1	2.667	1.386	0.24
LxS	1	2.241	1.165	0.282
LxW	1	4.167	2.166	0.143
SxW	1	3.13	1.627	0.204
LxSxW	1	0.074	0.039	0.845
Error	208	1.923		

Delayed Recall

In the delayed recall condition (Table 9), there were no significant findings of main effects for length ($F(1, 46) = .742$, $p = .393$), structure ($F(1, 46) = .878$, $p = .354$), or comprehension check warning ($F(1, 46) = .098$, $p = .756$). No significant interaction effects were observed for length*structure ($F(1, 46) = .633$, $p = .430$), length*warning ($F(1, 46) = 1.994$, $p = .165$), structure*warning ($F(1, 46) = 1.697$, $p = .199$), or length*structure*warning ($F(1, 46) = 1.673$, $p = .202$).

Table 9

Analysis of Variance Results for Main and Interaction Effects at Delayed Recall

Variable	df	MS	F	sig.
Main Effect of Length (L)	1	0.94	0.742	0.393
Main Effect of Structure (S)	1	1.112	0.878	0.354
Main Effect of Warning (W)	1	0.124	0.098	0.756
LxS	1	0.802	0.633	0.43
LxW	1	2.526	1.994	0.165
SxW	1	2.151	1.697	0.199
LxSxW	1	2.12	1.673	0.202
Error	46	1.267		

Delayed Recognition

In the delayed recognition condition (Table 10), there were no significant findings of main effects for length ($F(1, 46) = .011$, $p = .917$), structure ($F(1, 46) = .072$, $p = .790$), or comprehension check warning ($F(1, 46) = .443$, $p = .509$). No significant interaction effects were observed for length*structure ($F(1, 46) = .080$, $p = .779$), length*warning ($F(1, 46) = 1.332$, $p = .254$), structure*warning ($F(1, 46) = .800$, $p = .376$), or length*structure*warning ($F(1, 46) = 1.078$, $p = .305$). As across all three time points there were no statistically significant main effects of length, structure or comprehension-check warning, nor significant interactions effects, analysis of these measures was terminated without need for a planned-contrasts analysis.

Table 10

Analysis of Variance Results for Main and Interaction Effects at Delayed Recognition

Variable	df	MS	F	sig.
Main Effect of Length (L)	1	0.025	0.011	0.917
Main Effect of Structure (S)	1	0.162	0.072	0.79
Main Effect of Warning (W)	1	1.003	0.443	0.509
LxS	1	0.18	0.08	0.779
LxW	1	3.014	1.332	0.254
SxW	1	1.811	0.8	0.376
LxSxW	1	2.439	1.078	0.305
Error	46	2.262		

Additional Analyses

Modified Immediate Recall Comprehension Score

As primary analyses were all non-significant, additional post-hoc analysis of the modified comprehension composite (described on page 60), which consists of a sum of only the comprehension items for *compensation, procedure, cost to participate,* and *ability to withdraw from study*, was carried out for the immediate recall measurement point. This analysis used a 2x2x2 ANOVA approach identical to the main analyses (Table 11). Use of this measure still did not find any significant main effects of length ($F(1,208) = 1.212$, $p = .307$), structure ($F(1,208) = .084$, $p = .987$), or comprehension-check warning ($F(1,208) = 2.013$, $p = .094$).

Table 11

Modified Comprehension Analysis of Variance Results for Main and Interaction Effects at Immediate Recall

Variable	df	MS	F	sig.
Main Effect of Length (L)	1	1.042	0.595	0.442
Main Effect of Structure (S)	1	0.005	0.003	0.959
Main Effect of Warning (W)	1	1.671	0.954	0.33
LxS	1	1.671	0.954	0.33
LxW	1	4.449	2.539	0.113
SxW	1	2.449	1.398	0.238
LxSxW	1	0.042	0.024	0.878
Error	208	1.752		

Repeated Measures Analysis of Variance

In order to determine if there was a significant difference between participant comprehension at the immediate versus delayed recall measurement points and if any main or interaction effects had a significant effect on comprehension between these two time points, a 2 (measurement time point) x 3 (condition) repeated measures ANOVA (Table 12) was conducted using data from all participants that completed both the first and second portions of the study (N = 54). No significant within-subjects difference was found between the measurement points ($F(1, 46) = .008$, $p = .934$), nor were any significant interaction effects present between measurement time and length ($F(1, 46) = .012$, $p = .917$), structure ($F(1, 46) = .011$, $p = .214$), warning ($F(1, 46) = .675$, $p = .416$), length*structure ($F(1, 46) = .021$, $p = .886$), length*warning ($F(1, 46) = .723$, $p = .400$), structure*warning ($F(1, 46) = 2.015$, $p = .163$), or length*structure*warning ($F(1, 46) = .041$, $p = .840$).

Additionally, no significant between-subjects main effects were observed for length ($F(1, 46) = 1.063$, $p = .308$), structure ($F(1, 46) = .013$, $p = .911$), warning ($F(1, 46) = .902$, $p = .347$), length*structure ($F(1, 46) = .601$, $p = .442$), length*warning ($F(1, 46) = .2.562$, $p = .109$), structure*warning ($F(1, 46) = .161$, $p = .69$), or length*structure*warning ($F(1, 46) = 1.648$, $p = .206$).

Table 12

Repeated Measures Analysis of Variance for Immediate Recall and Delayed Recall Comprehension

Variable	df	MS	F	sig.
Within Subjects				
Time (Immediate v Delayed)	1	0.008	0.007	0.934
Time*Length	1	0.012	0.011	0.917
Time*Structure	1	1.769	1.59	0.214
Time*Warning	1	0.751	0.675	0.416
Time*Length*Structure	1	0.023	0.021	0.886
Time*Length*Warning	1	0.804	0.723	0.4
Time*Structure*Warning	1	2.241	2.015	0.163
Time*Length*Structure*Warning	1	0.046	0.041	0.84
Error	46	1.066		
Between Subjects				
Length	1	2.196	1.063	0.308
Structure	1	0.026	0.013	0.911
Warning	1	1.862	0.902	0.347
Length*Structure	1	1.242	0.601	0.442
Length*Warning	1	4.451	2.562	0.109
Structure*Warning	1	0.333	0.161	0.69
Length*Structure*Warning	1	3.403	1.648	0.206
Error	46	2.065		

2 x 3 Mixed Method ANOVA for Delayed Recall and Recognition

To determine if any conditions created a significant difference between participants' ability to recall information from the informed consent documents compared to being able to recognize this information from among a set of three distractors, a 2 within (delayed recall vs. delayed recognition) x 3 between (condition) mixed method ANOVA (Table 13) was conducted using data from all participants that completed the second portion of the study (N = 54). A significant difference was identified between the two measurements ($F(1, 46) = 91.145$, $p < .001$), with significantly higher comprehension scores occurring in the recognition task than the recall task. This finding is highly consistent with a broad body of research indicating that individuals tend to show improved ability to correctly identify previously encountered stimuli in recognition tasks compared to recall tasks at similar time points (Wechsler, 2009).

No significant interaction effects, however, were found between the measurements and length ($F(1, 46) = .405$, $p = .527$), structure ($F(1, 46) = 1.305$, $p = .0.259$), warning ($F(1, 46) = .259$, $p = .613$), length*structure ($F(1, 46) = .136$, $p = .714$), length*warning ($F(1, 46) = .013$, $p = .909$), structure*warning ($F(1, 46) = 1.069$, $p = .235$), or length*structure*warning ($F(1, 46) = .007$, $p = .934$). Additionally, no significant between-subjects main effects were observed for length ($F(1, 46) = .234$, $p = .631$), structure ($F(1, 46) = .078$, $p = .781$), warning ($F(1, 46) = .338$, $p = .564$), length*structure ($F(1, 46) = .321$, $p = .574$), length*warning ($F(1, 46) = .2.037$, $p = .160$), structure*warning ($F(1, 46) = .003$, $p = .959$), or length*structure*warning ($F(1, 46) = 1.677$, $p = .202$).

