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UNIVERSITY OF NORTHERN COLORADO

Greeley, Colorado

The Graduate School

A METHODOLOGICAL REVIEW OF THE CROSS-CULTURAL
ETHICAL DILEMMAS THAT EXIST WITHIN
THE INFORMED CONSENT PROCESS:
WHEN ETHICAL CONSIDERATIONS
IN HUMAN RESEARCH DIFFER

A Dissertation Submitted in Partial Fulfillment
of the Requirements for the Degree of Doctor of
Doctor of Philosophy

Suzanne Victoria Landram

College of Education and Behavioral Sciences
Department of Applied Statistics and Research Methods
Applied Statistics and Research Methods

August 2018

This Dissertation by: Suzanne Victoria Landram

Entitled: A Methodological Review of the Cross-Cultural Ethical Dilemmas that Exist within the Informed Consent Process: When Ethical Considerations in Human Research Differ

has been approved as meeting the requirement for the Degree of Doctor of Philosophy in the College of Education and Behavioral Sciences in Department of Applied Statistics and Research Methods, Program of Applied Statistics and Research Methods

Accepted by the Doctoral Committee

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Date of Dissertation Defense_____

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ABSTRACT

Landram, Suzanne Victoria. *A methodological review of the cross-cultural ethical dilemmas that exist within the informed consent process: When ethical considerations in human research differ.* Published Doctor of Philosophy dissertation, University of Northern Colorado, 2018.

The purpose of this study was to (a) explore researchers' and participants' experiences with the consent process in cross-cultural human research, and to (b) offer culturally responsive methods of how cross-cultural consent could be negotiated. Despite the lack of empirical studies, there has been much theoretical debate concerning the appropriateness of the Western approach to informed consent in developing countries (Dawson & Kass, 2005). Therefore, a qualitative approach to exploring past cross-cultural studies' researchers' and participants' views was needed to gain an in-depth and clearer understanding of these ethical issues, as well as what appropriate measures need to be taken to improve the current informed consent process as it pertains to cross-cultural human research. Seventeen in-depth case study interviews were collected that offered insight on the ethical issues that exist surrounding the informed consent process. A thematic analysis was conducted and the findings organized into two broad sections. Findings such as trust, cultural orientation, and cross-gender interactions are discussed further in Chapter V leading to recommendations that could be made at the individual as well as national levels of the Institutional Review Board in an effort to help lessen the ethical dilemmas that occur in cross-cultural research studies. Implications of the findings from this study are in the areas of the researcher understanding how to gain true consent

from participants in a culturally responsive manner and how cultural orientation fits into the practice of cultural humility. Culturally complex research practices such as those mentioned in this study are all aspects that a cultural competent researcher should apply to their own research practice. Such aspects can help contribute constructive and critical knowledge for a greater cause. The findings and recommendations from this research, as well as similar research studies that examine the cultural complexities that exists, can help to further cultural responsive research practices.

Which side should you spread when you butter your bread?

For Yooks, it's the top; Zooks, the bottom instead.

Between the two lands, they build a big wall,

That soars over everyone—the big and the small.

The issue, to us, isn't that big a deal,

But to these ooky fellas, it feels very real.—Dr. Seuss, 1984

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I also would like to dedicate this dissertation in memory of Sophia Montoya-Gonzalez who sat with me day and night through this endeavor until she was too ill to do so. I miss you every day and have thought of you every step of the way. To Sophia and Dad I love you both and miss your guidance; and to Tank, my love, thank you for making me stick with it.

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CHAPTER I

INTRODUCTION

Statement of the Methodological Problem

The popularity of cross-cultural human research is increasing in various fields such as medical, psychology, sociology, anthropology, global business, and the military. Cultures with "no previous experience of human subjects' protection are increasingly involved in clinical studies, creating a need for greater discussion about transferability of such efforts across cultures" (Adams et al., 2007, p. 446). Thus the complexity in how to negotiate the various ethical differences between the cultures has become a major issue. Many researchers, globally, admit to the added value of having some universal ethical regulations and or guidelines to follow when seeking consent or assent from participants in human research (Angell, 1997; Holmes, 1997; Hyder & Wali, 2006; Ijsselmuiden & Faden, 1992). Other researchers argue that standards in cross-cultural research should be more flexible and be more accommodating to each culturally diverse setting (Adams et al., 2007; Fadare & Porteri, 2010; Lakes et al., 2012, Killawi et al., 2014; Marshall, 2008; Upvall & Hashwani, 2001). Regardless, cross-culture researchers' and former participants state the need for better standards, guidelines, and cross-cultural sensitivity protocols from ethical research committees (e.g., Institutional Review Board, IRB) when it comes to cross-cultural human-subject based research or what will be more commonly referred to in this study as cross-cultural human research.

One notable example of when conflict may be present in cross-cultural research is when the researcher is trying to gain informed consent. The informed consent process is vital in the research process; thus, the informed consent process is the primary cross-cultural ethical issue and point of discussion in this study. Informed consent is "the cornerstone of the ethical conduct and regulation of research; it has been a focus of attention in guidelines for conducting research and the ethical oversight of research" (Bhutta, 2004, p.771).

It is through the informed consent process that the researcher conveys all aspects of the proposed research, answers any initial questions the participant may have, and establishes the participant's agreement to take part in the study. The information required in the consent form conveys the requirements of that institution's review board (IRB), thus allowing for little acknowledgment of complex cultural differences in values and communication. For example, through a survey study conducted by Dawson and Kass (2005), the researchers found that most of their respondents believed that U.S. regulations should allow for more flexibility in the informed consent process. In gaining informed consent cross-culturally, a difference in ethical and cultural perspectives becomes a major problem. Therefore, according to the theory of cultural relativism, there is no singular truth on which to base ethical or moral behavior, as our interpretations of reality are influenced by our own culture. In Western cultures, informed consent is based on upholding two ethical factors: autonomy and voluntariness. I use quote marks around the word Western to denote the bifurcated nature of this discussion. Any Western culture has multiple subcultures and overlapping cultures that do not fit the norms presented here. This cultural complexity in a globalized world is what is of interest in this study.

First, a participant's autonomy relies on that individual's capability of discussing personal goals and acting under the direction of such deliberation (Office for Human Research Protections [OHRP], n.d.). "To respect autonomy is to give weight to an autonomous person's considered opinions and choices while refraining from obstructing their actions unless they are detrimental to others" (United States, 1978). Voluntariness, the second ethical factor, means that the participant has independently given valid consent or agreement to be in a particular study. "This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another to obtain compliance" (United States, 1978). These two elements of ethical consent, autonomy, and voluntariness, while considered essential by Western ethical research standards, appear not to be equally valued and upheld in all cultures. Collectivistic cultures value the importance of the group as a whole over that of the individual. Individualism can be observed in the cultures of Western Europe and Northern America, whereas collectivism can be primarily seen in the cultures of Asia, Africa, and parts of Europe and Latin America (Nelson & Fivush, 2004). Kornyo (2015) explained that in collectivist cultures "the notion of consent is accepted by the elder/chief of the community on behalf of the people." A researcher's mistake of not understanding this cultural norm can lead to irreparable consequences if the researcher decides to forgo the cultural standards of the group and seeks out individual consent. However, Western researchers are still responsible for gaining individual consent to satisfy their IRB and federal guidelines. Other ethical dilemmas that make gaining informed consent from cross-cultural participants problematic include and are not limited to issues of confidentiality, the

pressure to participate in the research, lack of comprehension and understanding of the consent, and language and literacy barriers (Killawi et al., 2014). So what is a researcher in this position to do?

Purpose of the Methodological Aspect of the Research

The purpose of this study was to (a) explore researchers' and participants' experiences with the consent process in cross-cultural human research and to (b) offer culturally responsive methods of how cross-cultural consent could be negotiated. Solving these challenges requires culturally informed strategies to obtain and document informed consent (Dawson & Kass, 2005). Only a few survey research studies (Fiske, Gilbert, Lindzey & Jongsma, 2010; Hyder & Wali, 2006; Killawi et al., 2014) have been conducted to examine how potential participants perceive cross-cultural research. Despite the lack of empirical studies, there has been much theoretical debate concerning the appropriateness of the Western approach to informed consent in developing countries (Dawson & Kass, 2005). A qualitative approach to exploring past cross-cultural studies' participants' and researchers' views was needed to gain an in-depth, clearer understanding of these ethical issues, and what appropriate measures need to be taken to improve the current informed consent process as it pertains to cross-cultural human research. Therefore, through this study, a qualitative in-depth interview approach was taken in order to gain valuable insight from experienced cross-cultural researchers as well as former cross-cultural participants on the ethical issues that exist surrounding the informed consent process.

Description of Study

The reader should note that, throughout the study, the word "participant" will be used instead of "subject" unless quoting the literature. Although research "subject" is the more traditional of the two terms, I believe the use of the word "participant" describes an individual who takes part in a research study rather than someone who is a subject of study, and the word is inherently more respectful and personal in my opinion. Note that where the word subject was retained is in direct quotes and U.S. Common Rule language.

A multiple case study approach was used to gain a better understanding of individuals' perceptions of what it was like to participate in a cross-cultural study or to be the primary investigator (PI) in a cross-cultural study where the ethical understanding of informed consent was hard to negotiate. The participants' and researchers' personal experiences may differ, but they are all bounded by the ethical problems that arose during the informed consent process. By sharing their experiences, they contributed a voice of understanding and reasoning that could possibly help prevent others from encountering the same ethical dilemmas. Cross-cultural human research is essential, yet finding the appropriate avenues in which to conduct these studies where either side's cultural standards and regulations have not been disregarded nor infringed upon is even more essential.

As previously mentioned, during this study I employed an in-depth interview approach. This method is a core qualitative research method and is a powerful way of generating rich information from the participants on their views and interpretations (Merriam, 2015). All participants were asked the same structured questions in a semi-structured format (Appendix B), and each interview took 60 to 90 minutes to complete.

The amount of time each interview took depended on the amount of information each participant was willing to disclose. These in-depth interviews were conducted in two settings, (a) a mutually agreed upon public place, and (b) in a computer-mediated communication (CMC) format. The qualitative data obtained from these interviews were analyzed using a qualitative thematic analysis that would help identify similarities and themes that emerge across all of the participant's interviews. The patterns and themes that emerge will contribute to identifying underlining ethical issues that exist and will offer, based on the findings, a more culturally responsive method of how cross-cultural consent could be negotiated.

Rationale for the Methodological Aspect of the Study

Researchers conducting cross-cultural clinical trials have made efforts to design a more flexible informed consent process (Emanuel, Wendler, Killen, & Grady, 2004; Karim, Karim, Coovadia & Susser, 1998; Pace, Grady & Emanuel, 2004). These developments should be seen in all fields and for anyone wanting to conduct cross-cultural research. However, an approach to guidelines and standards for cross-culture research becomes increasingly complex across areas of study. As Adams et al. (2007) suggested: "the issues of comprehension and retention of research aims, methods, risks, benefits and informed consent procedures have also been shown to be unevenly understood and accepted" (p. 446). Therefore, the rationale for conducting this study was to gain a better methodological understanding of the cross-cultural ethical dilemmas that exist regarding the consent process. Other considerations besides differences in social norms such as age, gender, and socioeconomic status can add to the complexity and difficulty in conducting a cross-cultural research. Adams et al. (2007) proposed that the

ethical dilemmas that the researcher faces stems out of two needs: first, the researchers need to make every effort to meet their institutional standards for protecting human subjects; and second, the need to be flexible in their ability to accommodate foreign cultural, national, and ethical priorities. How is a researcher to satisfy both needs?

Research Questions

The aim of this study was to explore the shared experiences of researchers and participants as to the cross-cultural ethical dilemmas that exist when it comes to the informed consent process. A qualitative in-depth interview methodological approach was taken to offer insight into the development of more culturally responsive methods of negotiating cross-cultural consent and on how to establish and maintain positive rapports cross-culturally. Based on the literature review and theoretical bases on individuals' perceptions and interpersonal interactions, through this study I sought to answer the following research questions:

Q1   What are possible cross-cultural implications of participant consent and how might researchers enact informed consent across cultures?

Q2   How are competing ethical values, in human research, negotiated in cross-cultural research?

Q3   When it comes to consent, how should competing ethical values in cross-cultural research be addressed (negotiated)?

Q4   How does the data collection process, experienced during this research study, compare between the in-person method and the computer-mediated method?

Q5   How well do participants understand consent directly after the consent form has been given to them in an interview setting (i.e., computer-mediated communication (CMC) vs. in-person interviews)

Summary of Chapter I

The complexity in how to negotiate the various ethical differences between the cultures has become a major issue. Many researchers, globally, admit to the added value of having some universal ethical regulations and or guidelines to follow. However, other researchers argue that a one size fits all approach does not work and that the standards in cross-cultural research should be more flexible and be more accommodating to each culturally diverse setting. Regardless, cross-culture researchers' and former participants state the need for better standards, guidelines, and cross-cultural sensitivity protocols from ethical research committees. The purpose of this study was to (a) explore researchers' and participants' experiences with the consent process in cross-cultural human research and to (b) offer culturally responsive methods of how cross-cultural consent could be negotiated. Research on the subject has been limited to only a few survey research studies (Fiske et al., 2010; Hyder & Wali, 2006; Killawi et al., 2014) have been conducted to examine how potential participants perceive cross-cultural research. A qualitative approach to exploring past cross-cultural studies' participants' and researchers' views was needed to gain an in-depth, clearer understanding of these ethical issues, and what appropriate measures need to be taken to improve the current informed consent process as it pertains to cross-cultural human research.