Table 13

2x3 Mixed Between-Within Analysis of Variance for Delayed Recall and Delayed Recognition Comprehension

Variable	df	MS	F	sig.
		Within Subjects		
Measure (Delayed Recall v Delayed Recognition)	1	91.145	111.965	>.001
Measure*Length	1	0.33	0.405	0.527
Measure*Structure	1	1.062	1.305	0.259
Measure*Warning	1	0.211	0.259	0.613
Measure*Length*Structure	1	0.111	0.136	0.714
Measure*Length*Warning	1	0.011	0.013	0.909
Measure*Structure*Warning	1	1.536	1.079	0.235
Measure*Length*Structure*Warning	1	0.006	0.007	0.934
Error	46	1.066		
		Between Subjects		
Length	1	0.635	0.234	0.631
Structure	1	0.212	0.078	0.781
Warning	1	0.916	0.338	0.564
Length*Structure	1	0.871	0.321	0.574
Length*Warning	1	5.53	2.037	0.16
Structure*Warning	1	0.007	0.003	0.959
Length*Structure*Warning	1	4.553	1.677	0.202
Error	46	2.065		

CHAPTER 5

DISCUSSION

The purpose of this study was to explore modifications made to the informed consent process that had previously been made in Batchelder (2012) through the lens of several information processing theories. This earlier study found increases in comprehension of informed consent by participants relative to the previous work by Ascheman (2009) and by Batchelder (2012). The current study took the modifications that had been made to the informed consent documents and divided them into three core components: length, structure and comprehension check warning. The aim of this study was to examine which of these modifications or interactions between modifications contributed most significantly to improvements in comprehension of informed consent documents to give researchers better direction for creation of these important documents. As evidenced in the results section, however, the modifications in this study did not result in any significant main or interaction effects despite having sufficient data to achieve power commensurate with what would be expected based on the levels of comprehension in Batchelder (2012). Indeed, overall comprehension of the components of informed consent was considerably lower than expected, with a mean comprehension rating of 2.34 of a possible seven points at immediate recall, far lower than what was observed in the previous study. It is also notable that the mean comprehension ratings at immediate and delayed recall were consistently low across conditions. These low ratings of comprehension included IRB and important bioethical dimensions of informed consent such as risk, awareness of the potentially intrusive buccal swab procedure, and who would have access to participants' data. The informed consent modifications tested in this study did not enhance awareness, comprehension, or short term recall of central elements of consent in this posed hypothetical investigation.

A closer examination of the results of this study paint a picture that both supports the existing information processing models being examined and suggests some intriguing possible complications with studies that involve multiple independent components that necessitate several informed consent documents. These same complications give a glimpse into a flaw in this study, which sets the stage for two distinct directions for future research; one path toward a modified protocol that may yield more insightful results about how Batchelder (2012) was able to achieve such unusually high comprehension among participants, and the other toward a careful examination of the use of multiple-consent protocols and their efficacy in generating true comprehension among participants relative to single, albeit more complex, consent documents.

Information Processing in the Informed Consent Process

Structure – Stopping Bottom-Up Processing

The intent of the modification to the structure of the informed consent documents presented as the core manipulation in this study was to attempt to activate *top-down processing* (Navon, 1977; Navon, 1983). By modifying the highly visible global features of the informed consent document, it was hypothesized that participants would be forced to attend more closely to the more minute, local features of the document and thereby improve comprehension. This hypothesis did not bear fruit, though this is unlikely to be in contradiction to the well-established body of research that supports both the cognitive (Breitmeyer, 1975; Henning, Hertz & Broadbent, 1975; Hughes, 1986) as well as neurocognitive (Fink, Marshall, Halligan, Frith, Frackowiak & Dolan, 1997; Evans, Shedden, Hevenor & Hahn, 2000) existence of this phenomenon. Rather, it would appear that the modifications made to the structure of the informed consent documents presented as the central manipulation of the study

were not significant enough to trigger the activation of the kind of top-down processing that would be expected if participants believed they were viewing a wholly new stimulus.

It is also distinctly possible that participants simply chose not to attend to the stimuli presented. As discussed at length below, the tools used for this study were only able to track global time spent for completion of the entire study by participants. This leaves the possibility that, as there was nothing to stop participants from just passing the manipulation informed consent documents over rapidly, participants chose to ignore that page almost entirely. These two ideas are not exclusive, but are rather entirely complimentary. If participants were to see a section of the study that activated bottom-up processing of the document, activation of that schema would quite probably lead participants to believe that nothing new was being presented and simply passed the information over.

Both of these potential explanations are highlighted by the pattern of participant responding to comprehension questions that were either consistent with other studies within the department that this study was conducted within, or unique to the manipulation informed consent documents. As demonstrated in Table 14, participants responded correctly to questions about the manipulation informed consent document at a far higher frequency for items that were consistent with the non-manipulation informed consent document presented at the beginning of the study, which was consistent with other informed consent documents that participants may have been exposed to in other studies in the department that this study was conducted within. At even finer detail of examination, *every* participant that responded to the question regarding time needed to complete the study responded in a manner that *would* be indicative of comprehension of the more globally-used informed consent documents, such as the one seen in Appendix O. The current standard for studies within the department this research was conducted in was thirty minutes for one research credit toward an undergraduate psychology or communication sciences class that required such credits, which was what

all responses indicated. The manipulation informed consents (Appendices A through H), however, intentionally indicated *fifty* minutes for the compensation of one research credit. This lends strong support to the idea that participants were responding to the manipulation informed consent from a bottom-up, or schema-activated, standpoint that resulted in responding consistent to previous informed consent documents that they *had* attended to from a top-down method of processing the information.

Table 14

Comprehension at Immediate Recall of Consistent vs Unique Items

		Comprehended	Not Comprehended
Consistent Items			
	Compensation	73.10%	16.90%
	Cost	66.70%	33.30%
	Ability to Leave	50.90%	49.10%
Unique Items			
	Confidentiality	2.80%	97.20%
	Risk	3.20%	96.80%
	Time	0.00%	100%
	Procedure	37.50%	62.50%

Comprehension Check Warning and Length – Effortful Processing

The activation of either effortful or automatic processing both hinge on a single concept: attention to the stimulus to be processed. In this sense, attention is a component that is necessary, but not alone sufficient, for comprehension in the informed consent process. As became increasingly apparent in the analysis of participant responding seen in Table 9 above, schema activation leading to

bottom-up processing across all conditions of this study meant participants were not attentive to the details in the manipulation informed consent documents. Without that fundamental cornerstone of information processing, activation of effortful processing as defined by Hasher & Zacks (1979) is frankly impossible. From that theoretical framework, the lack of any main or interaction effects without the fundamentally necessary activation of top-down processing fits all of these models perfectly, albeit regrettably for the purposes of this study. It still stands to reason from this view that activation and maintenance of effortful processing may still have a significant effect on both recall and recognition of informed consent information, but until the activation of attention is satisfied this by nature will not be able to be appropriately measured.

The use of a comprehension check warning was hypothesized to be a potential method to increase the likelihood of effortful processing, while decreasing the length of the document may increase the ability of participants to maintain that higher level of processing throughout the information being presented. Neither of these hypotheses were supported by this study, but the use of a comprehension check warning may be potentially be modified to serve the more fundamental need to activating attention and stopping bottom-up processing if its use were to be modified slightly. As the comprehension check warning was *part* of the manipulation informed consent documents when it was being presented, it follows from an information processing standpoint that it was ignored when bottom-up processing was activated in the same way that all other information was. If the comprehension check warning were moved to an earlier position, such as on an individual page prior to the actual informed consent document so as not to activate bottom-up processing immediately while being short enough to have a reasonable likelihood of being processed effortfully by participants. This in turn may increase the likelihood of participants not engaging in bottom-up processing and assuming they know

the contents of the document being presented based on existing schemata about informed consent documents and thereby increasing likelihood of meaningful comprehension.

Immediate vs. Delayed Comprehension

By the same logic as seen regarding effortful processing, without initial attention leading to improvements in immediate recall of the details of an informed consent document, there can be no reasonable expectation of comprehension at any later point. As evidenced by the differences in the very large normalized sample used in the Wechsler Memory Scale, Third Edition (WMS-III), respondents of all types tend to see a decrease in the actual *amount* of information retained over time, but they may still fall within the same general range of memory ability they would be considered in with a lower response score at the delayed measurement (Wechsler, 2009). As comprehension was low across all conditions in the immediate measurement, it follows that both the delayed recall and delayed recognition would be similarly low. In short, this component of the study was also fundamentally tied to activation of attention through top-down processing, and since that bar was not met it is subsequently unsurprising that no significant differences were found between the immediate and delayed measurement points.

Limitations of the Study

A key limitation of this study was the use of two informed consent documents, with the first being used as a distractor against the true purpose of the study and the second as the actual modified informed consent document against which comprehension was ultimately tested. As discussed above, participants appear to have gleaned much of their information about many core components of the informed consent process from the first document, as well as other similar documents used within the psychology department of the institution where this study was conducted that held uniform standards

for many pieces (such as the ratio of 30 minutes per one research credit). To help better measure the information of *only* the manipulation informed consent, much of this otherwise uniform information was modified *a priori* in the manipulation consent document. As discussed, the current study was unable to find any significant differences between conditions on comprehension, but it was noted that responses in several of the components of informed consent would have been correct for the first (non-manipulation) informed consent document. It is possible, then, that participants may have been confused about which informed consent document they were to respond to during comprehension checks, or that they may have been primed to an existing schema regarding what is 'supposed to be' in an informed consent document within this particular psychology department when reading the first document. Either case represents a limitation in this study that may have prevented finding any differences that may actually exist between the status quo and modified versions of the informed consent documents. Fortunately, such a flaw is relatively simply to fix with modifications to the protocol in future studies, as will be discussed at length below.