Chapter II discusses the specific language on the international and federal ethical research regulations, standards and guidelines (e.g., Nuremberg Code, Helsinki Declaration, Title 21, CFR parts 50 & 56 and Title 45, CFR part 46). Followed by a methodological review of current cross-cultural research standards and how competing values are being attended and negotiated presently. Lastly, a description of the consent

form process and the different types of consent is presented with particular attention paid to describing the various assumptions of cultural differences on how consent can be established.

CHAPTER II

LITERATURE REVIEW

This Chapter begins with a brief introduction to the history of research ethics with human subjects. Next, a methodological literature review of the regulations, standards, and guidelines that exist, today, internationally and federally is presented, followed by a review of what cross-cultural research and how competing values are being attended to and negotiated presently. Finally, the importance of gaining cross-cultural consent, the different types of consent, and what kind of consent issues may arise when conducting cross-cultural research are explored. Throughout this chapter, historical references such as the Tuskegee Syphilis Study, the Nuremberg trials after World War II (WWII), the Human Radiation Experiments, the Stanford Prison experiment, and other such cases of unethical research practices are discussed along with their impact on current ethical standards. As a reminder to the reader, the word "participant" will be used instead of "subject" unless quoting the literature.

The History of Research Ethics with
Human Subjects

Ethics, a forever evolving and repeated revision of ethical codes, is evidence that humanity is "trying to improve human morals and values" (Ghooi, 2011, p. 75). Ethics has always played a major role in human research since before the Common Era (BCE). For instance, the emergence of autopsy and dissection was a regular and integral part of medical practice in ancient Greece in 3rd century BCE, a practice that was revived in medieval Italy in the early 14th century and would eventually spread throughout Europe

(Park, 1994; Olry, 1997; French, 1999). Much knowledge was gained at the beginning of 3rd century Greece concerning the health of the human body by early physicians Halophiles and Erasistratus (Elizondo-Omaña, García-Rodríguez, & Guzmán-López, 2005). Before Halophile and Erasistratus, little was known about the body due to religious moral and aesthetic taboos that limited the exploration of the human body (Von Staden, 1992). It is a belief that these early physicians overcame cultural stigmas to establish Alexandria at the heart of literacy and scientific learning (Ghosh, 2015). By the beginning of the 4th century BCE, the renowned Greek physician Hippocrates composed what is known today as the Hippocratic Oath. Miles stated, "there is little known about the origin or the how widely accepted the Hippocratic Oath was at the time" (as cited in Merriam & Tisdell, 2015). History is unclear on how much power the Hippocratic Oath actually had, in fact some scholars speculate that there may have been other, similar, medical oaths used at that time. However, the Hippocratic Oath is the sole surviving text (Merriam & Tisdell, 2015). Centuries later in medieval Europe (12th and 13th century) the church played a critical role in the changing of public attitudes towards human research by defining, through doctrines, the boundaries around human dissection, easing the public's discomfort and decreasing public protests (Park, 2009).

Research is the root from where most of our anatomical as well as physiological knowledge stems, and over the course of the next several centuries, the expansion of research involving humans expanded as did malpractice. Ghosh (2015) stated that:

> In 19th century England, the means of cadaver procurement at a time when human dissection was synonymous with capital punishment depended upon illegal means such as grave robbing, body snatching and even murder for human bodies, which led to legalization of the use of unclaimed bodies, most of whom were poor people (p. 153).

Most experimentally based human research relied heavily on the use of criminals, those deemed mentally insane, and the impoverished before there were any set regulations and standards for the protection of human subjects in research (Mitchell et al., 2011). As the gradual change of the publics' attitude transformed from outrage and protest over the use of human bodies to that of acceptance and curiosity through the centuries, it became a learning tool and a public event (Ghosh, 2015; Landram, 2018).

Over time, the conduct of scientists, doctors, and researchers involving humans resulted in a variety of ethical concerns. Could the findings from unethically conducted research be justified if the knowledge obtained was performed for the sake of helping the human race, and could the research, no matter how it was obtained, still be worthy, valuable, and justifiable? From this question stemmed the basis for what has now grown to universal ethical standards as well as individual nations having their own set of ethical regulations, standards, and guidelines that hold scientists, doctors, or anyone else researching humans accountable for their actions. For example, Thomas Percival presented his book Medical Ethics: or, a Code of Institutes and Precepts Adapted to the Professional Conduct of Physicians and Surgeons, which was adopted to the Professional Conduct of Physicians and Surgeons in 1803 (Lynöe, 1999). Another example would be the Weimar Republic in Germany that passed a directive in 1931, which included a demand for the informed consent of research participants (Hoeyer, Dahlager, & Lynöe (2005). Coincidentally, the ethical codes passed by the Weimar Republic would be the same codes that the Nazi doctors and administrators would be charged with violating sixteen years later.

**Methodological Review: Regulations, Standards,
and Guidelines Ethics in Research**

What follows is a thorough discussion on why international as well as U.S.

federal rules and regulations of ethics in human subject research exist today. It is

important to discuss the history of these ethical regulations, standards, and guidelines

before addressing cross-cultural human subject research ethics. Discussing ethics in

human research can be beneficial by first, building a sound basis of what ethical

implications exist today and secondly, by understanding how these ethics are or are not

applicable when conducting cross-culture human research. As Kress (2011) stated, "the

most grotesque forms of harm are easily identified in biomedical research (e.g., Nazi

Experiments, Tuskegee Syphilis Experiments)" (p. 127). However, there have been

psychological and sociological studies that have also harmed people as well such as the

Stanford prison experiment (Zimbardo, 1973), and Humphrey's "tea room" study

(Humphreys, 1975). Each of these cases will be discussed in further detail below.

**International Existing Ethical Provisions in
Research on Human Subjects**

Nuremberg Code

The series of military tribunals held after the end of World War II, in which the

German authorities were prosecuted, are collectively known as the Nuremberg Trials.

The results of the Doctors' Trials held in the city of Nuremberg, Germany led to the

creation of the Nuremberg Code in 1947. The German physicians and administrators

were found guilty of crimes against humanity for their inhumane treatments of human

subjects (Angell, 2005). Several German doctors were convicted in Nuremberg for

violations of human dignity, which is the basis of why the informed consent process was

established, such as the principle that individuals must never be sacrificed for the benefit of society. The Nuremberg trials had a practical impact on contemporary research ethics (Rothman, 1991). Close examination of this code reveals that it has an uncanny resemblance to the Guidelines for Human Experimentation of 1931. Ironically enough, these guidelines for therapeutic and scientific research on human subjects were first published as a Circular of the Reich Minister of the Interior (Ghooi, 2011), which illustrates the magnitude of what can transpire if such actions are not upheld.

Although the Nuremberg Code has no legal power of authority (Talk: Nuremburg Code, n.d.); it is still universally recognized. The Nuremberg Code is made up of ten principles (guidelines). Six out of the ten principles were derived from the 1931 Guidelines for Human Experimentation (Ghooi, 2011). These ten articles are directly quoted, below, and were referenced from the National Institution of Health (Friedmann & Sprecher, 1954):

1. The voluntary consent of the human subject is essential. It means that the person involved should have the legal capacity to give consent. Also, the participant should be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or another ulterior form of constraint or coercion.The participant should also have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject, the nature, duration, and purpose of the experiment should be made known to them. The method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may come from his

   participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rest upon each who initiates director engage in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.

10. During the experiment, the scientist in charge must be prepared to terminate the experiment at any stage. If there is probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject (p. 1248).

Helsinki Declaration

Several emerging cases for greater patient autonomy emerged in the United States during the 1950's and 1960's. National policy changes took place such as the Resolution on Human Experimentation of 1954, and the Jewish Chronic Disease Hospital case in 1963. These national policy changes led to the World Medical Association's (WMA) Declaration of Helsinki in 1964 (Brody, 2001). Much like the Nuremberg Code, the Helsinki Declaration is made up of ethical principles for medical research involving human subjects, but also includes research on identifiable human material and data. The Declaration is addressed to physicians. However, even though the Declaration of Helsinki is the responsibility of the WMA, the document should be considered the property of all humanity (Human & Fluss, 2001). Since being adopted by the WMA in 1964, the Declaration of Helsinki has been amended nine times with the latest update being in October of 2013 (World Medical Association, 2013). Due to a significant amount of principals contained in the Declaration of Helsinki, only those principles that are relevant to this study, in particular, will be discussed in further detail below. Each principal presented falls under one of the following categories (a) Research Ethics Committees, (b) Privacy and Confidentiality, (c) Informed Consent, and (d) Research Registration and Publication.

Firstly, the Research Ethics Committees' principle states that:

> The research protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor, and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research subjects outlined in this Declaration. The committee must

have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions (World Medical Association, 2013, p. 2192).

Next, the Privacy and Confidentiality principle states "every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information" (World Medical Association, 2013, p. 2192). Third, under Informed Consent eight principles are addressed which include:

1. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

2. In medical research involving human subjects, capable of giving informed consent, each potential subject must be adequately informed of the following: the aim of the investigation, methods applied, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and risks of the study, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Particular attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician, or another appropriately qualified individual, must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed. All medical research subjects should be given the option of being informed about the general outcome and results of the study.

3. When seeking informed consent for participation in a research study, the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations, the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

4. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative.

These individuals must not be included in a research study that has no likelihood of benefit for them. Unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed by persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

5. When a potential research subject who is deemed incapable of giving informed consent can give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

6. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be conducted if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances, the physician must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorized representative.

7. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

8. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage, and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such cases, the research may be conducted only after consideration and approval of a research ethics committee (World Medical Association, 2013, p. 2192-3).

Lastly, two principles classified under WMA's Research Registration and Publication and Dissemination of Results category include:

1. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

2. Researchers, authors, sponsors, editors, and publishers all have ethical obligations about the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and

accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations, and conflicts of interest must be declared in the publication. Reports of research not by the principles of this Declaration should not be accepted for publication (World Medical Association, 2013, p. 2193-4).

International Compilation of Human Research Standards (ICHRS)

The Office for Human Research Protections (OHRP) does have set regulations and guidelines in place for Department of Health and Human Services-supported (HHS) research outside the United States, which is collectively known as the International Compilation of Human Research Standards (ICHRS). The ICHRS is comprised of over 1,000 laws, regulations and guidelines protecting human research participants in over 100 countries (International Compilation, n. d). These laws, regulations, and guidelines are divided into seven categories:

1. General, applicable to most or all types of human subjects research

2. Drugs and Devices

3. Research Injury

4. Privacy/ Data Protection

5. Human Biological Materials

6. Genetic

7. Embryos, Stem Cells, and Cloning

**Federally Existing Ethical Provisions in Research on
Human Subjects**

**Food and Drug Administration
(FDA)**

The Pure Food and Drug Act was the first regulation put into action to protect

human participants' ethical rights in research (Darrow, Sarpatwari, Avorn, & Kesselheim,

2015). The Federal Drug Administration (FDA) originated out of the Pure Food and Drug

Act, passed in 1906, as a federal consumer protection agency. Before this date, there were

no consumer regulations and the Nuremberg Code would not be drawn up for another 40

years. Partially due to the international spending of the National Institute of Health

(NIH), the provisions set forth by the FDA on ethical standards has always had an

influence on Europe and the rest of the world (Kapp, 2006). The sources of influence

reflect what has been described as the Western notion of individuality, which also

influenced the Universal Human Rights Declaration (Mutua, 2002). Thus, medical

research ethics has tended to take the protection of the individual as its main objective

irrespective of the political or cultural context (Hoeyer et al., 2005). Informed consent, as

explained by Rotham (1991), has become a matter of fundamental importance in human

research, sustained and codified by the FDA and major funding bodies. The FDA

complies with Title 21 Code of Federal Regulations (CFR) part 50 and part 56.

Title 21 Code of Federal Regulations Part 50. In part 50, the FDA regulations

for the Protection of Human Subjects are established (National Institutes of Health, n.d.).

The first code, Title 21 CFR part 50, is comprised of four subparts. Subpart A describes

the general provisions that are designed to "protect the rights and safety of subjects

involved in investigations filed with the FDA" (United States Department of Health and

Human Services, 2017). It is subpart B, in particular, that is of interest to this study, as this subpart deals with the informed consent of human subjects. Section 50.20 provides the general requirements for informed consent, which are: (a) the human subject's willingness to participate in the study must be voluntary; (b) the language contained in the consent form must be written in language understandable to the subject; and (c) no language should be contained within the consent form that waives any legal rights of the participants or releases the legal rights of the investigator, the sponsor, the institutions or its agents from liability for negligence (Code of Federal Regulations Title 21, n.d.). Exceptions from the general informed consent requirements are found in section 50.23 of Title 21 CFR part 50. Exceptions to the general informed consent requirements must be feasible, and the researcher must certify in writing the reason for an exception. Many of the exceptions to gaining informed consent under the FDA are medical, military and pharmaceutically based reasons. Exceptions that apply to behavioral research are such things as (a) a participant is confronted by a life-threatening situation in which their identity must be kept secret, or (b) informed consent cannot be obtained from the participants because "of an inability to communicate with, or obtain legally effective consent from the participant" (United States Department of Health and Human Services, 2017).

**United States Department of Health
and Human Services (HHS)**

On April 11, 1953, the Department of Health, Education, and Welfare (HEW) was created. In 1979 the Department of Education split from HEW, and the HHS was formed (Ballotpedia, n.d.). This "cabinet-level department of the Federal Executive Branch" is the United States government's primary agency for protecting the health of all

Americans and providing essential human services, especially for those who are least able to help themselves." (Secretary, n.d.). The Secretary of HHS advises the president on the "health, welfare, income security plans, policies, and programs of the Federal Government" (HHS, n.d.). The FDA and the NIH are both HHS-funded agencies.

National Institute of Health (NIH)

Created in 1887, the NIH was, originally, a one-room laboratory set up within the Marine Hospital Service (National Institute of Health, 2016). It was not until 1966 that the NIH adopted requirements stating that each institution receiving federal funds for research must provide assurance of the existence of a system of peer review. The NIH also indicated that researchers must obtain informed consent from each participant, "and have a reasonable assessment of risk and potential benefits of the research" (McCally, Cassel, & Kimball, 1994, p. 11).

Belmont Report

Horrendous acts of unethical treatment of human subjects are the reason the National Research Act (1974) was signed into U.S. law (Pub. L. 93-384). The United States has its infamous history of horrendous acts of treatment on human subjects in medical as well as behavioral research, and it is through the passing of this law that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research created what is now known as the Belmont Report. The Belmont Report is a summary of the ethical principles identified by the Commission. It is a product of "an intensive four-day period of discussions that were held in February of 1974 at the Smithsonian Institution's Belmont Conference Center", hence the name Belmont Report (United States, 1978). Moreover, the objective of the Belmont Report is

to provide "an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects" (United States, 1978). The Report itself consists of three parts: (a) Boundaries between Practice and Research, (b) Basic Ethical Principles, and (c) Applications. Part B of the Report, Basic Ethical Principles, is of main interest to this study and will be discussed in further detail.

Part B of the Report is comprised of four main principles and defines the ethical conduct that any researcher conducting human subject research should be familiar with and must uphold throughout the entirety of their study. These four principles will be discussed in further detail below with historical references given as examples.

Respect for persons. The Belmont Report defines two distinct principles within the area of respect. The first principle states that individuals should be treated as autonomous while persons with diminished autonomy should be given additional protections (Salganik, 2014). Furthermore, it is of the utmost importance that the participant provides some form of consent before the start of the study. Informed consent should always be the first option in gaining consent, however, various circumstances allow for other forms of consent to be used. These other forms of consent and the special underlying situations in which they apply are defined later in this chapter. Depending on the nature of the study, some researchers suggest periodical or process consent throughout the duration of the study. The Belmont Report gives three elements of informed consent: (a) information, (b) comprehension, and (c) voluntariness. One historical reference and a horrible reminder of why this principle, Respects for Persons, was created is the U.S. government-sponsored Radiation Experimentation and Human Participant Abuses that occurred between the years of 1945-1975 and involved over a

thousand human subjects (McCally et al., 1994). Cantwell explained that these experiments were conducted to "prepare America for nuclear attacks during the Cold War years following World War II" (2001, par. 1). Few of the participants of the experiments gave informed consent while most of the participants had no idea they were being subjected to radioactive materials (Claremont Graduate Univeristy, n.d.). Cantwell (2001) explained that none of these experiments were made public until 1993 when a journalist from the Albuquerque Tribune released a story identifying 18 Americans who were secretly injected with plutonium (par.8). This breaking news unleashed a fury of nationwide protest demanding the release of the secret files and documents. The secret files relating to plutonium via the Manhattan Project were the only files issued by the government at that time (McCally et al., 1994). These experiments were carried out on indigenous people, the mentally challenged, institutionalized teenagers, pregnant women, newborns, male prisoners, enlisted military personnel, cancer patients, psychiatric patients, and even patients suffering from rheumatoid arthritis (Cantwell, 2001). McCally et al. (1994) list other groups of Americans exposed to radiation in the government-sponsored experiments as well, such as the Marshall Islanders, uranium miners, nuclear weapons production workers as well as those people living downwind from the government-sponsored radiation programs.

Beneficence. The principle of beneficence signifies that what is best for the participants should always take priority over what is best for the research. The efforts behind this principle are for researchers to "minimize all risks to participants as well as maximize benefits to the participants and the studied population" (Salganik, 2014, par.4). An example of where the beneficence of the participants was not valued is the infamous

Stanford Prison Experiment. Dr. Philip Zimbardo in 1971 was the lead investigator on a

psychological research experiment. It is of note that Dr. Zimbardo received approval

from the IRB at Stanford University (Tolich, 2014). The goal of the experiment was to

see how people might conform to the roles of guard and prisoners. The research was a

human-subject based behavioral study in which a role-playing exercise simulated prison

life (McLeod, 2017.). The study included a group of 21 male participants who were

randomly assigned the role of a prisoner or correctional officer (Banyard & Flanagan,

2005). The study was to take place over the course of two weeks; unfortunately, the all

too real experiment had to be stopped on the sixth day. What happened in those six days

did irreversible psychological damage to the participants. Banyard and Flanagan (2005)

stated that the participants playing the role of prisoner became "meek and withdrawn

even depressed while the participants playing the role of correctional officers became

increasingly violent and appeared to forget their real identity" (p. 134). One issue raised

from this study was beneficence. Zimbardo argued that the findings from this study

would be beneficial to learn more about prison violence. Inopportunely, the study carried

little weight in its generalization of the conclusions and made no big significant impacts

on the prison system (Banyard & Flanagan, 2005). Zimbardo's biggest mistake was that

he could not comprehend that the risks of this experiment greatly outweighed the benefits

causing psychological damage to the participants.

Justice. Third, the principle of justice is addressed. Research involving human

subjects should never be conducted on one group of individuals while another group

reaps benefits from the findings. One specific ethical situation that is recognized as one

of the most unjust research studies conducted in U.S. history is the Tuskegee Syphilis

Study. The study consisted of three phases and took place at Tuskegee University in Alabama. The first step carried out in the years of 1932-33 were intended to collect medical data on a group of men living with syphilis, untreated, for a minimum of five years (Gray, 2013). The U.S.'s Center for Disease Control stated, "out of the 600 men enrolled in the study, 399 were living with syphilis and 201 did not have the disease" (Center for Disease Control and Prevention, 2016, par.3). From the male participants'perspectives, the goal of the study was to obtain free health care, of which the first step was to take a blood test (Gray, 2013). The study took a turn at the start of the second phase, in 1933, when the U.S. Public Health Service (PHS) officials involved in the study pushed to extend the study indefinitely to see the longitudinal effects of what happens when syphilis goes untreated (Gray, 2013). What is even more condemning and unjust is that penicillin, the cure for syphilis, was discovered only a few years earlier by Scottish scientist and Nobel laureate Alexander Fleming in 1928. During the first two phases at no time were the men who had contracted the disease ever educated on their illness. It has been recorded that while some of the doctors involved said nothing to their patients; other doctors told the infected men that they had "bad blood" (Gray, 2013). The third and final phase of the study began in the mid-1960s and had, by that time, evolved into a tradition within the PHS (Gray, 2013). These men were left untreated and what happened next was a pivotal point in American history. The African-American Civil Rights Movement (1954-68) was in full swing and coming to a head. Gray (2013) indicated that while those directly involved in the study were still not directly confronting the moral issues involved in the Tuskegee Syphilis Study, there was a growing sense that "the original purpose of the experiment could no longer be defended as providing

meaningful insights toward the future prevention and treatment of syphilis" (p. 49). It should be noted that syphilis is in no way confined to the African-American male population, so the generalizations of the findings were never externally valid. Also, the Tuskegee Syphilis study is just one of many research studies conducted on African Americans for the benefit of White Americans (Washington).

Lastly, a historical case in which not all three of the Belmont Report's principles (respect, beneficence, and justice) were upheld is Humphreys' Tearoom Trade Study. This study involved male encounters in public restrooms, where nearly a 100 men were observed engaging in sexual acts as Humphrey, the researcher, pretended to be a "watch queen" (i.e., a voyeur and lookout) (Neuman, 1997). Humphreys posed as a market researcher and obtained, via police registers, the participants' license numbers, their names, and addresses. In disguise, over a year later, Humphreys used a false story about a health survey to interview the subjects at their personal residences. The subjects never consented, deception was used, and Humphrey knew the individuals' names, which could be used to blackmail them, to end their heterosexual marriages, or to initiate criminal prosecutions (Neuman, 1997). Haggerty (2004) characterized these studies as the "Inescapable referents in any discussion of research ethics in the social sciences. Each of these tragic events raises important questions about informed consent, deception, and manipulation of subjects, all of which are issues that ethics committees continue to grapple with today" (Mills, 2003, p. 399).

Office for Human Research Protections

Relatively new, the OHRP was created in June of 2000 within the HHS (OHRP Regulations, n.d.). The OHRP provides ethical oversight of medical and behavioral research conducted or supported by the HHS (U.S. Department of Health and Human Services, 2007). The OHRP "oversees the function and performance of individual IRBs and the process of informed consent" (Drazen, 2003, p. 1378). Drazen explained that it is "the responsibility of the OHRP to investigate when there is a reason to believe that the procedures, on the protection of human subjects, have not been appropriately followed" (2003, p. 1378). The OHRP's main operations are to make sure that IRBs are complying with a set of regulations, known as Title 45 CFR Part 46, that are in agreement with the U.S. FDA rules and guidelines (Office of Human Research Protection Regulations, n.d.).

Title 45 Code of Federal Regulations Part 46. This part of the CFR was specifically written to educate the IRB on how the protection of human subjects should be regulated. The basic ethical principles of conducting human research are collectively known as the 'Common Rule' (Federal Policy, n.d.). The Common Rule regulations are in place to govern IRBs and came into effect in 1981 following the 1975 revision of the Declaration of Helsinki (Office of Human Research and Protection, n.d.). In 1991 these regulations became part of the HHS's Title 45 CFR part 46 (Federal Policy, n.d.), which consists of five subparts each used to determine how all human research should be conducted and regulated by IRBs and to make sure researchers are in compliance with (a) basic HHS policy for protection of human research subjects; (b) additional protections for pregnant women, human fetuses and neonates involved in research; (c) additional protection pertaining to biomedical and behavioral research involving prisoners and

subjects; (d) additional protections for children involved as subjects in research; and (e) registration of Institutional Review Boards (Office of Human Research and Protection Regulations, n.d.). The Common Rule is covered, as previously discussed, under FDA's Title 21 CFR parts 50 and 56. The Common Rule, also referred to as Federal Policy, is also included in 18 other agencies. Each of these agencies "includes in its chapter of the Code of Federal Regulations (CFR) section numbers and language that are identical to those of the HHS codification at 45 CFR part 46, subpart A"(Office of Human Research and Protection Regulations, n.d.)

American Psychological Association (APA)

The American Psychological Association (APA) first published its Ethical Principles of Psychologist and Code of Conduct, also commonly referred to as the Ethics Code, in 1953, shortly after the end of World War II (American Psychological Association, 2002). The Ethics Code has been revised nine times since the first draft in 1953 with the most recent one published in 2002 and amended in 2010 (American Psychological Association, 2010). The Ethics Code consists of five basic principles on how to conduct research:

1. Beneficence and Nonmaleficence

2. Fidelity and Responsibility

3. Integrity

4. Justice

5. Respect for people's rights and dignity

These five general principles of the APA's Ethics Code are explained in full detail in this study's Methodology Chapter (Please see Chapter III Methodological Ethics

section). The Ethical Standards section of the APA's Ethics Code is made up of ten

ethical standards that pertain to any practicing psychologists or psychologist in academia.

The endless variety of situations that can arise when studying human behavior has shaped

and sculpted the APA's Ethics Code on ethical standards, guidance on resolving ethical

issues, competence, human relations, privacy/confidentiality, advertising/public

statements, record keeping/fees, education/training, research/publication, assessment and

therapy (APA, 2010). What are of interest to this study are the APA's Ethics Code rules

on when informed consent can be waived. The APA permits the absence of obtaining

informed consent in two instances. Smith (2003) stated that these two cases are when

authorized by law, federal or institutional regulations to do so, and when the research

would not reasonably be expected to distress or harm participants and involves one of the

following:

1. The study of normal educational practices, curricula or classroom
   management methods conducted in educational settings.

2. Anonymous questionnaires, naturalistic observations or archival research for
   which disclosure of responses would not place participants at risk of criminal
   or civil liability or damage their financial standing, employability or
   reputation, and for which confidentiality is protected.

3. The study of factors related to job or organization effectiveness conducted in
   organizational settings for which there is no risk to participants' employability
   and confidentiality is protected (p. 56).

Eissenberg et al. (2006) explained, "The risks and potential benefits exist for

virtually any research with human participants, including psychological research" (par.

4). Thus, members of the APA and similar professional societies are expected to conduct

human participant research in "strict adherence to applicable federal laws and regulations, which includes prior review and approval by an IRB" (American Psychological Association, 2002, p. 1064).

Institutional Review Board (IRB)

In 1974, the HEW appointed a National Commission for the Protection of Human Subjects of Biomedical and Behavioral based research. In the HEW's final recommendations, adopted by the (at the time) newly established HHS, they recommended that every institution receiving any federal funds review all research projects prospectively to ensure ethical treatment of human subjects (Legal Information Institute, n.d.). The HEW also recommended that "each proposed project had to document the content of this review, as opposed to the earlier general institutional assurances of the process" (McCally et al., 1994). The HHS's Title 21 CFR part 56 refers directly to the provisions guiding the IRB application process.

Title 21 Code of Federal Regulations Part 56. The HHS's Title 21 CFR part 56- the IRB application is made up of five subparts. Subpart A- General Provisions establishes the scope, definition, circumstances in which IRB application is required, exemptions, and waiver of IRB application requirements (Legal Information Institute, n.d.). Subpart B- Organizational and Personnel explained the who, what and when questions. For example, who must register, what information must be in the IRB application, where an IRB application can be registered, and how the reviews for the IRB application are conducted (United States Department of Health and Human Services, 2017). Subparts A and B are used by any student, faculty or staff member of an educational institution to help guide their research study that involves human subjects.