Another limitation of this study is the demographics of the participants. While there was a larger-than-anticipated group of participants from minority ethnicities, the overall group is still largely representative of a primarily European/Caucasian population. While this is consistent with the composition of the institution at which this study was conducted, it presents difficulties in generalizing the effects, or rather lack thereof, to less homogenous populations of even just undergraduate students. The age make-up, also necessarily consistent with the institution, prevents reasonable generalization to populations outside of college-age individuals.

Use of the Qualtrics tool for data collection, while allowing for casting a wider net of potential participants, disrupted the ability to monitor conditions in which participants were actually participating in the study. While this was not ideal in terms of the ability to control the setting in which

participants were exposed to the study materials, it did allow for participants to engage in the study using technology that they were most comfortable with and with any adaptive reading software they may use as an accommodation for a disability. As described previously, data that represented extreme high-end response times to the total study were removed as part of the data cleaning process; the tools offered by Qualtrics to track participation did not provide time tracking for each individual task, and so it was not possible to examine how long participants spent reading any portion of the study.

Directions for Future Research

This study was not able to answer one of the core questions it had aimed to: why did the consent document modified for use in Batchelder (2012) have such abnormally high comprehension? That phenomena was unable to be replicated in this study, though several possible reasons for this have been discussed in the above section on the limitations of this study. Building from these limitations, two distinct directions for future research emerge; namely, a closer examination of the effects of presentation of multiple informed consent documents within complex studies and the ability of participants to meaningfully differentiate the independent details of each informed consent document, and a re-examination of Batchelder (2012) to determine what may have been missed that could lead to significant improvements in informed consent comprehension.

As previously noted, participants responded incorrectly to several of the core components of the manipulation informed consent documents at an alarming high rate, but their answers *were* consistent with the first informed consent document (Appendix O) presented at the start of the study (as well as other standard informed consent documents in the department in which this study took place). While a strong case can be made for the activation of information processing heuristics as a significant source of this lack of comprehension of the manipulation informed consent documents, it does raise the

question of how well participants in complex studies comprehend the independent components of multiple informed consent documents that may be displayed for different phases of a given study. This becomes an increasingly complex and ethically ambiguous question when framed from the context of behavioral genetic research, as information may be stored for a very long time in large databases used for a wide variety of research purposes (Ossorio & Duster, 2005) should participants consent to such. Protections exist against abusive use of this kind of data (Annas, Glantz & Roche, 1996; Genetic Information Nondiscrimination Act, 2008; Affordable Care Act, 2010) but much of the protection afforded by such legislation can be waived by participants through an informed consent process, except in cases involving vulnerable populations (Code of Federal Regulations, 46:116a, 2009). Understanding how multiple consent procedures effect comprehension of their components, then, becomes an ethical imperative if their use is to continue.

As this study was unable to replicate the effects on comprehension seen in Batchelder (2012), this suggests that either the manipulations were not significant enough to spur the type of cognitive information processing that was hoped, there was not enough power to detect an effect that may have been present, or that the findings of comprehension in Batchelder (2012) are themselves anomalous. To address the latter-most concern, a simple replication of the study described in Batchelder (2012) would provide evidence for or against this hypothesis, perhaps even more easily as only the first half of the protocol would be needed to get that information. The question of power is similarly easily answered by increasing the number of participants with an identical protocol, though it would likely be more worthwhile to examine other means of activating top-down processing of informed consent documents.

The modifications made by this study to the documents was already reasonably extensive, and so pursuing other potential methods of presentation may have better results. In particular, a helpful

distinction from the author's personal experience between a research study's informed consent and the informed consent process preceding a medical procedure is two-fold: first, a medical procedure requires a multi-format presentation of the data that generally includes both a written informed consent document as well as a verbal explanation of the same information by a professional, and second there must be evidence of comprehension by the patient or a competent individual legally responsible for the patient before a medical procedure can commence. The latter concern was one that this study attempted to address by adding a warning about a check for comprehension, though this did not generate a significant main effect. The former difference, however, may guide a shift in the informed consent process. It may be considered onerous in many research studies to conduct face-to-face informed consent processes, particularly if a study is reaching thousands of participants or more (Hochhauser, 1999). The advent of simple-to-use multimedia technology may serve two purposes in this regard: it would allow for both verbal and written presentation of informed consent materials, and it may in so doing activate top-down processing due to the novel nature of the presentation. The novelty of this approach may wear thin if it were to become a standard for informed consent, but presenting the same information in two media formats would also increase the likelihood of effortful processing of one or both presentations of the information. An experimental design to study this possibility would be simple to create using a 2 (video / no video) x 2 (written form / no written form) format, with the unusual cell of no written form and no video used to examine how participants would view the potential components of a study based on the title of the study alone, giving a baseline of what schemata for a research study may be.

Finally, as discussed in the section regarding effortful processing, it may be fruitful to re-examine the placement of some of the components being modified to improve comprehension and activate desirable information processing strategies. In particular, moving the comprehension check

warning to an individual section in online studies that precedes the presentation of the informed consent document may serve to both activate effortful processing and avoid having participants not see the warning due to activation of bottom-up processing of the entire informed consent document when the check is included within.

Conclusion

This study hinged, ultimately, on getting participants to attend to the information being presented. One of the fundamental assumptions being tested was that Batchelder (2012) had achieved this by essentially accidentally activating top-down information processing of their central manipulation, an informed consent document, by removing the basic structure common to informed consent documents that delineates what is being explained by each section of the document and instead explaining the same components in a shortened narrative format. Had that assumption been correct, it was expected that this study would show a difference between the comprehension of informed consent documents among participants who were given the information in a similarly unstructured format compared to those who received it in a more traditional structured format, at a minimum. It was further hypothesized that by warning participants that they would have to answer questions about the document would spur effortful processing of the information, while decreasing the length would increase the likelihood of maintaining effortful processing for the entirety of the document.

As the results indicate, this fundamental assumption was not supported by the data collected. Several possibilities to explain this have emerged from close examination of the data: the previous work may have been a statistical anomaly, there was not enough power to detect a potential existing difference, or the manipulation was not a significant enough change to prevent visual schema activation, or bottom-up processing, thereby having most participants pass over the core manipulation

in this study completely. While the idea that the findings in Batchelder (2012) represent statistical probability in social science research gone awry cannot be dismissed, the magnitude of difference between comprehension of informed consent documents in this work relative to previous research on informed consent comprehension would suggest that there may be other more plausible and more productive explanations to explore.

By that same argument, that there would not be enough power to detect a previously observed difference of a substantial magnitude (or to indeed even be close to a significant difference) is suspect. If a significant difference exists to be found between that status quo informed consent process in social sciences compared to the modifications made in Batchelder (2012), and if that difference is even close to as large as was seen in that study relative to previous works, then the power present in this study should have seen something to that end. Quite clearly, it did not and did not even come close to replicating those findings.

Participant responding, upon closer examination, looked remarkably like what you would expect from participants who, at best, glossed over the informed consent document that served as the independent variable in this study, but had seen several like it before. This gives strong support to the idea that participants engaged in bottom-up processing of the document. Activation of the 'large Midwestern university social science research informed consent' schema fits the existing data perfectly, but leaves many questions. If this study was unable to prevent activation of this schema despite using what had been hypothesized to be the core components from the previous work that prevented it before, what was missed that allowed for the previous findings? This hidden component may be at the core of what made the previous study's central manipulation work as well as it did, but this does precious little good until it can be determined what was.

While this work has progressed, however, the world has continued to turn and grow. It may be entirely possible to discover what the mystery component from the previous study is, but to engage in the laborious research to unpack and explore each possibility for this may be an ignored opportunity to look for new solutions instead of trying to reinvent old ones. Online data collection tools such as Qualtrics and SurveyMonkey, two programs used frequently within the department this study was conducted in, offer simple methods to imbed multimedia such as videos into data collection procedures. Using a multimedia presentation of the informed consent process may end up being a more powerful tool than anything that can be distilled from Batchelder (2012), and even as the author composes this conclusion, they are perhaps three keystrokes from being able to start filming from their computer, saving and editing this clip within the same software, and then being able to easily upload it as part of the informed consent process in any future study. This not only potentially increases the likelihood of true comprehension of a study's components, but with certainty would increase accessibility to studies for individuals with, for example, visual impairments or learning disorders.