The other subparts serve as guidelines for the acting institute's committee members to abide by or enforce. Subpart C refers to the functions and operations such as how each application will be reviewed, the categories of risk each application possesses, the core criteria for getting an IRB application approved, suspension or termination conditions of an IRB application, as well as guidelines for cooperative research (Code of Federal Regulations, n.d.). Cooperative research is any research involving multiple institutions. Subpart D and E of Part 56 are comprised of how the review boards should handle records and reports as well as administrative actions for noncompliance. The IRB application covers an assortment of ethical issues found in human research, including participant safety/freedom from coercion, potential benefits, and any possible risks of harm from being in the research (Eissenberg et al., 2006.). Despite the well-intended role of reviewing and regulating each research conducted to protect participants, IRBs and their way of handling research applications have increasingly become subject to critique and controversy (Makhoul et al., 2014). One area of critique that is the basis of the current study is how IRBs should regulate the informed consent process in a cross-cultural setting (Adams et al., 2007; Angell, 1988; Benatar, 2004; Grady, 2015; Killawi et al., 2014; Liamputtong, 2008; Makhoul et al., 2014; Vreeman et al., 2012).

Changes to the Common Rule. It should be noted that at the time of this study the IRB made changes to the Common Rule that were scheduled to take effect at the beginning of 2018 (with the exception that all cooperative research projects had an additional two years to comply). Six key changes were made to the Common Rule.

Although all of the updates were not directly related to this study, I find it relative and important to go through each of these updates and discuss their impact on the consent process.

The Common Rule will now require that information essential to the prospective participant's involvement in the research must be explained in the consent discussion and established at the beginning of the consent form. Therefore, this requirement, which was already common in most researchers' practices, is one more step in making sure that the participant understands what they are consenting to before they sign.

Additional requirements for obtaining broad consent for research with biospecimens or individually identifiable data include additional new elements intended to cover secondary research. Broad consent may be obtained in lieu of informed consent obtained only for storage, maintenance, and secondary research uses of private information and identifiable biospecimens. If using biospecimens for commercial profit, the consent must inform the participant of any potential use and must disclose information on whether the participant will share or not share in any commercial profit. Information must be disclosed if the research will or might include whole genome sequencing. The consent must explain the types of research that may be conducted with identifiable private information or identifiable biospecimens.

There were also updates to the exempt categories listed in the Common Rule; these categories have expanded from six to eight categories. The two new exempt categories include amended regulations for secondary research: The amended regulations create a new exemption for secondary research involving identifiable private information, which is regulated under HIPAA, or collected biospecimens. Research may be classified

as exempt if (a) the identifiable information is already available to the public, (b) the information is not re-identified, and the researcher does not attempt to re-identify it, (c) the secondary research is already regulated under HIPAA, or (d) the secondary research is conducted by, or on behalf of, a federal entity and involves the use of federally generated non-research information as long as the information remains covered under existing federal privacy rules (Wanerman et al., 2017). Under some of the new categories, exempt research would be required to undergo limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens (Federal Policy for the Protection of Human Subjects 2017). The amended regulations create a new exemption for secondary research and for the storage and maintenance of identifiable private information or identifiable biospecimens if the subject or donor has given a broad consent. Any secondary research may be exempt if the broad consent was properly obtained and documented, and if an IRB determines that the secondary research is within the scope of the broad consent. (Wanerman et al., 2017).

Next is the authorization for a single institutional review board (sIRB) for cooperative research. All U.S. institutions engaged in multi-site cooperative research must use a single IRB (sIRB) to cover the portion of research that is conducted in the United States, except for (a) cooperative research for which more than sIRB review is required by law, or (b) any such research that the federal department or agency supporting or conducting the research determines that the use of a single IRB is not appropriate.

The criteria for IRB approval of research included amendments to the regulations on the category of vulnerable subjects. It has been amended to include children, prisoners, and individuals with impaired decision-making capacity and persons who are economically or educationally disadvantaged (Federal Policy for the Protection of Human Subjects, 2017). For IRB approval of research in which broad consent was proposed the amended regulations revise the following criteria (a) The IRB must review the appropriateness of the process proposed for obtaining broad consent, (b) ensure that the required elements of broad consent were appropriately included in the broad consent form (or process if broad consent is to be obtained orally), and (c) determine that consent is appropriately documented or that a waiver of documentation is appropriate. If a change is made for research purposes in the way that identifiable private information or identifiable biospecimens are stored or maintained, the IRB must determine that adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data.

The Common Rule eliminates the requirement to conduct continuing review of ongoing research for minimal risk studies that qualify for expedited review; and for studies in which (a) data analysis, including analysis of identifiable private information or biospecimens, or (b) accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.

Methodological Review of Cross-Cultural Research:
When Social Norms Differ

One of the most challenging problems in conducting cross-cultural research is, as Kornyo (2015) stated, "an internal conflict of ethical norms that poses a conundrum for the researcher" (par. 1). According to Benatar (2004), ethical dilemmas related to cross-

cultural human research occur at two levels. "On one level there are those who are concerned with and primarily interested in doing research to advance knowledge, and on another level there are those who, although supporting the need for research, are more sensitive to the potential exploitation of vulnerable participants, especially in developing countries" (Benatar, 2004, p. 576).

The Western emphasis placed on autonomy when it comes to informed consent for research participation is not universally shared (Marshall, 2008). Some scholars, such as Angell (1988), believe that the researcher should not enforce their social norms on a native group they are researching as this may create a kind of "ethical imperialism". Ethical imperialism is the ideology that there is one universal moral standard, regardless of location or culture (Schermerhorn, Hunt, & Osborn, 2000). Moreover, the researcher may also encounter certain norms that may conflict with some of the established regulations (i.e., Declaration of Helsinki, Nuremberg Code, and FDA). Grady (2015) explained how "cultural differences manifest in both the practice of informed consent- that is, what is told to whom and who makes decisions- as well as in an understanding of the normative underpinnings of informed consent as respect for individual autonomy" (p. 855). Empirical evidence suggested that an individual's culture may influence their moral values and other key values (e.g., loyalty, compassion, solidarity) and that these values may be seen as more important than autonomy (Turner, 2005). Researchers wishing to conduct cross-cultural research involving human subjects should show respect to individuals by being receptive to the individual's culture as well as respectful of their cultural values. Yet, as Grady (2015) suggested, "respecting cultural values does not negate the need to respect the persons for whom the research is being considered, or the

need to respect the persons for whom the research is being conducted on, nor does it negate the need to implement respectful and appropriate procedures" (p. 856). In other words, it is the researcher's duty to make sure that the participants' cultural values are being upheld. Yet in the end, the researcher is still bound to their own institution's ethical regulations, and thus, the required approach to informed consent becomes based on those ethical guidelines and regulations.

Cultural Competency

Culture itself can be defined as a set of learned traditions, principles, and guides of behavior that are shared among members of a particular group (Turner, 2005). Ethnic groups, businesses, institutes, neighborhoods, and even classrooms have their own cultures. Culture is dynamic, constantly changing and reshaping, there is diversity within cultures, and each person is a member of many cultures. Cultures are like "underground rivers that run through our lives and relationships, giving us messages that shape our perceptions, attributions, judgments, and ideas of self and other" (LeBaron, 2003, par. 1). Cultural competence can be defined as "a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals and enables that system, agency, or those professionals to work effectively in cross-cultural situations" (Cross, Bazron, Dennis, & Isaacs, 1989, p. 13). Operationally defined, "competence is the integration and transformation of knowledge about individuals and groups of people into specific standards, policies, practices, and attitudes used in appropriate cultural settings to increase the quality of services, thereby producing better outcomes" (Davis, 1997). Five essential elements to cultural competency are: (a) valuing diversity, (b) capacity for cultural self-assessment, (c) consciousness of the "dynamics" inherent when cultures

interact, (d) institutionalization of cultural knowledge, and (e) developing adaptations to service delivery which reflects in the understanding between and within cultures (Stith-Williams, 2009). Cultural competency in education is the implementation of guidelines, regulations, and standards that are upheld on the institution or agency level. As a teaching practice, it involves the ability to acquire knowledge of education-related beliefs, attitudes, and practices to improve student achievement. As a research method, this approach would require the researcher to "know different groups in ways that acknowledge and honor all people and the groups they represent" (Cross et al., 1989).

Cultural Responsiveness

When the researcher is aware of and responsive toward the participant's traditions, rituals, ways of life, and customs as well as their own then they are considered as culturally responsive. Lahman, Geist, Rodriguez, Graglia, and DeRoche (2010) point out that when we are culturally responsive "we must first be aware of the cultures in which we are personally embedded and then attempt to understand others' cultures" (p. 1401). Cultural responsive teaching practices involve using the cultural characteristics, experiences, and perspectives of ethnically diverse students as conduits for teaching them more effectively (Gay, 2002, p. 106). Although cultural responsiveness is not just limited to ethnical diversity, it is the focus of the current study. Cultural responsive education is a framework that recognizes the importance of including students' cultural references in all aspects of learning (Ladson-Billings, 1994). The main goal of culturally responsive teaching is to enhance ethnically diverse students' academic experiences, through their own cultural and experiential filters, essentially improving their academic performance (Foster, 1995). Culturally responsive practices provide services that acknowledge that

culture is central to learning, and encourages students and others to learn by building on the experiences, knowledge, and skills they bring to the classroom, group, office or meeting (Stith-Williams, 2009). Explicit knowledge about cultural diversity is imperative to meeting the educational needs of ethnically diverse students (Gay, 2002).

Likewise, researchers need to learn the fundamental knowledge in a given culture before conducting a research study with participants. This responsiveness is crucial to meeting the needs of the ethnically diverse participants the researcher wants to study. Lahman et al., (2010) helped to summarize the culturally responsive values, which any researcher involved in cross-cultural research should follow. These values summarized by Lahman et al., (2010) are: "(a) explicit recognition, valuing, and discussion of cultural differences, (b) validating the world-views of participants, (c) explicitly discussing power differentials and (d) acknowledging non-traditional research methods may work better with participants of differing cultural values" (p. 1402). Along with these four core values gaining detailed factual information on the cultural norms of a specific ethnic group that is of interest is critical before the start of any cross-cultural research endeavor. Cultural responsiveness in the classroom is a similar concept and relates well to the dynamics posed between that of a researcher and their participants in a cross-cultural study. Much like the knowledge that teachers need to have on cultural diversity amongst their students, the knowledge a researcher must possess needs to go well beyond the "mere awareness of, respect for, and general recognition of the fact the ethnic groups have different values or express similar values in various ways" (Gay, 2002, p. 107). Furthermore, to be culturally responsive researchers must be receptive yet firm and persistent. Cultural responsiveness requires an affirming attitude toward cultural

differences (Villegas & Lucas, 2002). Therefore, IRB should also demonstrate cultural

competence for a clearer and efficient guidance on how cross-cultural research involving

human subjects should be conducted. Cultural responsiveness, on the other hand, is the

responsibility of the individual researchers conducting cross-cultural research studies. It

is the researcher's duty to become aware of the participants' traditions, rituals, ways of

life, and customs.

How Cross-Cultural Research is Currently Being
Regulated in Institutional Review Board
Supported Research

As previously discussed, the HHS's OHRP oversees the individual IRBs and the

process of informed consent (Drazen, 2003, p. 1378). The OHRP states that all IRBs

must attain proper knowledge of the local research context for work being conducted

internationally. These regulations provided under the OHRP guidance letters in Title 45

CFR Part 46:

1. IRBs must be capable of ensuring that (if applicable) (i) the selection of subjects is equitable; (ii) the privacy of topics is protected, and confidentiality of data is maintained; (iii) informed consent is appropriate; and (iv) adequate safeguards to protect the rights and welfare of vulnerable subjects have been put into place [45 CFR 46.111(a)(3),(a)(4),(a)(7),(b), and 46.116].

2. An IRB designated under an approved Federal Wide Assurance has a responsibility to ensure that its members possess sufficient knowledge of the local research context to satisfy these requirements. This responsibility stands regardless of the IRB's geographic location relative to the institution and the research. It is particularly critical where the research involves greater than minimal risk to subjects or vulnerable categories of subjects (University of North Georgia, 2017).

Researchers wanting to conduct cross-cultural research must show their local IRB

that these guidelines are being upheld. To show this documentation of the researcher's

knowledge and awareness, the local customs must be provided to the researcher's review

board members before the start of the study. This information is usually completed through a basic description of the research context and supported with relevant and current peer-reviewed research articles that give insight into the social, cultural and political context of the culture the researcher wants to study.

Second, the researcher must also demonstrate the cultural appropriateness of the research design and its research protocols. Specifically, the researcher needs to describe how "consent procedures, the recruitment process, negotiation of site access and protocols are culturally sensitive and appropriate" (University of North Georgia, 2017, p. 2).

However, when it comes to how consent can be gained from individuals who come from collectivistic societies, the Institutional Review Board guidelines are directed back to the documentation of informed consent in 45 CFR 46.117, which states that informed consent shall be documented by the use of a written consent form except when:

1. The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (Office of Human Research and Protection Regulations, n.d., par.1-3).