This study did not find data that supported the hypotheses presented, but it underscores a long legacy of evidence for minimally 'informed' consent among participants in social sciences studies (Handelsman & Martin, 1992; Wagner, 1998; Walfish & Ducey, 2007; Ascheman, 2009; Pedersen et al., 2011; Hudgins et al., 2013). At its inception, the informed consent process was designed to one that protected the right to autonomy of the individual following much research that we now consider highly unethical. Based on this and other works examining the informed consent process, this field is not currently passing muster to adequately ensure an informed choice to participate in research by potential participants. It has become a checkbox in the broader process, a form that has fresh details entered into a well-worn template before data collection. Harm has not emerged from this, and safeguards such as institutional review boards exist to help prevent that, but perhaps *because* there has

not yet been harm done it is time to revisit fundamental assumptions about the ‘what’ and ‘why’ of this process. As Hochhauser (1999) elegantly points out, informed consent is not a single document, but rather a process designed to both give all necessary information to participants and then seek out their consent to engage in a study. As this project draws to a close, it lays out several avenues, both traditional and modern, for exploration to meaningfully improve this process and meet the challenge of informing consent.

CHAPTER 6

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APPENDIX A – CONTROL CONDITION (LONG, STRUCTURED, WITHOUT COMPREHENSION CHECK WARNING) INFORMED CONSENT DOCUMENT

INFORMED CONSENT DOCUMENT

Title of Study: **Gene CCR5's Role in Personality Variation**
Investigators: **Zachary R Batchelder, M.S.**
Norman Scott, Ph.D.

This brief genetic sampling procedure will take less than 50 minutes to complete. Please take your time in deciding if you would like to participate in the near future. Questions may be addressed to the principle investigator (zacharyb@iastate.edu). You must be 18 years or older to participate in this study. As indicated in your psychology course syllabus, participation in research studies is one option for earning experimental credit.

INTRODUCTION

The purpose of this study is to examine how variations in the gene CCR5 influences the expression of specific personality traits. You are being screened to participate in this study because you are an undergraduate student (age 18+) enrolled in a qualifying course.

DESCRIPTION OF PROCEDURES

If you agree to participate in this study, your participation will last less than fifty minutes. During the study, you may expect the following study procedures to be followed: A buccal (cheek) swab will be obtained and stored for later genetic processing. You will be asked to share your unique participant ID number so that your genetic information may be matched up to your screening information.

RISKS

While participating in this study, you may experience the following risks: some mild discomfort or irritation at the site of buccal swabbing. In rare cases some individuals may have a mild allergic reaction to the material used for the swabbing procedure, including mild inflammation and increased discomfort, though these are temporary. Additionally if your identity becomes linked to your genetic information, there is a small (less than 1%) chance that your genetic information may be used as a basis for determination of eligibility for some forms of life insurance and/or in criminal investigations.

BENEFITS

If you decide to participate in this study there will be no direct benefit to you. It is hoped that the information gained in this study will benefit society by providing valuable information about how the CCR5 gene contributes to variations in personality traits.

COSTS AND COMPENSATION

You will not have any costs from participating in this study. You will be compensated for participating in this study (approx. 50 minutes) with one research credit toward your ComSt 101, Psych 101, Psych 230, or Psych 280 class(es) consistent with the Psychology Department guidelines. This will be in addition to the credit received for the online screening.

PARTICIPANT RIGHTS

Your participation in this study would be completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. Additionally, all records will be stored in the National Genetic Heritage Database (NGHD), which is accessible to all other researchers participating in NGHD projects and programs. Participants in the NGHD include other researchers, law enforcement agencies (including but not limited to local, state and federal law enforcement agencies), medical practitioners and medical, dental and life insurance companies. These records may contain private information. To ensure confidentiality to the extent permitted by law, the following measures will be taken: All data will be collected anonymously. An arbitrarily assigned numeric code will be used on all forms instead of name. Data files will be kept for no longer than five years and will be destroyed at the end of this period, except in the case of the NGHD in which the data will be stored indefinitely. Electronic data will be stored on the investigators' computers and NGHD secure servers in password protected computer files accessible only by the investigators and NGHD projects and programs contributors. If the results are published, only aggregate group data, not individual responses, will be reported. Due to the nature of genetic data, it is possible that your data may be identifiable as your unique responses, though the likelihood of this is very low.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study. For further information about the study contact Zachary Batchelder: zacharyb@iastate.edu or Norman Scott: nascott@iastate.edu. If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Responsible Research, Iowa State University, Ames, Iowa 50011.

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PARTICIPANT SIGNATURE

Your digital confirmation, by responding yes or no to the following question, indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. Please print a copy of this informed consent document for you records.

After you have having read this form and understood what is being asked, do you wish to be contacted to set up a time for genetic sampling?

1-Yes
2-No

APPENDIX B – SHORT, STRUCTURED, WITHOUT COMPREHENSION CHECK WARNING CONDITION INFORMED CONSENT

INFORMED CONSENT DOCUMENT

Title of Study: **Gene CCR5's Role in Personality Variation**
Investigators: **Zachary R Batchelder, M.S.**
Norman Scott, Ph.D.

This procedure will take less than 50 minutes to complete. Please take your time in deciding if you would like to participate in the near future. Questions may be addressed to the principle investigator (zacharyb@iastate.edu). You must be 18 years or older to participate in this study.

INTRODUCTION
This study will examine how variations in the gene CCR5 influence personality traits. You are being screened to participate because you are an undergraduate student (age 18+) enrolled in a qualifying course.

DESCRIPTION OF PROCEDURES
Your participation will last less than fifty minutes. During the study a buccal (cheek) swab will be obtained and stored. You will be asked to share your unique ID number so that your genetic information may be matched up to your screening information.

RISKS
Possible risks include: mild discomfort at the site of swabbing. In rare cases, a mild allergic reaction to the material used for the swabbing, including mild inflammation and increased discomfort, though these are temporary. If your identity becomes linked to your genetic information, there is a small (less than 1%) chance that your genetic information may be used as for determination of eligibility for some forms of life insurance and/or in criminal investigations.

BENEFITS
There will be no direct benefit to you. It is hoped that this study will benefit society by providing information about how the CCR5 gene contributes to personality traits.

COSTS AND COMPENSATION
You will not have any costs from participating in this study. You will be compensated with one research credit toward your class(es) in addition to the credit received for the online screening.

PARTICIPANT RIGHTS

Your participation in this study would be completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits.

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations. However, federal government regulatory agencies, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. Additionally, all records will be stored in the National Genetic Heritage Database (NGHD), which is accessible to all other researchers participating in NGHD projects and programs, including other researchers, law enforcement agencies, medical practitioners and medical, dental and life insurance companies. To ensure confidentiality all data will be collected anonymously with a random numeric code instead of name. Data files will be kept for no longer than five years and will be destroyed at the end of this period, except in the case of the NGHD in which the data will be stored indefinitely. Electronic data will secured in password protected computer files. It is possible that your data may be identifiable, though the likelihood of this is very low.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study. For further information about the study contact Zachary Batchelder: zacharyb@iastate.edu or Norman Scott: nascott@iastate.edu. If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Responsible Research, Iowa State University, Ames, Iowa 50011.

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PARTICIPANT SIGNATURE

Your digital confirmation, by responding yes or no to the following question, indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. Please print a copy of this informed consent document for you records.

After you have having read this form and understood what is being asked, do you wish to be contacted to set up a time for genetic sampling?

1-Yes
2-No

APPENDIX C – LONG, NARRATIVE, WITHOUT COMPREHENSION CHECK WARNING CONDITION INFORMED CONSENT

INFORMED CONSENT DOCUMENT

This brief genetic sampling procedure will take less than 50 minutes to complete. Please take your time in deciding if you would like to participate in the near future. Questions may be addressed to the principle investigator (zacharyb@iastate.edu). You must be 18 years or older to participate in this study. As indicated in your psychology course syllabus, participation in research studies is one option for earning experimental credit.

The purpose of this study is to examine how variations in the gene CCR5 influences the expression of specific personality traits. You are being screened to participate in this study because you are an undergraduate student (age 18+) enrolled in a qualifying course.

If you agree to participate in this study, your participation will last less than fifty minutes. During the study, you may expect the following study procedures to be followed: A buccal (cheek) swab will be obtained and stored for later genetic processing. You will be asked to share your unique participant ID number so that your genetic information may be matched up to your screening information.

While participating in this study, you may experience the following risks: some mild discomfort or irritation at the site of buccal swabbing. In rare cases some individuals may have a mild allergic reaction to the material used for the swabbing procedure, including mild inflammation and increased discomfort, though these are temporary. Additionally if your identity becomes linked to your genetic information, there is a small (less than 1%) chance that your genetic information may be used as a basis for determination of eligibility for some forms of life insurance and/or in criminal investigations.

If you decide to participate in this study there will be no direct benefit to you. It is hoped that the information gained in this study will benefit society by providing valuable information about how the CCR5 gene contributes to variations in personality traits.

You will not have any costs from participating in this study. You will be compensated for participating in this study (approx. 50 minutes) with one research credit toward your ComSt 101, Psych 101, Psych 230, or Psych 280 class(es) consistent with the Psychology Department guidelines. This will be in addition to the credit received for the online screening.