Currently, no exceptions exist within the U.S. IRB guidelines that acknowledge the collectivistic societies approach to gaining consent. U.S. IRB guidelines also do not recognize that even though they may obtain individual consent from participants they still have not gained 'true' informed consent. True informed consent of the participant

requires more than a signature, and it requires more than just voluntary consent of the participant as stated in the IRB guidelines (45 CFR 46, n.d.). Factors that can prevent true informed consent from being obtained are factors such as potential participants may be pressured to participate in the research from overseeing authorities, they may lack comprehension and understanding of the consent, or a language and/or literacy barrier may exist (Killawi et al., 2014). These factors will be discussed in further detail below. True informed consent can only be obtained when the researcher can ensure that the participant understands as well as comprehends: (a) the context of the research; (b) that the participant has not been pressured by anyone else to participate; (c) the appropriate protocol for obtaining their consent has been approved by both culture's overseeing research review boards; and lastly, (d) that the participant has given ongoing consent throughout the research process. Only then can the researcher ensure that true informed consent has been obtained.

Empirical Evidence of How Competing Values are Being Attended to and Negotiated

The World Medical Association (WMA) as well as the Council of International Organization of Medical Science both revised their ethical regulations, respectively, in 2000 and 2002, for medical research to include ethical guidelines and standards pertaining to how medical research involving human subjects in a cross-cultural study should be treated (Bhutta, 2004). These cross-cultural guidelines have played a prominent role in regulating human research involving antiretroviral drugs in Africa (Molyneux, Wassenaar, Peshu, & Marsh, 2005). Consideration of procedures that emphasize true understanding of consent procedures can be imperative when conducting cross-cultural research (Marshall, 2008). A medical research study conducted by Molyneux et al.

(2005) in rural Kenyan communities discussed the difficulties they encountered while trying to gain informed consent. They found that the problems they encountered when trying to obtain informed consent in low-income communities differed from the issues encountered in high-income settings (Molyneux et al., 2005). In rural Kenyan communities, the chiefs and elders were the ones who provided the researchers with access to certain areas of the community where their research could be carried out, but these leaders did not have authority to decide which households or individuals could participate. The primary consenting authority of the households were the fathers: however, in homes where the father was absent, the mother was the household decision-maker, or that authority went to the other males or elders in the extended families (Molyneux et al., 2005). Leong and Lyons (2010) noted that authority hierarchies, the importance of decision making in a community, and a wide range of literacy levels are all considered culturally sensitive factors that researchers need to consider when attempting to obtain true informed consent abroad.

A biomedical study conducted by Adams et al. (2007), in the Tibet Autonomous Region (TAR) of the People's Republic of China, involved examining cultural competence when it comes to the informed consent process for clinical biomedical research on rural Tibetan villagers. The research results were the product of a two-year effort of establishing a culturally appropriate informed consent process. The informed consent was specifically needed for researchers to conduct "a triple-blind, double placebo-controlled randomized clinical trial of a Tibetan medicine compared with Misoprostol for reducing postpartum blood loss" (Adams et al., 2007, p. 445). The authors' conclusion through this research found that to develop an appropriate informed

consent procedure that acknowledged and adhered to the Tibetan context required

flexibility in negotiations between the nations, home institutions, and local research

teams in cross-cultural human research (Adams et al., 2007). Through this research, the

authors became aware that cross-cultural informed consent issues stemmed not only from

cross-cultural differences between the two cultures but also in how the different nations

constructed their human research protection institutes. Other nations may perceive the

United States's IRB insistence on written consent as unreasonable. Adams et al. (2007)

suggested that "insistence on doing things only one way can appear to some collaborating

individuals or institutions as acts of intellectual and ethical imperialism" (p. 464).

A study on human research subject protection conducted by the U.S. Embassy in

Beijing (2000) found that the political climate and literacy levels in some parts of China

were problematic for U.S. researchers attempting to achieve true informed consent. The

study reported that "money paid by a foreign researcher to a county official to do

research may result in those county officials using the money to buy a car and order

health workers in the villages to do work without compensation" (United States Embassy

Beijing, 2000). It was also reported that the local officials, in these areas, have power

over the village farmers who are often unwilling to say "no" to their requests (United

States Embassy Beijing, 2000). Scenarios of this sort may create ethical problems for

researchers trying to obtain consent from villagers due to the consent not being truly

autonomous. Another ethical problem that the U.S. Embassy Beijing (2000) encountered

was that many of the potential participants were unwilling to sign the informed consent

form due to fear of the political power struggles in China. Countries in which reversals political power or political uprisings are frequent, make obtaining true informed consent difficult.

In a survey conducted by Hyder and Wali (2006) which explored the opinions of researchers from developing countries, 84% of the researchers agreed that a measuring tool should be used to measure participants' understanding of the research context and agreed that cross-cultural human research should allow for more flexibility in how informed consent is obtained. Flexibility in the informed consent process should stem from thorough examinations of both cultures' values on consent.

An example of when cross-cultural values were not negotiated is the experience that a physician from Yale University had when trying to carry out an HIV study in Tanzania, in which the ethical expectations of the researchers' and participants' cultures clashed (Christakis & Panner, 1991). The study involved drawing blood samples from both the mothers and their infants upon the infant's birth. The researcher's IRB required that the participants be informed of their test results. However, this conflicted with the local Tanzanian authorities who were worried that the results could cause psychological trauma to the women. The local authorities were also cognizant of the fact that no meaningful therapy was available for HIV-positive individuals in Tanzania and insisted that the Western researchers not tell the participants that blood was being taken or what the outcomes of the tests were. This study, which was invaluable to the host nation and the researcher, was abandoned because these two cultures were not able to compromise.

There are also incidents in which the data obtained from one research study have been used in other research in which the original participants did not consent. One such

example of this is the Diabetes Project that researchers from Arizona State University

(ASU), conducted in 1989 in collaboration with the Havasupai Tribe in a remote part of

the Grand Canyon. The research included health education, collecting and testing blood

samples, and genetic association testing to search for links between genes and diabetes

risk. Several years of testing resulted in minimal findings linking the Havasupai tribal

people and Type II Diabetes. Where this study ran into ethical issues was when ASU

researchers used blood samples in unrelated DNA-based studies including studies on

schizophrenia, migration, and inbreeding, all of which are found to be taboo topics

among the Havasupai people (Rubin, 2004). It was a member of the Havasupai tribe who

after attending an ASU lecture learned that tribal members' blood samples were being

used without their consent (Rubin, 2004). In the lawsuit that followed the Havasupai

people (Havasupai Tribe of the Havasupai Reservation v. Arizona Board of Regents and

Therese Ann Markow 2004) expressed their concerns on the lack of informed consent,

violation of civil rights through mishandling of blood samples, unapproved use of data,

and violation of medical confidentiality (National Congress of America Indians, n.d.).

The samples were to be used for research on behavioral and medical disorders, but no

Havasupai members were told this would include studies on schizophrenia (Hart &

Sobraskne, 2003). All tribal members who participated were lead to believe, via language

included in their informed consents, that the samples were used for genetic research on

diabetes. Many genetic-based studies that had used these blood samples were published

in the years that followed. These scientific publications included Nature magazine

(Dalton, 2004), the New England Journal of Medicine (Mello & Wolf, 2010), in the

Phoenix Magazine (Bommersbach, 2008), even on the front page of the New York Times

(Harmon, 2010). The naming of the Havasupai tribe in these studies put each participant's personal identification at risk. Around the time that the original study was conducted, the Havasupai census consisted of 650 tribal members, of whom 400 had participated in the study. "For potentially stigmatizing research such as on inbreeding or schizophrenia, identification of individuals becomes a concern" (National Congress of America Indians, n.d.). The lawsuit ended in an out-of-court settlement in which the Havasupai Tribe received $700,000. Sadly, no legal precedent on how informed consent issues in research should be handled ever materialized because the case was settled outside of court. The case raised issues of just and respectful research practices involving indigenous people (Garrison, 2013). Specifically, this case shed light on the effects of research harms on the community, challenged the appropriateness of particular types of research, and questioned the adequacy of informed consent (Santos, 2008).

The Importance of Gaining Consent

Guidelines such as the Nuremberg Code, Helsinki Declaration, and The Belmont Report are standards, rules, and regulations put in place to help prevent future wrongdoings to human subjects in the name of science. "Science should never transform or consider people as instruments to be employed for scientific purposes" (Bhattacharya, Dhiman, & Chaturvedi, 2016, p. 182). One of the most important principles at the center of each of these guidelines is the importance of gaining consent from a participant. It is through these universal and federal research guidelines and standards, mentioned above, that make gaining consent from a participant essential to the credibility of the study. The establishments of these standards and guidelines help to maintain some order of conduct amongst researchers in various research communities such as medical, behavioral, and

anthropological human-based research. There is still a long way to go in developing ways of assuring that every participant's rights are being protected in human research. Much progress, to date, has been made in the areas of obtaining informed consent as well as other types of consent that can be achieved when informed consent does not apply or presents a risk to the participant(s).

Individual Versus Community Decision-Making Processes

In cultural environments "characterized by a communitarian perspective, beliefs about autonomy are embedded within sociocentric patterns of family ties and community obligations" (Marshall, 2008, p. 209). In these cultures, it is best if researchers consult with community leaders or tribal elders before initiating the study (Dickert & Sugarman, 2005). These types of 'collectivistic' cultures, which emphasize the needs of a group over the needs of an individual, operate through relationships (Ruiz-Casares, 2014a). Other community members act as consultants or permission granters (Osamor & Kass, 2012). An example of this can be shown through the Japanese culture of health care. In cancer cases, Japanese doctors will "not inform the patient of the diagnosis but instead share this information with the patient's family members" (Alvarado, Ferron & Krayem, 2015, p.10). This cultivates the idea that the patient takes a passive role in their health care, which is in high contrast to Western ideology on patient's health care (Saldov, Kakai, McLaughlin, & Thomas, 1998).

In Western Kenya, community assemblies known as mabaraza were consulted in a long-term study of children separated from their parents or orphaned, and they recommended community decision-making in the consent process for biomedical and behavioral research (Vreeman et al., 2012). This study also raised concerns about the

importance of making sure all those involved in a study know the benefits and purpose of the study. Many of the community members assumed any biomedical research would involve HIV testing or HIV-related outcomes, due to this region's high HIV risks and involvement in past HIV-related biomedical research (Vreeman et al., 2012).

Additionally, in many cultures, it is common for the wife to seek permission from their husband before participating in a research study (Molyneux et al., 2005). Molyneux et al. (2005) discovered firsthand, from a study they conducted in a coastal town in Kenya, that the male head of a household is the one who provides consent for their family members to participate in a study. As Ngare (2007) explained, "although a woman may want to take part in a given study, without her husband's approval she cannot, and if she chose to participate without his approval, her behavior might be viewed as defiant and result in family conflict" (p. 32). This issue was seen by a researcher conducting a malaria drug trial in rural Kenya. It seemed that some of the women were eager to participate but did not want to sign the consent form. These women did not understand why they needed to sign the consent form after verbally agreeing to be a participant. Marshall (2008) points out that from the women's perspectives, "this request may have been viewed as insincerity on the part of the researcher and possibly as evidence of a hidden agenda that was not being revealed" (p. 211). From the women's point-of-view, consenting to be in the study meant offering their valuable time out of their regular daily routines to be there with the researchers and that should have been enough indication that they were willingly consenting to participate. Therefore, the researchers' implication of a signature to show consent would insinuate that their own word and physical presence was

not sincere enough. This crack in the foundation of trust being formed between the participants and the researcher may lead the participants to find the researcher insincere and deceiving.

Different Types of Consent

Informed/Express/Explicit

Informed consent, also sometimes referred to as valid consent, involves "giving sufficient information about the research and ensuring that there is no implicit coercion so that prospective participants can make an informed and free decision about their involvement" (Bhattacharya et al., 2016, p. 183). Hallinan, Forrest, Uhlenbrauck, Young, and McKinney (2016) suggested that the process should be "understandable, that participant satisfaction with the consent process matters and that a proper consent process will improve retention and adherence within a study" (p. 1). Unfortunately, the informed consent process often falls short of upholding these standards (U.S. Dept. of HHS, 2011, p. 4451). Making it a long process that uses a lengthy consent form with complex language can affect the outcome of any study. In September of 2015, a revision to the Common Rule suggesting a shorter informed consent form was proposed (U.S. Dept. of HHS, 2015). The Clinical Trials Transformation Initiative (CTTI) stated that the Informed Consent Project, "with objectives to identify and understand existing informed consent improvement efforts, identify barriers to communication of informed consent elements, and develop recommendations for improving the informed consent process that will enhance understanding by potential participants about the study for which they are being recruited" (Hallinan et al., 2016, p. 4).

Elements of informed consent. Gaining informed consent is not just something that takes place at the beginning of a study. It is a process needing to be established before participation takes place, and should be maintained throughout the research (Bhattacharya et al., 2016, p. 183). Bhattacharya et al. (2016) discussed some basic elements of informed consent, which can all be categorized under the ethical, legal and practical dimensions of informed consent (p. 182). The ethical perspective of informed consent is based on the principle of autonomy. A participant's autonomy means that they voluntarily, by their free will, decided to participate in a given research experiment. It indicates that the participant was not forced to be in the research. One of the key criterions of autonomy is establishing that the participant is competent and fully comprehends what they are consenting to; if competency cannot be established, then from a legal perspective consent has not been obtained. The next element of informed consent is the authorized element of informed consent and "from a legal perspective, informed consent is defined regarding an agreement, or process by which the rights of individuals to agree or to refuse treatment are upheld" (Bhattacharya et al., 2016, p. 182). Using practical terminology is the last element of informed consent discussed by Bhattacharya et al. (2016). Practical terminology refers to investigators using language that the participant understands to inform them of the reason for their study and any associated risks and/or benefits to the participant for being in the study. A statement describing how the participant's identity will be kept confidential is provided to the participants, as well as any records or artifacts obtained that could be used to identify the participant. Also, an explanation of whom to contact for answers to questions about the

research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject must also be provided to the potential participant (United States Department of Health and Human Services, 2017.).