Your participation in this study would be completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. Additionally, all records will be stored in the National Genetic Heritage Database (NGHD), which is accessible to all other researchers participating in NGHD projects and

programs. Participants in the NGHD include other researchers, law enforcement agencies (including but not limited to local, state and federal law enforcement agencies), medical practitioners and medical, dental and life insurance companies. These records may contain private information. To ensure confidentiality to the extent permitted by law, the following measures will be taken: All data will be collected anonymously. An arbitrarily assigned numeric code will be used on all forms instead of name. Data files will be kept for no longer than five years and will be destroyed at the end of this period, except in the case of the NGHD in which the data will be stored indefinitely. Electronic data will be stored on the investigators' computers and NGHD secure servers in password protected computer files accessible only by the investigators and NGHD projects and programs contributors. If the results are published, only aggregate group data, not individual responses, will be reported. Due to the nature of genetic data, it is possible that your data may be identifiable as your unique responses, though the likelihood of this is very low.

You are encouraged to ask questions at any time during this study. For further information about the study contact Zachary Batchelder: zacharyb@iastate.edu or Norman Scott: nascott@iastate.edu. If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Responsible Research, Iowa State University, Ames, Iowa 50011.
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PARTICIPANT SIGNATURE

Your digital confirmation, by responding yes or no to the following question, indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. Please print a copy of this informed consent document for you records.

After you have having read this form and understood what is being asked, do you wish to be contacted to set up a time for genetic sampling?

1-Yes
2-No

APPENDIX D – LONG, STRUCTURED, WITH COMPREHENSION CHECK WARNING CONDITION INFORMED CONSENT

INFORMED CONSENT DOCUMENT

Please read the following document carefully. A few brief written questions to assess your understanding will be presented after you read this document. Your answers to those questions will not in any way affect your ability to participate in the study.

Title of Study: **Gene CCR5's Role in Personality Variation**
Investigators: **Zachary R Batchelder, M.S.**
Norman Scott, Ph.D.

This brief genetic sampling procedure will take less than 50 minutes to complete. Please take your time in deciding if you would like to participate in the near future. Questions may be addressed to the principle investigator (zacharyb@iastate.edu). You must be 18 years old to participate in this study. As indicated in your psychology course syllabus, participation in research studies is one option for earning experimental credit.

INTRODUCTION

The purpose of this study is to examine how variations in the gene CCR5 influences the expression of specific personality traits. You are being screened to participate in this study because you are an undergraduate student (age 18+) enrolled in a qualifying course.

DESCRIPTION OF PROCEDURES

If you agree to participate in this study, your participation will last less than fifty minutes. During the study, you may expect the following study procedures to be followed: A buccal (cheek) swab will be obtained and stored for later genetic processing. You will be asked to share your unique participant ID number so that your genetic information may be matched up to your screening information.

RISKS

While participating in this study, you may experience the following risks: some mild discomfort or irritation at the site of buccal swabbing. In rare cases some individuals may have a mild allergic reaction to the material used for the swabbing procedure, including mild inflammation and increased discomfort, though these are temporary. Additionally if your identity becomes linked to your genetic information, there is a small (less than 1%) chance that your genetic information may be used as a basis for determination of eligibility for some forms of life insurance and/or in criminal investigations.

BENEFITS

If you decide to participate in this study there will be no direct benefit to you. It is hoped that the information gained in this study will benefit society by providing valuable information about how the CCR5 gene contributes to variations in personality traits.

COSTS AND COMPENSATION

You will not have any costs from participating in this study. You will be compensated for participating in this study (approx. 50 minutes) with one research credit toward your ComSt 101, Psych 101, Psych 230, or Psych 280 class(es) consistent with the Psychology Department guidelines. This will be in addition to the credit received for the online screening.

PARTICIPANT RIGHTS

Your participation in this study would be completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. Additionally, all records will be stored in the National Genetic Heritage Database (NGHD), which is accessible to all other researchers participating in NGHD projects and programs. Participants in the NGHD include other researchers, law enforcement agencies (including but not limited to local, state and federal law enforcement agencies), medical practitioners and medical, dental and life insurance companies. These records may contain private information. To ensure confidentiality to the extent permitted by law, the following measures will be taken: All data will be collected anonymously. An arbitrarily assigned numeric code will be used on all forms instead of name. Data files will be kept for no longer than five years and will be destroyed at the end of this period, except in the case of the NGHD in which the data will be stored indefinitely. Electronic data will be stored on the investigators' computers and NGHD secure servers in password protected computer files accessible only by the investigators and NGHD projects and programs contributors. If the results are published, only aggregate group data, not individual responses, will be reported. Due to the nature of genetic data, it is possible that your data may be identifiable as your unique responses, though the likelihood of this is very low.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study. For further information about the study contact Zachary Batchelder: zacharyb@iastate.edu or Norman Scott: nascott@iastate.edu. If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Responsible Research, Iowa State University, Ames, Iowa 50011.

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PARTICIPANT SIGNATURE

Your digital confirmation, by responding yes or no to the following question, indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have

been given the time to read the document and that your questions have been satisfactorily answered. Please print a copy of this informed consent document for you records.

After you have having read this form and understood what is being asked, do you wish to be contacted to set up a time for genetic sampling?

1-Yes
2-No

APPENDIX E – SHORT, NARRATIVE, WITHOUT COMPREHENSION CHECK WARNING CONDITION INFORMED CONSENT

INFORMED CONSENT DOCUMENT

Title of Study: **Gene CCR5's Role in Personality Variation**
Investigators: **Zachary R Batchelder, M.S.**
Norman Scott, Ph.D.

This procedure will take less than 50 minutes to complete. Please take your time in deciding if you would like to participate in the near future. Questions may be addressed to the principle investigator (zacharyb@iastate.edu). You must be 18 years or older to participate in this study.

This study will examine how variations in the gene CCR5 influence personality traits. You are being screened to participate because you are an undergraduate student (age 18+) enrolled in a qualifying course.

Your participation will last less than fifty minutes. During the study a buccal (cheek) swab will be obtained and stored. You will be asked to share your unique ID number so that your genetic information may be matched up to your screening information.

Possible risks include: mild discomfort at the site of swabbing. In rare cases, a mild allergic reaction to the material used for the swabbing, including mild inflammation and increased discomfort, though these are temporary. If your identity becomes linked to your genetic information, there is a small (less than 1%) chance that your genetic information may be used as for determination of eligibility for some forms of life insurance and/or in criminal investigations.

There will be no direct benefit to you. It is hoped that this study will benefit society by providing information about how the CCR5 gene contributes to personality traits.

You will not have any costs from participating in this study. You will be compensated with one research credit toward your class(es) in addition to the credit received for the online screening.

Your participation in this study would be completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits.

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations. However, federal government regulatory agencies, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. Additionally, all records will be stored in the National Genetic Heritage Database (NGHD), which is accessible to all other researchers participating in NGHD projects and programs, including other researchers, law enforcement agencies, medical practitioners and medical, dental and life insurance companies. To ensure confidentiality all data will be collected anonymously with a random numeric code instead of name. Data files will be kept for no longer than five years and will be destroyed at the

end of this period, except in the case of the NGHD in which the data will be stored indefinitely. Electronic data will secured in password protected computer files. It is possible that your data may be identifiable, though the likelihood of this is very low.

You are encouraged to ask questions at any time during this study. For further information about the study contact Zachary Batchelder: zacharyb@iastate.edu or Norman Scott: nascott@iastate.edu. If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Responsible Research, Iowa State University, Ames, Iowa 50011.

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After you have having read this form and understood what is being asked, do you wish to be contacted to set up a time for genetic sampling?

1-Yes
2-No

APPENDIX F – SHORT, STRUCTURED, WITH COMPREHENSION CHECK WARNING CONDITION INFORMED CONSENT

INFORMED CONSENT DOCUMENT

Please read the following document carefully. A few brief written questions to assess your understanding will be presented after you read this document. Your answers to those questions will not in any way affect your ability to participate in the study.

Title of Study: **Gene CCR5's Role in Personality Variation**
Investigators: **Zachary R Batchelder, M.S.**
Norman Scott, Ph.D.

This procedure will take less than 50 minutes to complete. Please take your time in deciding if you would like to participate in the near future. Questions may be addressed to the principle investigator (zacharyb@iastate.edu). You must be 18 years or older to participate in this study.

INTRODUCTION
This study will examine how variations in the gene CCR5 influence personality traits. You are being screened to participate because you are an undergraduate student (age 18+) enrolled in a qualifying course.

DESCRIPTION OF PROCEDURES
Your participation will last less than fifty minutes. During the study a buccal (cheek) swab will be obtained and stored. You will be asked to share your unique ID number so that your genetic information may be matched up to your screening information.