Written. Obtaining written consent from a participant requires more than just their signature on a consent form. It requires that the potential participant is provided a consent form with language that is comprehensible to them, explaining in detail the reason for the study, any risks, harms, or benefits to the participant for being in the study. The researcher should go over this consent form verbally with each potential participant as well. The researcher should also give the potential participant ample time to ask questions or express any of their concerns; this will help to ensure that the subject understands the information.

Short form. An alternative to the written consent document Title 45 CFR 46.117 permits the use of a short form written consent document (Informed consent, 1995). The short form document can be utilized, for instance, when the potential participant does not speak English. A short form document containing written documentation that the elements of consent have been presented orally to the potential participant is required of a short form, as well as a written summary of what was submitted and discussed orally. The participant must be given a copy of the short form document as well as the summary. This type of informed consent also requires a witness to be present at the time of explanation.

Witness signatures. Witness signatures, also known as witnessed consent, are required when the potential participant does not read English. Title 21 CFR 50.27 also requires witness consent when obtaining informed consent from a potential participant

who is capable of comprehending the language but is physically unable to read, write, talk or is blind (University of California Office of Research, 2014). Granted, this method of gaining consent will only work if the potential participant can indicate in some form (e.g., blinking of eyes, raising eyebrows, etc.) that they consent to participate in a given study. The IRB requirements also suggest that the witness must be an independent party, such as an adult who is not a member of the study team (Food and Drug Administration, n.d.). It should be noted that in most cases a relative could serve as an impartial witness, however, some have argued that relatives may not be impartial and suggest that a person with no familial or financial ties to the patient serve in this role (University of California Office of Research, 2014). The witness must sign the consent form that all the requirements for informed consent have been satisfied and that the participant's consent is voluntary (University of California Office of Research, 2014).

Verbal consent. Federal regulations require that informed consent is signed by the participant or by a legally authorized representative of the participant. However, there are certain exceptions to this rule when using informed consent. For instance, a participant who can understand and comprehend the English language, but who may be physically unable to talk or write may be eligible to participate in a given study without a third party witness. The potential participant must be able to (a) retain the ability to understand the concepts of the study and evaluate the risks and benefits of being in the study when it is explained verbally, and (b) can indicate approval or disapproval to study entry (Food and Drug Administration, n.d.). If the IRB grants a waiver of documentation of informed consent, the investigator should follow the steps below:

- Step One: The Investigator (or an IRB approved designee), must explain the study to the potential subject verbally, providing all pertinent information

(purpose, procedures, risks, benefits, alternatives to participation, etc.), and must allow the potential subject many opportunities to ask questions.

- Step Two: Following this verbal explanation, the potential subject may be provided with a study information sheet (written summary - if required by the IRB) and must be afforded sufficient time to consider whether or not to participate in the research. "Sufficient time" can range from minutes to hours, dependent on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and potential alternatives.

- Step Three: After allowing the potential subject time to read the study information sheet, the Investigator must answer any additional questions the potential subject may have and may obtain verbal agreement to participate in the research. A waiver of documentation of informed consent must be approved by the IRB in order to obtain verbal consent from potential subjects (University of California Office of Research, 2014, par. 5).

Informed consent with vulnerable populations. Minors and special adult populations who are "recruited as research subjects may be compromised in their ability to provide truly informed and voluntary consent requiring special safeguards to ensure that their rights are protected" in the consent process (Bhattacharya et al., 2016, p. 185). Participants that are categorized as vulnerable in the U.S. are children, minors, pregnant women, fetuses and human in vitro fertilization, cognitively impaired persons, and prisoners. The Belmont report also describes groups such as racial minorities, the elderly, the economically disadvantaged and the very sick as vulnerable populations (Bhattacharya et al., 2016, p. 185). Note that those in the military at the general service level do not fit into one of these categories.

Children and minors. Bhattacharya et al., (2016) stated that "researchers must practice respect for the rights of the subject within the proposed consent procedures, which should be developmentally appropriate to the age and circumstances of the child" (p. 185). These authors also explain the following IRB Child Assent form criteria Parental Consent:

1. Parental permission or consent in writing is required for all minors under the age of 18 who participate in research except for emancipated minors.

2. Adolescent's Written Assent: From about junior high or middle school onward, a child's written assent is needed (in addition to parental consent), because children in this age group usually can read and comprehend a well-constructed assent form. However, the investigator should use additional verbal explanations whenever needed.

3. Child's Assent: For elementary school-aged children, the investigator should obtain (in addition to parental consent) the child's assent to participate. The explanation to the child should contain elements of consent expressed in a form the child can understand. A conversational question-and-answer setting is often necessary to achieve this goal. Also, the child's assent should be positive, that is, not merely lacking dissent. If the child is old enough to render a signature, investigators are required to obtain a signed assent form.

4. Very Young Child's Assent: For children below school age (e.g., infants, toddlers, and preschoolers) the investigator should give explanations that match the level of understanding. In many instances, the children's nonresistant behavior may be interpreted as assent, but the investigator must use special care to discontinue the participation of children who appear to experience undue stress from the research procedures (Bhattacharya et al., 2016, p. 185).

Other cases such as when the children are wards of the State or any other agency are outlined in Title 45 CFR 46 and Title 21 CFR 50 (United States Department of Health and Human Services, 2017).

Pregnant women, fetuses, and human in-vitro fertilization. Under subpart B of Title 45 CFR, 46 special circumstances exist for research involving vulnerable populations such as fetuses, pregnant women, and human in-vitro fertilization. Research involving pregnant women, under these regulations, states:

1. No pregnant woman may be involved as a subject unless: (1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

2. Father's Consent. Research may be conducted only if the mother and father are legally competent and have both given their informed consent after having been fully informed regarding possible impact on the fetus, except that the

father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape (Special Populations, 2004, p.2).

Also, studies in which pregnancy is coincidental to subject selection may:

1. Inadvertently include pregnant women. Federal regulations require that, when appropriate, subjects be provided a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable as part of the informed consent process.

2. The IRB must judge whether the mother's participation would pose any risk to the fetus or nursing infant. In some studies, the IRB may need to ensure that non-pregnant subjects are advised to avoid pregnancy or nursing for a time during or following the research. Furthermore, where appropriate, subjects should be advised to notify the investigator immediately should they become pregnant. In some instances, there may be potential risk sufficient to justify requiring that pregnant women either be specifically excluded from the research or studied separately.

Regulations for research activities involving fetuses (In Utero) states:

1. No fetus in utero may be involved as a subject in any research activity covered by this Policy unless the IRB determines either: (1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

2. Research may be conducted only if the mother and father are legally competent and have both given their informed consent, except that the father's consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape (Special Populations, 2004, p. 3).

Cognitively impaired. Cognitively impaired adults are considered to be from a vulnerable population. Adults who are deemed to be cognitively impaired have a diminished capacity such as a severe mental disability that impairs the individual's reasoning or judgment. Mental disabilities alone should not disqualify a person from

consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent (Penslar & Porter, 2001).

Conditions associated with cognitive impairment in adults, such as dementia and delirium, can cause great suffering to affected patients as well as to their families. Cognitive impairment limits the ability of the individual to consent to participate in a research study through normal IRB informed consent procedures. However, research involving impaired adults is greatly needed to help make clinical care for these individuals better and to help understand and ease the suffering that is caused by these various cognitive impairments.

Therefore, the appropriate protocol for gaining consent from a vulnerable population such as this is a protocol that includes special circumstances that clearly demonstrate how the researcher intends to ensure that the interests of the participants are being protected throughout the entire study (Bhattacharya et al., 2016).

Chapter Six of the HHS's IRB Guidebook, on Title 45 CFR part 46.111(b) and Title 21 CFR56.111 (b), states that:

1. Persons formally adjudged incompetent have a court-appointed guardian who must be consulted and consent on their behalf. Officials of the institution in which incompetent patients reside (even if they are the patient's legal guardians) are not generally considered appropriate since their supervisory duties may give rise to conflicting interests and loyalties.

2. Family members or others financially responsible for the patient may also be subject to conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances. IRBs should bear this in mind when determining appropriate consent procedures for cognitively impaired subjects.

3. Some individuals may be incompetent and have no legal guardian. One such example would be mentally disabled adults whose parents "voluntarily"

institutionalized them as children and have never subsequently gone through formal proceedings to determine incompetence and have a guardian appointed. Another example would be geriatric patients with progressive cognitive disorders (e.g., senile dementia of the Alzheimer type). Typically, a spouse or adult child of such patients' consents to their medical care, but no

one is a "legally authorized representative." The extent to which family members may legally consent to the involvement of such patients in research (especially if no benefit to the subjects is anticipated) is not clear.

4. Because no generally accepted criteria for determining competence to consent to research (for persons whose mental status is uncertain or fluctuating) exist, the role of the IRB in assessing the criteria proposed by the investigator is of major importance. The selection of an appropriate representative to consent on behalf of those unable to consent for themselves must be accomplished without clear guidance from statutes, case law, or regulations. Within the boundaries of existing legal precedents, IRBs can be creative in helping investigators formulate appropriate procedures in these uncertain areas. IRBs should be sure, however, to seek legal advice to determine the applicability of state laws that might affect the participation of legally incompetent persons in research.

5. The National Commission recommended that guardianships established for purposes of authorizing participation in research be limited to the provision and continuance (or withdrawal) of permission regarding the subject's participation in the research. The National Commission also urged that, despite the fact that consent may be obtained from a legally authorized representative or guardian, the feelings and expressed wishes of an incompetent person should still be respected. IRBs should consider whether to require investigators to solicit prospective subjects' "assent" (i.e., the willing and, to the extent possible, knowledgeable participation of those unable to give legally valid consent). IRBs should also determine whether an incompetent person's refusal to participate in research should override consent given by a legal guardian. The National Commission recommended that such decisions be based on the amount of risk involved in the research and the likelihood that the subjects will derive health benefits from their participation.

6. The National Commission also recommended that in the case of research involving more than minimal risk, the objection of an adult subject who is incapable of consenting should be binding, unless the individual's participation is specifically authorized by a court of law, the intervention is expected to provide a direct health benefit to the subject, and the intervention is available only in the context of the research. Note, however, that where local law allows institutionalized persons the right to refuse therapy, objections to participation may not be overridden. The National Commission recommended that, in certain cases, a consent auditor be appointed by the IRB

to determine whether proposed subjects consent, assent, or object to their participation in research, especially if the research involves more than minimal risk and no foreseeable direct benefit (Penslar & Porter, 2001, par. 19-22).

The National Commission recommended that, in certain cases, a consent auditor should be appointed by the IRB to determine whether proposed subjects consent, assent, or object to their participation in research, especially if the research involves more than minimal risk and no foreseeable direct benefit (Penslar & Porter, 2001).

Prisoners. Researchers who are trying to obtain consent primarily from prisoners must not portray any "advantages that would unduly influence their ability to weigh the risks involved in the research" (Bhattacharya et al., 2016, p. 185). As outlined in Title 45 CFR 46, researchers should notify prisoners before the start of their participation that no "direct effect upon their parole or treatment" will come from their consent to participate (Office of Human Research and Protection Regulations, n.d.). Prisoner research also requires a knowledgeable advocate for detainees (e.g., a prisoner, social worker, justice professor) review the entire IRB application for potential ethical issues due to the inmate's highly decreased autonomy in general (Office for Human Research Protections, 2016).

Obtaining a certificate of confidentiality. The purpose of a Certificate of Confidentiality (CoC) is to protect the privacy of the participants by restricting the disclosure of identifiable, sensitive information to anyone not connected to the research except when the participant consents or in a few other specific situations (National Institute of Health, 2016). Researchers who are not working on a government-sponsored research via HHS must apply to the NIH or the FDA (whichever one is applicable in the

given situation) to request a CoC. A CoC is issued to researchers conducting studies in

biomedical, behavioral, and clinical or other research in which identifiable, sensitive

information is collected (National Institute of Health, 2016).

NIH considers research in which identifiable, sensitive information is collected or

used, to include:

1. Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46.

2. If the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

3. Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;

4. Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or

5. Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act (National Institute of Health, 2016, par.6-9).

Implicit/Implied Consent

This type of consent differs from informed/express/explicit because it is used

when formal methods (e.g., written or verbal) of gaining consent are not applicable. A

participant who fills out an anonymous questionnaire is an example of gaining implied

consent. By completing the questionnaire and giving it back to the researcher, the participant implies their consent to participate in the research. The implicit consent process is commonly used in research performed via the Internet. Social scientists began using the internet for studies in the late 1990s. The Internet was "simply a new medium for delivering conventional methods, most often surveys, to new populations in a cost-effective manner (Fiske et al., 2010, p. 90). Today, many researchers conduct online research due to the accessibility to a wider number of potential participants. Many of whom would not be so readily available if not for the Internet. However, the Common Rule in research ethics that was encapsulated in the HHS's Title 45 CFR part 46, in 1991, did not have guidelines for conducting ethical research in an online environment. Heilferty (2011) discussed that "care must be taken with Internet expression since unique questions arise about data collection regarding ownership, copyright, and selection of representative material" (p. 948). Eynon, Schroeder, and Fry (2009) suggested that when researchers conducting online research are faced with an ethical problem, they should look to the legal system in the jurisdiction where they are conducting the study. However, this suggestion does not work for researchers conducting cross-cultural research online.