RISKS
Possible risks include: mild discomfort at the site of swabbing. In rare cases, a mild allergic reaction to the material used for the swabbing, including mild inflammation and increased discomfort, though these are temporary. If your identity becomes linked to your genetic information, there is a small (less than 1%) chance that your genetic information may be used as for determination of eligibility for some forms of life insurance and/or in criminal investigations.

BENEFITS
There will be no direct benefit to you. It is hoped that this study will benefit society by providing information about how the CCR5 gene contributes to personality traits.

COSTS AND COMPENSATION
You will not have any costs from participating in this study. You will be compensated with one research credit toward your class(es) in addition to the credit received for the online screening.

PARTICIPANT RIGHTS

Your participation in this study would be completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits.

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations. However, federal government regulatory agencies, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. Additionally, all records will be stored in the National Genetic Heritage Database (NGHD), which is accessible to all other researchers participating in NGHD projects and programs, including other researchers, law enforcement agencies, medical practitioners and medical, dental and life insurance companies. To ensure confidentiality all data will be collected anonymously with a random numeric code instead of name. Data files will be kept for no longer than five years and will be destroyed at the end of this period, except in the case of the NGHD in which the data will be stored indefinitely. Electronic data will secured in password protected computer files. It is possible that your data may be identifiable, though the likelihood of this is very low.

QUESTIONS OR PROBLEMS

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After you have having read this form and understood what is being asked, do you wish to be contacted to set up a time for genetic sampling?

1-Yes
2-No

APPENDIX G – LONG, NARRATIVE, WITH COMPREHENSION CHECK WARNING CONDITION INFORMED CONSENT

INFORMED CONSENT DOCUMENT

Please read the following document carefully. A few brief written questions to assess your understanding will be presented after you read this document. Your answers to those questions will not in any way affect your ability to participate in the study.

Title of Study: **Gene CCR5's Role in Personality Variation**
Investigators: **Zachary R Batchelder, M.S.**
Norman Scott, Ph.D.

This brief genetic sampling procedure will take less than 50 minutes to complete. Please take your time in deciding if you would like to participate in the near future. Questions may be addressed to the principle investigator (zacharyb@iastate.edu). You must be 18 years or older to participate in this study. As indicated in your psychology course syllabus, participation in research studies is one option for earning experimental credit.

The purpose of this study is to examine how variations in the gene CCR5 influences the expression of specific personality traits. You are being screened to participate in this study because you are an undergraduate student (age 18+) enrolled in a qualifying course.

If you agree to participate in this study, your participation will last less than fifty minutes. During the study, you may expect the following study procedures to be followed: A buccal (cheek) swab will be obtained and stored for later genetic processing. You will be asked to share your unique participant ID number so that your genetic information may be matched up to your screening information.

While participating in this study, you may experience the following risks: some mild discomfort or irritation at the site of buccal swabbing. In rare cases some individuals may have a mild allergic reaction to the material used for the swabbing procedure, including mild inflammation and increased discomfort, though these are temporary. Additionally if your identity becomes linked to your genetic information, there is a small (less than 1%) chance that your genetic information may be used as a basis for determination of eligibility for some forms of life insurance and/or in criminal investigations.

If you decide to participate in this study there will be no direct benefit to you. It is hoped that the information gained in this study will benefit society by providing valuable information about how the CCR5 gene contributes to variations in personality traits.

You will not have any costs from participating in this study. You will be compensated for participating in this study (approx. 50 minutes) with one research credit toward your ComSt 101, Psych 101, Psych 230, or Psych 280 class(es) consistent with the Psychology Department guidelines. This will be in addition to the credit received for the online screening.

Your participation in this study would be completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

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After you have having read this form and understood what is being asked, do you wish to be contacted to set up a time for genetic sampling?

1-Yes
2-No

APPENDIX H –SHORT, NARRATIVE, WITH COMPREHENSION CHECK WARNING CONDITION INFORMED CONSENT

INFORMED CONSENT DOCUMENT

Please read the following document carefully. A few brief written questions to assess your understanding will be presented after you read this document. Your answers to those questions will not in any way affect your ability to participate in the study.

Title of Study: **Gene CCR5's Role in Personality Variation**
Investigators: **Zachary R Batchelder, M.S.**
Norman Scott, Ph.D.

This procedure will take less than 50 minutes to complete. Please take your time in deciding if you would like to participate in the near future. Questions may be addressed to the principle investigator (zacharyb@iastate.edu). You must be 18 years or older to participate in this study.

This study will examine how variations in the gene CCR5 influence personality traits. You are being screened to participate because you are an undergraduate student (age 18+) enrolled in a qualifying course.

Your participation will last less than fifty minutes. During the study a buccal (cheek) swab will be obtained and stored. You will be asked to share your unique ID number so that your genetic information may be matched up to your screening information.

Possible risks include: mild discomfort at the site of swabbing. In rare cases, a mild allergic reaction to the material used for the swabbing, including mild inflammation and increased discomfort, though these are temporary. If your identity becomes linked to your genetic information, there is a small (less than 1%) chance that your genetic information may be used as for determination of eligibility for some forms of life insurance and/or in criminal investigations.

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PARTICIPANT SIGNATURE

Your digital confirmation, by responding yes or no to the following question, indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. Please print a copy of this informed consent document for you records.

After you have having read this form and understood what is being asked, do you wish to be contacted to set up a time for genetic sampling?

1-Yes
2-No

APPENDIX I – COMPREHENSION RECALL QUESTIONAIRRE RATER KEY

Please answer the following questions regarding this study to the best of your ability:

1) How much would you be paid to participate in this study? (*Compensation)*

*Key: **any of:** Nothing; $0; No money; One credit/research credit; Class credit*

2) Who will have access to information gathered by this study? (*Confidentiality)*

*Key: **any of:** federal government regulatory agencies; auditing departments of Iowa State University; the Institutional Review Board; **AND any of:** the NGHD; researchers working with a national database; local, state, federal law enforcement; medical practitioners; medical, dental, life insurance companies*

3) What are the risks associated with this study? (*Risk*)

*Key: **any of:** Mild discomfort; irritation (from swabbing); possible allergic reaction **AND any of:** chance for information to be linked to identity; denial of life insurance or use of data in criminal investigations*

4) How long should this study take to participate in? (*Time Required*)

Key: 50 minutes or less

5) What will you do / what will happen in the study if you choose to participate? (*Procedures*)

Key: a cheek (buccal) swab will be taken or will be taken and stored

6) What, if any, are the costs to you for participating in this study? (*Cost*)

Key: None; Nothing; No Costs

7) If you choose to participate, when can you withdraw from the study? (*Ability to Leave*)

Key: Any time (or any variation thereof)

APPENDIX J – COMPREHENSION DELAYED RECALL QUESTIONAIRRE

Please answer the following questions regarding the informed consent you previously read for the study entitled '**Gene CCR5's Role in Personality Variation'.**

1) What will you do / what will happen in the study if you choose to participate? (*Procedures*)

_____

2) What are the risks associated with this study? (*Risk*)

_____

3) How much would you be paid to participate in this study? (*Compensation)*

_____

4) If you choose to participate, when can you withdraw from the study? (*Ability to Leave*)

_____

5) What, if any, are the costs to you for participating in this study? (*Cost*)

_____

6) How long should this study take to participate in? (*Time Required*)

_____

7) Who will have access to information gathered by this study? (*Confidentiality)*

_____

APPENDIX K – COMPREHENSION DELAYED RECOGNITION QUESTIONAIRRE

Please select *one* answer for each of the following questions regarding the informed consent you previously read for the study entitled '**Gene CCR5's Role in Personality Variation'.** *(Correct answers italicized)*

1) What will you do / what will happen in the study if you choose to participate? (*Procedures*)

a) Write my thoughts about the link between genetics and personality.

b) Give a buccal (cheek) swab to be stored for later genetic processing.

c) Watch a brief (<5 minutes) video and respond to a questionnaire.

d) Fill out an online survey.

2) What are the risks associated with this study? (*Risk*)

a) There are no risks associated with this study.

b) Some chance of serious swelling and bleeding at the site of the buccal swabbing, and a high risk (>15% chance) of having genetic information uniquely identified to participants.

c) Some mild discomfort or irritation at the site of buccal swabbing, and a possible but rare allergic reaction to the cheek swab.

d) Potential for mild personal discomfort while answering some questions.

3) How much would you be paid to participate in this study? (*Compensation)*

a) No money, but one research credit will be awarded.

b) No money and no research credits.

c) $10.00 and one research credit.

d) $25.00 and no research credits.

4) If you choose to participate, when can you withdraw from the study? (*Ability to Leave*)

a) At any point in the study with no penalty.

b) At any point in the study, but without compensation if this is within the first 10 minutes of the study.

c) Only in the first 10 minutes of the study.

d) You may not withdraw once you agree to participate in the study.

5) What, if any, are the costs to you for participating in this study? (*Cost*)

a) A $10.00 deposit for lab materials, refundable after samples are processed.

b) A non-refundable $5.00 fee for genetic processing.

c) A $15.00 deposit for lab materials, refundable after samples are processed

d) There are no costs for participating in this study.

6) How long should this study take to participate in? (*Time Required*)

a) More than 50 minutes.

b) The amount of time necessary was not described.

c) Less than 50 minutes.

d) Less than 10 minutes.

7) Who will have access to information gathered by this study? (*Confidentiality)*

a) Only the researchers conducting the study.

b) Any groups working with the National Genetic Heritage Database (NGHD), as well as federal and local (university) quality-assurance auditors.

c) Any federal, state or local regulatory or research agencies that file appropriate information requests through specially designated courts.

d) Researchers conducting the study, as well as other interested groups within their university department.

APPENDIX L – IPIP NEO PERSONALITY SCALE

In the following section, there are phrases describing behaviors. Please use the rating scale below to describe how accurately each statement describes you. Describe yourself as you generally are now, not as you wish to be in the future.

Very Inaccurate	Moderately Inaccurate	Neither Inaccurate Nor Accurate	Moderately Accurate	Very Accurate
1	2	3	4	5

1. Feel comfortable around people.
2. Have frequent mood swings.
3. Believe that others have good intentions.
4. Don't see things through.
5. Tend to vote for conservative political candidates.
6. Waste my time.
7. Suspect hidden motives in others.
8. Carry out my plans.
9. Am always prepared.
10. Respect others.
11. Am very pleased with myself.
12. Tend to vote for liberal political candidates.
13. Am skilled in handling social situations.
14. Don't like to draw attention to myself.
15. Feel comfortable with myself.
16. Am the life of the party.

17. Seldom feel blue.
18. Find it difficult to get down to work.
19. Insult people.
20. Don't talk a lot.
21. Panic easily.
22. Have a good word for everyone.
23. Am not easily bothered by things.
24. Do just enough work to get by.
25. Get back at others.
26. Have little to say.
27. Have a sharp tongue.
28. Make plans and stick to them.
29. Rarely get irritated.
30. Keep in the background.
31. Carry the conversation to a higher level.
32. Do not like art.
33. Accept people as they are.
34. Enjoy hearing new ideas.
35. Would describe my experiences as somewhat dull.
36. Believe in the importance of art.
37. Am often down in the dumps.
38. Avoid my duties.
39. Make people feel at ease.
40. Get chores done right away.

41. Avoid philosophical discussions.
42. Often feel blue.
43. Make friends easily.
44. Have a vivid imagination.
45. Pay attention to details.
46. Cut others to pieces.
47. Know how to captivate people.
48. Dislike myself.
49. Am not interested in abstract ideas.
50. Do not enjoy going to art museums.

APPENDIX M – IPIP NEO ITEM POOL

NEUROTICISM - *10-item scale (Alpha = .86)*

\+ keyed

Often feel blue.

Dislike myself.

Am often down in the dumps.

Have frequent mood swings.

Panic easily.

– keyed

Rarely get irritated.

Seldom feel blue.

Feel comfortable with myself.

Am not easily bothered by things.

Am very pleased with myself.

EXTROVERSION - *10-item scale (Alpha = .86)*

\+ keyed

Feel comfortable around people.

Make friends easily.

Am skilled in handling social situations.

Am the life of the party.

Know how to captivate people.

– keyed

Have little to say.

Keep in the background.

Would describe my experiences as somewhat dull.

Don't like to draw attention to myself.

Don't talk a lot.

OPENNESS TO EXPERIENCE - *10-item scale (Alpha = .82)*

+ keyed

Believe in the importance of art.

Have a vivid imagination.

Tend to vote for liberal political candidates.

Carry the conversation to a higher level.

Enjoy hearing new ideas.

– keyed

Am not interested in abstract ideas.

Do not like art.

Avoid philosophical discussions.

Do not enjoy going to art museums.

Tend to vote for conservative political candidates.

AGREEABLENESS - *10-item scale (Alpha = .77)*

+ keyed

Have a good word for everyone.

Believe that others have good intentions.

Respect others.

Accept people as they are.

Make people feel at ease.

– keyed

Have a sharp tongue.

Cut others to pieces.

Suspect hidden motives in others.

Get back at others.

Insult people.

CONSCIENTIOUSNESS - *10-item scale (Alpha = .81)*

+ keyed

Am always prepared.

Pay attention to details.

Get chores done right away.

Carry out my plans.

Make plans and stick to them.

– keyed

Waste my time.

Find it difficult to get down to work.

Do just enough work to get by.

Don't see things through.

Shirk my duties.

APPENDIX N – SONA POSTING FORM

STUDY POSTING FORM

PRINCIPAL INVESTIGATOR (*Faculty Supervisor*): Norman Scott

RESEARCHERS: Zachary Batchelder

STUDY NAME & NUMBER: **Gene CCR5's Role in Personality Variation**

BRIEF ABSTRACT:

This study is designed to screen participants for specific personality trait groupings. Participants will complete an initial personality measure in the first portion, then complete additional measures one week after the first portion. This is a two-part online survey, maximum 100 total minutes, 2 research credits total for participation in both portions.

STUDY DESCRIPTION (*Must be exactly as approved by IRB*):

The purpose of this anonymous online study is to screen undergraduate students for specific personality trait groupings being examined by behavioral genetics researchers. You are being invited to participate in this study because you are an undergraduate student (age 18+) enrolled in a qualifying course.

If you agree to participate in this study, your participation will initially last for approximately 50 minutes, followed by another 50 minute period one week after the first presentation. During the study, you may expect the following study procedures to be followed: You will be asked to complete an online survey about your personality, followed by a second online survey one week following completion of this. One credit will be awarded for completion of each portion, totaling two possible credits. While we would like you to complete all the items, during your participation, you may skip any question that you do not wish to answer or that makes you feel uncomfortable.

ELIGIBILITY REQUIREMENTS:

DURATION (*Minimum 50min.): 100 minutes (two 50-minute portions one week apart)*

CREDITS: 2 credits

PREPARATION:

IRB APPROVAL CODE:

IRB APPROVAL EXPIRATION:

IS THIS AN ONLINE STUDY? Yes

APPENDIX O – WEB-BASED INFORMED CONSENT DOCUMENT

INFORMED CONSENT DOCUMENT

Title of Study: **Gene CCR5's Role in Personality Variation**
Investigators: **Zachary R Batchelder, M.S.**
Norman Scott, Ph.D.

This anonymous online research study that will take less than 50 minutes per portion (two total portions) to complete. Please take your time in deciding if you would like to participate. Please feel free to ask questions at any time. You must be 18 years old to participate in this study. As indicated in your psychology course syllabus, participation in research studies is one option for earning experimental credit.

INTRODUCTION

The purpose of this study is to screen participants for specific personality trait groupings for potential participation in a behavioral genetics study. You are being invited to participate in this study because you are an undergraduate student (age 18+) enrolled in a qualifying course.

DESCRIPTION OF PROCEDURES

If you agree to participate in this study, your participation will last for approximately one hundred total minutes, with two sections of approximately fifty minutes each occurring one week apart. During the study, you may expect the following study procedures to be followed: You will be asked to complete an online survey about your personality and, if your personality profile matches with specified research interests, view an invitation and informed consent document for participation in a behavioral genetics study. While we would like you to complete all the items, during your participation, you may skip any question that you do not wish to answer or that makes you feel uncomfortable.

RISKS

While participating in this study, you may experience the following risks: some mild personal discomfort when you respond to personal questions about yourself. Most often, however, students do not find these questions to be too personal or too difficult.

BENEFITS

If you decide to participate in this study there will be no direct benefit to you. It is hoped that the information gained in this study will benefit society by providing valuable information about how specific personality traits are affected by genetics.

COSTS AND COMPENSATION

You will not have any costs from participating in this study. You will be compensated for participating in this study (approx. 100 minutes) with two research credits, one credit for each portion, toward your ComSt 101, Psych 101, Psych 230, or Psych 280 class(es) consistent with the Psychology Department guidelines.

PARTICIPANT RIGHTS

Your participation in this study is completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. These records may contain private information. To ensure confidentiality to the extent permitted by law, the following measures will be taken: All data will be collected anonymously. An arbitrarily assigned numeric code will be used on all forms instead of name. Data files will be kept for no longer than five years and will be destroyed at the end of this period. Electronic data will be stored on the investigators' computers in password protected computer files accessible only by the investigators. If the results are published, only aggregate group data, not individual responses, will be reported. Your anonymity will be assured.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study. For further information about the study contact Zachary Batchelder: zacharyb@iastate.edu or Norman Scott: nascott@iastate.edu. If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Responsible Research, Iowa State University, Ames, Iowa 50011.