The Association of Internet Research (AOIR) was developed in 1999 as an international, member-based support network promoting critical and scholarly Internet research, independent from traditional disciplines and existing across academic borders (AoIR 2016, n.d.). The AOIR created ethical guidelines for conducting online research. However these guidelines are hard to follow since they are constantly changing as new technologies are developed (Eynon et al., 2009).

Post Hoc Informed Consent

This type of consent is obtained after the research has taken place. An example of when post hoc consent is necessary would be when an intervention is a fundamental element in a field experiment. One of the primary goals of experiments on the ground is to examine how people behave in a natural setting. In many instances, trying to gain informed consent from potential participants most likely reduces the experiment's external validity (i.e., generalizing the findings). "When interventions are involved, and consent would interfere with external validity, researchers must take more than the usual amount of caution to ensure that participants will not be harmed, distressed, annoyed, or embarrassed" (Fiske et al., 2010, p. 90).

Proxy Consent

Proxy consent may be necessary when working with vulnerable participants. This type of consent should only be used when the participants cannot consent themselves (e.g., people with Alzheimer's). Criteria, agreed upon by all parties involved (i.e., the researcher, the authorized representative of the participant, and the participant) should be used to identify signs that the participant is unwilling to take part or wishes to terminate the research interaction, and fully understands to what they are consenting (Newcastle University, n.d.).

Process Consent

Process consent is when the researcher checks with participants through the entire study to make sure the participant remains comfortable (Lahman, Mendoza, Rodriguez & Schwartz, 2011). This type of consent is more appropriate to use in research studies that involve ongoing consensual interaction between the researcher and the participants.

Process consent is also referred to as iterative consent due to the continuous consent between the researcher and participant on the disclosure of incidental findings (Holzer, 2015). Ramos (1989) described process consent as an "ongoing consensual decision-making, where emerging difficulties are discussed openly" (p. 61). Munhall (1991) first referred to process consent as a way of "encouraging mutual participation and mutual affirmation between the researcher and the participant offering an opportunity to actualize a negotiated view" (p. 269). Usher and Arthur (1998) explain how informed consent should not "be a 'static' one-time thing when conducting research that involves more than one interaction between the researcher and participant" (p. 696). Member checks and process consent differ in that process consent is a model of how informed consent should be rechecked and maintained over the duration of the research. Member checks, on the other hand, is a method used to ensure the reliability and credibility of a study as related to the data obtained. Member checks are explained in more detail in Chapter III.

Process Responsiveness

Process responsiveness is a concept linked closely to process consent (Lahman et al., 2010). As such, this type of consent is not static in nature, but rather an ongoing process that can help ensure the researcher that the participant is still comfortable with each step of the study. Lahman et al. (2011) explained that "process responsiveness may include ensuring participants are comfortable with how the research is progressing, their information is being interpreted in a manner that makes sense to them, alternative

interpretations are heard and included in the data, and they understand how the data will be used for future manuscripts and presentations" (p. 317). Processive responsiveness is, therefore, a more holistic, relationally oriented approach.

Cultural Differences on How Consent is Established

Informed, reasoned, and voluntary consent is core to the ethical conduct of research, but the norms for what this means vary across cultures (Ruiz-Casares, 2014b). Leong and Lyons stated how ethical codes were not "created in vacuums but are instead contextualized and reflect the culture of the country in which the codes have been developed" (2010, p. 254). There are rising concerns about the appropriateness of applying a Western approach to how informed consent is gained in non-Western countries (Killawi et al., 2014). Informed consent is a standard practice and regulation for conducting human research in the United States as well as many other countries. However the "focus on an individual's rights to self-determination" is not the norm for all cultures. Instead, many cultures have a community collective or hierarchical ways in which decisions of this nature are determined. Informed consent at the community level can conflict with Western standards for voluntary individual decisions (Ruiz-Casares, 2014a). The diversity of standards and norms, when it comes to human research across cultures, may cause complications when trying to obtain consent from participants. When differences in cultural norms do occur, tension can arise over preferred approaches (Fadare & Porteri, 2010). Below is a list of many areas in which the social norms may differ between the two cultures when it comes to the informed consent process. These factors will be discussed in further detail:

- Pressure to participate in the research

- Lack of comprehension and understanding of the concepts present in the informed consent form

- A language and/or literacy barrier may exist

- Lack of confidentiality

- Individual vs. community decision-making processes (which has already been discussed)

Pressure to Participate

Dawson and Kass (2005) wrote of two main types of challenges that a person from a collective society had to face with voluntariness to take part in a study. They are "the pressures of community and family hierarchies and the difficulty in turning down research which offers direct benefit, especially in settings of scarcity" (Dawson & Kass, 2005, p. 1218). Tribal leaders or community heads may pressure individuals into participating in certain studies. It should be noted that this pressure on the person may be seen as negative in the autonomous sense but may be seen as honorable and one's duty from a collectivist perspective. Researcher Ruiz-Casares (2014a) found herself in this exact predicament when leading a study on child-protection in Laos. Ruiz-Casares (2014a) first sought explicit permission from the local district and village authorities to conduct the research, satisfying the Laos village's consent standards. However, she was still left with the problem of needing to satisfy her institutional standards on gaining individual informed consent from parents and assent from children. Ruiz-Casares stated, "We learned to respect individuals' silences and left unstructured time so that people could depart before group discussions" (2014a, p.304). By doing so, Ruiz-Casares

created an environment in which potential participants who declined to participate "were not singled out by their community in socially damaging ways" (2014a, p. 304). Of course, this approach was responsive to the community in which Ruiz-Casares (2014a) was studying, but this inventive response to assessing voluntary involvement was essential to the study's validity. Gaining consent cross-culturally requires receptiveness, persistence, and patience on the researcher's part. Liamputtong (2008) explained that these criteria must be sustained throughout the study from start to finish.

Comprehension and Understanding

Another issue that can arise is when studying cultures in which the participants are literate, but they lack comprehension and understanding of the consent form. Just because someone can read a consent form does not necessarily mean that they understand what is written, especially when the language tends to be of high level and codified with Western terms. Nor does it mean that they comprehend what the researcher, or translator, has said. Bhutta stated, "Even in regions with adequate literacy, there may be a poor understanding of the nature of the research" (2004, p. 273). There are still "no processes associated with obtaining informed consent that are concerned with participants' actual understanding of their obligation or implications associated with participating in the project" (Leong & Lyons, 2010, p. 255).

Language and Literacy Barriers

Researchers must "find more ways to present information clearly, particularly to non-literate participants" (Ruiz-Casares, 2014a, p. 304). The IRB requirement of written consent is problematic when trying to conduct research in societies that have limited use of or no written language. For instance, Navajo was not a written language originally,

making it one of the key issues when attempting to study the Navajo culture. To make the typical legal documents needed to obtain consent in Navajo, "significant linguistic expertise is necessary, and even then, to properly convey the ideas of informed consent one needs to resort to awkward translations and phrasings" (Alvarado et al., p. 10). All efforts of translating letters for informed consent are of no use when studying cultures with low levels of literacy (Leong & Lyons, 2010). In some cultures, the value of verbal agreements outweighs that of written consent, which might be viewed as suspicious (Ruiz-Casares, 2014a). In fact, Ruiz-Casares writes that "the very act of requesting signatures could create mistrust and the misperception that participants are entering into binding agreements that they will not be able to withdraw from" (2014a, p. 304). The signing of written contracts can be perceived as "integral to many interpersonal interactions and well entrenched in societal values and jurisprudence; consent can render actions morally permissible that would otherwise be wrong" (Grady, 2015, p. 855). Various research studies have shown that depictions of research aims, methods, and procedures through the use of photographs, pictures, diagrams, and even film help to render research coherent, ethical, and gives fully contextual ways that augment written documentation (Adams et al., 2007). Language barriers may also be a vital role in obtaining informed consent. Even when participants and researchers share the same language, in some settings there may be no equivalent word or phrase to express the meaning of difficult scientific concepts or terms used by the researcher (Marshall, 2008). Translation of consent forms from one language to the other may diminish or modify the original content, even when using an interpreter.

Summary of Chapter II

The nature of ethical research is forever changing and evolving, as does the world around us. As the globalization of human research increases so does the need for ethical considerations in cross-cultural studies. Informed consent has developed into a legal and ethical concept that is vital to research (Berg, Appelbaum, Lidz, & Parker, 2001). Marshall (2008) suggested, "Beliefs about who should provide consent for research participation also affects the process of obtaining consent" (p. 210). The lack of appropriate and flexible ethical standards for cross-cultural consent in research stems from a lack of understanding of the social norms of the culture being studied. Faden and Beauchamp (1986) believed that there are two basic differences in the meaning of informed consent: (a) autonomous authorization by a research participant, and (b) institutionally, by legally valid authorization, determined by a complex web of general rules, policies, and social practices. Universal guidelines regarding ethics and specific ethical dilemmas when it comes to gaining informed consent, do not seem to be appropriate or applicable in all cases. Christakis and Paneer (1991) believe that universal guidelines are problematic in two ways. One, universal guidelines "obscure real and legitimate cross-cultural differences in ethical expectations" (p. 214), by trying to make the research process homogenous for all cultures - a one size fits all approach. The second problem is with the existing guidelines that are "ambiguous about their objectives and purposes" (Christakis & Panner, 1991, p. 214). As Adams et al. (2007) state, the "onus falls on the U.S. members of international research teams to convey to their U.S. IRBs the rationale for revising standard protocols for informed consent given specific cultural constraints; it also falls on the U.S. IRBs to respond flexibly" (p. 464). The

difficulty with conducting cross-cultural research is only magnified when "alternative ethical visions must be reconciled with the broad, predominantly Western orientation of existing international guidelines" (Christakis & Panner, 1991, p. 214). Difficulties in satisfying conflicting ethical expectations have blocked many important and critical studies from being conducted. One of the biggest hurdles in cross-cultural research is that certain research protocols that are unacceptable in the West may be seen as acceptable in non-Western countries, and there is no negotiation between the ethical committees. The research can be stopped for ethical reasons. Yet, how ethical is it to stop research that is critical to a given society? Should not there be an obligation for negotiations to take place? I find abandoning or not approving critical research due to different ethical standards neglectful at the very least. I believe it is the duty of all ethical committees to negotiate their differences and to come up with amicable and satisfying solutions. If people in positions of power are the only ones who decide what research projects are worth pursuing, then all science will have nothing to offer but a reproduction of the images that elite groups wish to present (Scheper-Hughes, 2000).

Ethical Regulations Protect Who?

I would say that the biggest problem with institution ethical review boards does not fall on the given committee's overbearingness to oversee each study conducted by a researcher, but rather on the misguiding, misleading, flawed system of protecting the institution and not the participants or researchers conducting the studies (Landram, 2018). As Mills (2003) expressed from historical records of the first horrific offenses to the present day guidelines, it seems somewhere along the line the ethical codes for human research has wrongly fallen on the protection of the institutions rather than the

participants we so desperately want to study, responsibly and with respect. As a researcher, I have to agree with Mills (2003) these standards and regulations that we apply to each new study become a common form of practice that is routinely conducted at the beginning of each study. As stated by Landram (2018), "these 'common and routine' standards stem from a history of violations, malpractice and downright unethical treatments of human participants in research" (p. 239). This history should not be repeated. All researching institutions, today, strive to uphold ethical codes and have adopted improved standards of practice; but the main point is being overlooked (Landram, 2018).

CHAPTER III

METHODOLOGY

In Chapter III, I provide a detailed account of the methodology that was applied to guide this study. The methodology applied to any research endeavor serves as a strategic but malleable guide throughout the research experience (Hesse-Biber & Leavy, 2011). The purpose of this study was to (a) explore researchers' and participants' experiences with the consent process in cross-cultural human research and to (b) offer culturally responsive methods of how cross-cultural consent could be negotiated.

Therefore, the rationale as to why this study was being conducted was to gain a better methodological understanding of the cross-cultural ethical dilemmas that exist regarding the consent process. Other considerations besides differences in social norms such as age, gender, and socio-economic status can add to the complexity and difficulty in conducting a cross-cultural research study. Hence, a qualitative approach to exploring past cross-cultural studies' participants' and researchers' views was needed to gain an in-depth, clearer understanding of these ethical issues; and what appropriate measures needed to be taken to improve the current informed consent process as it pertains to cross-cultural research. Findings from this study could be useful to researchers who conduct cross-cultural research in areas where Western regulations do not apply.

As previously stated in Chapter I, the research questions that guided this study were:

Q1 What are possible cross-cultural implications of participant consent and how might researchers enact informed consent across cultures?

Q2 How are competing ethical values, in human research, negotiated in cross-cultural research?

Q3 When it comes to consent, how should competing ethical values in cross-cultural research be addressed (negotiated)?

Q4 How does the data collection process, experienced during this research study, compare between the in-person method and the computer-mediated method?

Q5 How well do participants understand consent directly after the consent form has been given to them in an interview setting (i.e., computer-mediated communication (CMC) vs. in-person interviews)?