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PARTICIPANT SIGNATURE

Your digital confirmation, by responding yes or no to the following question, indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. Please print a copy of this informed consent document for you records.

Do you wish to participate in this study after you have having read this form and understood what is being asked?

1-Yes
2-No

APPENDIX P – DEMOGRAPHICS QUESTIONNAIRE

Please answer the following questions:

1) What is your age?

a) 18-20

b) 21-22

c) 23-24

d) 25 or older

2) Please indicate your sex:

a) Male

b) Female

c) Transgender

d) Other

3) What is your school classification?

a) Freshman

b) Sophomore

c) Junior

d) Senior

e) Graduate or Other

4) What is your primary race/ethnicity?

a) Caucasian / European American

b) Black / African American

c) Hispanic / Latino/a

d) Hawaiian / Pacific Islander

e) Asian / Asian American

f) American Indian / Native Alaskan

g) Multiracial

h) Other

APPENDIX Q – DEBRIEFING STATEMENT

DEBRIEFING – TRUE PURPOSE OF THIS STUDY

Thank you for your participation. I want to reassure you that all your responses are confidential and will be combined with the responses of other participants to protect your identity. Before exiting this survey, we would like to tell you more about the research project. We ask that you not share the information with others who might participate in our study in the future. If a participant knew the study's purpose before participating, their data would be invalid and our findings would be invalid as a result.

The actual purpose of this study was not to screen participants for specific personality trait groupings for potential participation in a behavioral genetics study, but rather to see how much information students understood about a behavioral genetics study using different ways of presenting that information. In order to accurately evaluate students' comprehension with different methods, it was necessary to disguise the true purpose of the study. You viewed one of four methods of delivering information about a study (informed consent) that are being examined to try to improve how well students understand and remember important information about studies they are considering participating in.

The findings of this research have the potential to provide important insights into how research participants can better understand the research they are considering participating in. We did not tell you this information before because knowing the true purpose of the study could lead participants to consciously or unconsciously alter their responses. If that were to occur, the integrity of the research findings would be compromised. Again, for the integrity of this study, we ask that you not discuss these elements with other students.

FOLLOW-UP STUDY

In approximately one week you will receive an e-mail to participate in a second portion of this study. Please consider participating, as understanding how different methods of presentation of

informed consent information affect people's ability to remember the important details over time may help further improve this process for everyone.

YOUR RESPONSE DATA

If you do not want your response data to be used in our research, you may request that it be destroyed by emailing the primary investigator at (zacharyb@iastate.edu). However, due to the anonymous nature of your responses, you must make this request immediately following the debriefing so that your completion time can be associated with the otherwise anonymous data.

APPENDIX R – INFORMATIONAL PAMPHLET

Basic Elements of Informed Consent Documents

Purpose – Why is this research being conducted?

Description of Procedures – What will I be asked to do? How long will I be expected to participate?

Risks – What are potential negative consequences from participation?

Benefits – What are the desired outcomes I can expect?

Confidentiality – How will my information be protected?

Costs & Compensation – What costs will I incur? Will I be paid for participation?

Participant Rights – What are my rights as a participant?

Contact Information – Whom do I call if I have questions or problems?

The Signature – Your signature represents a commitment to participate in the study.

No consent document may include language that asks you to waive your legal rights, or that appears to release the investigators from liability for negligence.

Genetic Information Nondiscrimination Act (GINA)

This federal law protects Americans from discrimination due to differences in DNA that may affect health. It prohibits misuse by health insurers and employers.

GINA allows people to get genetic testing for which they previously feared would be used against them by insurers or employers.

Bill of Rights for Research Participants

You have the right to information on:

Why the research study is being done

What will happen during the research study

Whether any study procedures, drugs, or devices are different from standard care

The risks, side effects, and discomforts

The benefits from taking part in the study

Other treatment choices and their risks and benefits

Treatment in case of complications

You also have the right to:

Decide to participate or not participate without penalty and under no pressure

Ask questions at any time

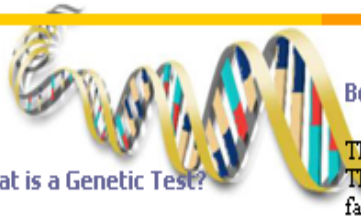
Receive a copy of the consent form

Understanding Genetic Research

Protecting your Privacy & Rights as a Research Participant

This pamphlet provides basic information regarding genetic testing, privacy protections, and informed consent.
It is important to read and understand any documents prior to consenting to participate in research or medical trials.

APPENDIX R (Cont.) – INFORMATIONAL PAMPHLET



What is a Genetic Test?

A genetic test is any analysis used to look at a person's genetic makeup. The test may examine DNA (deoxyribonucleic acid), RNA (ribonucleic acid), proteins, or other chemicals in cells that can indicate a genetic condition. This is usually done through blood, tissue, or cheek cell samples.

Genetic tests can be used to confirm a diagnosis, predict developing a disease in the future, or used for carrier screening to find out if a person has specific genes that increase the chance of a disease or birth defect occurring in his or her children.

DNA (Deoxyribonucleic Acid): A large molecule that carries all of the genetic information needed to operate a cell, make tissues, and control organ systems.

DNA Banking: The process of preserving and saving a person's DNA sample for future testing.

Benefits

There are several benefits of genetic testing. The knowledge can empower a person and family members to make important life planning decisions. Knowing about a certain disease gene might also provide important health information for a person's family. A person found to have an increased risk of a disease might want to choose preventive or therapeutic treatments.

Risks

Physical risks are usually minimal, typically not more than providing a blood sample. The greatest concern pertains to the way a genetic test result might change a person's life. The decision to have genetic testing can be stressful. You may have emotional reactions to learning you have a gene for a certain condition.

Sometimes a positive test result can affect family relationships. A person who decides to have genetic testing needs to consider whether to tell other family members. Furthermore, a genetic test may reveal unexpected relationships, such as nonpaternity (a different biological father).

FOR MORE INFORMATION ON GENETIC TESTING & GENETIC PRIVACY PROTECTION VISIT:

www.genome.gov

Other Concerns

What will happen to my sample after the genetic test is completed?

Some laboratories keep leftover samples for scientific or medical research. Some samples are submitted to DNA Banks or Repositories, where the sample may be available to you in the future. Most often, these repositories are used by researchers.

Because your genetic material contains a lot of information about you, it is important to know who will have access to this information and in what way your identifiable information can be used. A consent document should fully describe these details. If your questions are unanswered by the consent form or researchers. you

Researchers are required to provide you with important information about the study, assess your understanding of the information, and remind you that your participation is always voluntary. You should never sign a consent form without reading it and asking questions you have about your participation, privacy, and safety.

APPENDIX S: INSTITUTIONAL REVIEW BOARD APPROVAL

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office for Responsible Research
Vice President for Research
1138 Pearson Hall
Ames, Iowa 50011-2207
515 294-4566
FAX 515 294-4267

Date: 3/27/2015

To: Zachary R Batchelder
W113 Lagomarcino Hall

CC: Dr. Norman Scott
W271 Lagomarcino Hall

From: Office for Responsible Research

Title: Toward Comprehension: Improving Informed Consent in Behavioral Genetic Research

IRB ID: 15-124

Approval Date:	3/26/2015	**Date for Continuing Review:**	3/25/2017
Submission Type:	New	**Review Type:**	Expedited

The project referenced above has received approval from the Institutional Review Board (IRB) at Iowa State University according to the dates shown above. Please refer to the IRB ID number shown above in all correspondence regarding this study.

To ensure compliance with federal regulations (45 CFR 46 & 21 CFR 56), please be sure to:

- **Use only the approved study materials** in your research, **including the recruitment materials and informed consent documents that have the IRB approval stamp.**
- **Retain signed informed consent documents for 3 years after the close of the study,** when documented consent is required.
- **Obtain IRB approval prior to implementing any changes** to the study by submitting a Modification Form for Non-Exempt Research or Amendment for Personnel Changes form, as necessary.
- **Immediately inform the IRB of** (1) **all serious and/or unexpected adverse experiences** involving risks to subjects or others; and (2) **any other unanticipated problems involving risks** to subjects or others.
- **Stop all research activity if IRB approval lapses,** unless continuation is necessary to prevent harm to research participants. Research activity can resume once IRB approval is reestablished.
- **Complete a new continuing review form** at least three to four weeks prior to the **date for continuing review** as noted above to provide sufficient time for the IRB to review and approve continuation of the study. We will send a courtesy reminder as this date approaches.

Please be aware that IRB approval means that you have met the requirements of federal regulations and ISU policies governing human subjects research. **Approval from other entities may also be needed.** For example, access to data from private records (e.g. student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **IRB approval in no way implies or guarantees that permission from these other entities will be granted.**

Upon completion of the project, please submit a Project Closure Form to the Office for Responsible Research, 1138 Pearson Hall, to officially close the project.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.