A multiple case study approach was utilized in this study. Yin (1984) stressed that the use of multiple cases strengthens the results by potentially replicating patterns identified in the data thereby increasing the robustness of the findings. The case study method was used to gain an understanding of the individuals' perceptions of what it was like to participate in a cross-cultural study or to be the primary investigator (PI) in a cross-cultural study where the ethical understanding of informed consent was difficult to negotiate. Case studies are helpful in numerous ways. The need for case studies stems out of the desire to understand complex social phenomena; and the case study method allows the researcher to retain the holistic and meaningful characteristics of real-life events such as an individual's life cycle (Yin, 2009). Creswell (2012) defines a case study as a bounded system, such as a shared experience between multiple individuals, a process, an activity, event, or a program. For the purpose of this case study, the various cases were bounded by participants' personal identification of their experience in taking

part in a cross-cultural research study. Merriam (1998) stated that researchers conducting qualitative case study research should be primarily interested in: (a) how people interpret their experiences, (b) how they construct their worlds, and (c) what meaning they attribute to their experiences. Hesse-Biber and Leavy (2011) wrote that "methodology can be altered during the process of research to the extent to which a researcher's ontological and epistemological beliefs allow for modifications" (p. 4). This study complies with the applicable regulations set forth by the IRB Net as well as the IRB at my University. A letter acknowledging this study's active status and approval is shown in Appendix H.

Epistemology: To be or not to be

Crotty (1998) claims that the terms used in qualitative research, such as epistemologies, theoretical perspectives, methodology framework, and methods are "typically thrown together in a grab-bag style as if they were all comparable terms" (p. 3). The understanding and importance of these research design elements are vital to the researcher's decision making within the research design process. Therefore, the reader will be provided insight into my personal beliefs and some indication from where those beliefs and biases originated.

Epistemology, in short, can be thought of as justification of knowledge (Carter & Little, 2007). It is mainly concerned with providing a philosophical grounding for deciding what kinds of knowledge are possible and how we ensure knowledge is adequate and legitimate (Maynard, 1994). From my standpoint, personal epistemological stances should not just be objective or subjective, but to fully understand any perspective one must obtain insight subjectively as well as objectively. Ratner (2002) stated,

"objectivity is said to negate subjectivity since it renders the researchers as passive recipients of external information, devoid of agency, and the researcher's subjectivity denies the possibility of objectively knowing a social psychological world" (p.1).

In my estimation, the knowledge and the experiences I have gained in and out of academia have shaped my values and beliefs. Furthermore, my knowledge has been shaped and formed repeatedly with each new encounter I have had with others, with each new opportunity I have been given in life, and with each new experience, I have gained. It is my personal belief that the knowledge a person obtains and utilizes changes and shifts with each new experience they gain. When it comes to qualitative research I try to keep in mind, throughout the investigation process, what Creswell (2003) had expressed, that "knowledge is conjectural…. absolute truth can never be found" (p. 3).

Theoretical Perspective

As Guba and Lincoln (1994) wrote, "different tools are better suited for various projects…it is advisable to know when to use them, which depends entirely on the particular problem at hand." (p. 6). Through this study, I used a critical theoretical lens to review the cross-cultural differences in human research.

Critical Theory

Critical Theory stems from an interpretivist framework. Denzin and Lincoln (2008) stated that "qualitative research consists of a set of interpretive, material practices that make the world visible" (p. 4). Critical Theorists view all beliefs, realities, values, perspectives, and ideas in the natural social environment and examine the power dynamic that exists within each social context. Critical Theorists are concerned with empowering human beings to transcend the constraints placed on them by race, class, gender, religion

and/or sexual orientation (Fay, 1987; as cited in Creswell, 2013). Moreover, when it comes to conducting human research a power dynamic between the researcher and the participants is inevitable. Much like the power dynamic and assumed trust between a teacher and a student, the participant of a research study relies on the researcher for instructions and information about the research. Therefore, the researcher and the participant(s) cannot help but become, as Lincoln and Guba (1985) stated, "interactively linked with the values of the investigator inevitably influencing the inquiry," and following this logic it is believed the findings of the research are therefore value mediated (p. 10).

Finding this to be true, I rely heavily on the methodological techniques of a critical theorist perspective to minimize any biases I may have had regarding the study. The methodology behind Critical Theory is dialogic and dialectical, meaning that the findings are based on the dialogues recorded between the researcher and participants. I applied the Critical Theory methodological approach to the dialogues I obtained, from the interviews, to inquire into how the U.S. IRB's regulations and guidelines could change to include a more cross-culturally sensitive method when trying to gain consent. Moreover, as a researcher, I am always concerned with and checking that the knowledge I gain subjectively, via participants, does not overrule the knowledge I seek objectively regarding the problems I am investigating. Besides, critical theorists have revealed that 'objective' practices have been shown to be the most 'subjective' (Kincheloe & McLaren, 1994). As we cannot separate ourselves from what we know (i.e., subjectively derived knowledge) we must make a conscious effort not to force agendas, findings, nor personal beliefs on the participants. The phrase "cannot see the forest for the trees" comes to mind.

When the researcher fails to grasp the main issues because they are paying too close attention to the details, I believe it will result in an unbalanced perspective. The best practice for a critical theorist is to pay attention to the details (subjective perspective) but not to allow this to interfere with the conceptualization of the issues (objective perspective) that are presented.

Research Stance

My research background began in an animal-based research field. As an undergraduate student, I interned at Walter Reed Army Institute of Research (WRAIR) in their neuroscience/psychiatric laboratories, in Silver Spring, MD, working on chemical weaponry defense protocol. In this particular lab, rats were used as the subjects. My position in the lab was to help with monitoring and analyzing the electroencephalogram (EEG) recordings, as well as analyzing sections of damaged brain tissue. The protocols for the humane treatment of any living subject being researched at the facility were outlined and given to me, to study on day one of the internship. My experience at WRAIR gave me insight into the U.S. military's treatment of animal subjects in research. This was my first introduction to the ethical treatment of research subjects and it turned out to be a positive experience. Although I still have trouble with the idea of using animals in biological warfare testing, what I learned from this experience was how to respectfully and professionally handle and care for these animals. I hope for a day where animals do not have to be used in any biochemical testing. Yet, the reality is that although humans have come a long way in modern-day research technology, there is still vast room for improvement. In today's world, it is critical to understand the effects of certain biochemical warfare and to find anti-agents that can be used to counteract these effects.

As a graduate student, I expanded my research projects to include human participants. I had the opportunity to gain valuable insight into research ethics via my coursework training, the Collaborative Institutional Training Initiative (CITI) certification for human research that I had obtained, and through the research studies I had conducted involving vulnerable populations. Rogers (1997) defines a vulnerable population as any members of society who possess a degree of "susceptibility to health problems, harm or neglect" due to a level of perceived threat (p. 65). I chose to study the ethical dilemmas that exist within the consent process in cross-cultural research because I believed that the globalization of research and scholarly information cannot be ignored. The cross-cultural ethical dilemmas that grow out of cultural differences when it comes to the consent form needed to be addressed and changes to the dogmatic approaches of gaining consent need to be made still. Difficulties in satisfying conflicting ethical expectations have blocked many important and critical studies from being conducted. Again, I ask how ethical is it to stop research that is critical to a given society? Should not there be an obligation for negotiations to take place? I believe that it is the duty of all research ethics committees to negotiate their differences and to come up with amicable and satisfying solutions.

Research Ethics Stance

My research ethics stance is grounded firmly in the protection and ethical treatment of the study participants (Landram, 2018). As Mills (2003) expressed, "from historical records of the first horrific offenses to the present day guidelines, it seems

somewhere along the line the ethical code for human research has wrongly fallen on the protection of the institutions rather than the participants we so desperately want to study, responsibly and with respect".

As a researcher, I have to agree with Mills (2003), today's IRB standards and regulations that I apply to each new study become a common form of practice. However, these 'ordinary and routine' standards stem from a history of violations, malpractice, and downright unethical treatment of human participants in research. All of the ethical research codes, regulations, and protocols that we have today still place the research institutes at the heart of what is protected instead of the participants, the actual root or basis from where this knowledge is derived (Hoeyer et al., 2005). In fact, the history of human subjects in research includes a role of suffering and unwillingness on the participants' behalf. The focus has never been solely on the protection of the participants, but on the protection of the research institutions and then the participants (Landram, 2018).

Ethical Considerations

Ethical considerations must always be upheld when conducting any type of research on a living creature. Researchers using human or animal subjects in their research must abide by their IRB's, or Institutional Animal Care and Use Committee's (IACUC) outline of codes and regulations required for conducting research. As this study pertains to human research, I carried out the research according to the ethical codes and regulations outlined by my university's IRB. Throughout the study I applied the four principles proposed by Beauchamp and Childress (1983) which include: a) autonomy –

respecting the right of the individual, b) beneficence – acting in the best interest of others in mind, c) non-maleficence – as within the Hippocratic oath "do no harm"; and d) justice – emphasizing fairness and equality among individuals.

**Methodological Ethics: Ethical
Considerations in Using
In-depth Interviews**

The traditional role of the researcher, in the interview context, has been one of authority and control. However, one thing that the researcher does lack control over, in an interview setting, is how a participant may react to the questions they are asked. The participant may not want to answer some of the questions, or the participant may divulge personal information and later on regret it. The role of the interviewer is a tricky one. Interviewers must be aware and attentive to each of the ethical dilemmas that could arise. Crawford explained, "When two people face one another, the dialogue is conducted on several levels. The nature of words used, facial expressions and body language all communicate what the other part means" (Crawford, 1997, par. 1). The role of the interviewer requires engaging participants on the given topic without portraying themselves to be the participant's therapist, counselor, or confidant. The interviewer's role is never to give the participant personal advice. At the same time, the researcher must listen to and converse with each participant in a manner that is respectful, attentive, and receptive. Dillon, Madden, and Firtle (1994) believe that to be effective, the interviewer must:

1. Avoid appearing superior or condescending and make use of only familiar words
2. Put questions indirectly and informatively
3. Remain detached and objective
4. Avoid questions and question structure that encourages 'yes' or 'no' answers
5. Probe until all relevant details, emotions, and attitudes are revealed

6. Provide an atmosphere that fosters the respondent to speak freely, yet keeping the conversation focused on the issue(s) being researched (p. 124-125).

Confidentiality. Ethical issues involving an in-depth interview setting include such things as the interviewer or participant delving into areas unanticipated at first (Allmark et al., 2009). Of course, problems can happen when a participant reveals too much detail. Perhaps the participant meant to keep the information private or did not realize he/she had divulged such information. No matter the reason, the problem occurs when this information becomes a quote or comment in the researcher's write-up. While individuals may not be identifiable to the public, they may well be identifiable to peers also involved in the study or research context (Allmark et al., 2009). To minimize this ethical issue from this study, I employed two tactics. First, at the interview stage of this research, I tried not to probe into any areas of the participants' lives that they did not wish to share freely with me. Second, at the write-up stage, I asked participants to member check every comment and quote I used of the participants. A member check is a technique that consists of continually testing with participants the researcher's data, analytic categories, interpretations, and conclusions (Lincoln & Guba, 1985).

Another ethical confidentiality issue that may occur in an in-depth interview is the use of indicators in the write-up of the findings. Due to the nature of in-depth interviews in qualitative research, the number of participants is limited which makes the use of indicators to describe them another way they could be identified. For instance, the use of personal pronouns, which is the norm in English, to describe a participant's gender (e.g., he, she, him, and her) may be used to help identify a particular participant. Other such indicators that could be utilized, depending on the diversity of the sample, to identify an individual participant are such things as describing a participant's age, ethnicity,

nationality, social and economic status (SES), and even their education level may put a participant's identity in jeopardy. To eliminate this possible issue I only used such indicators to describe the participants as a whole. For instance, I had two groups: (a) a group representing former researchers, and (b) another group representing former participants. Instead of describing one participant's age I described the groups' range. By doing so, I was still able to represent the populations from which the participants were sampled from without outing a particular participant. In situations where a participant's direct quote was used, such as in any written reports or publications that were produced from this study, pseudonyms, chosen by the participants themselves, were used in most cases to protect the identity of the participant. In cases where a participant chose to use their real name, further steps to protect the confidentiality of their identity were taken. For example, not using attributing characteristics to describe them with that might be used to describe other participants such as their country of origin.

Power. Another ethical issue that I tried to address and reduce in this study was the power dynamic. When the research topic or questions asked are sensitive for a participant, the role of the interviewer may become closer to that of a counselor, therapist, or merely a confidante, especially if the interview evolves into several discussion sessions. Furthermore, a participant may be misled by the "apparent counseling methods of the interviewer; as such this may lead to the participant feeling disappointed by the lack of therapeutic intent revealed later" (Allmark et al., 2009, p. 6). Under no circumstances should the interviewer portray themselves as a counselor, therapist, or confidante to the participants of this study. To prevent this type of "false" role appearance, I did not give personal advice to any of the participants in this study. No

such scenario arose where I believed that a participant was asking for my help. However, if that situation would have occurred, I would have reminded the participant of my role as the interviewer and would have relayed to them that I was not a trained counselor, but that I did have information on where they could find a trained counselor with whom they could talk. This is where a counselor resource sheet with available free resources for students as well as non-students would be helpful.

Another ethical issue that must be kept in mind while conducting in-depth interviews is in how the interviewer engages with a participant. Through personal experiences, I have learned that it is best not to agree with what the participant is saying to simply try and keep them engaged in the conversation. Saying words such as "uh, huh," "right," "okay," "sure", and "yeah," seems to be a common occurrence in U.S. day-to-day conversations. The scenario is typical - one person is telling a story and to keep them talking, the other person keeps saying, "uh, huh" or "okay." While this may be acceptable language to use in a friendly conversation, I find this not to be acceptable for an interviewer conducting an interview because it sends a message to the participant that the interviewer agrees with what they are saying. Using such language can prohibit the participant from trying to explain everything in-depth if they believe that the interviewer knows what they are talking about and agrees with what they are saying. The use of this language can potentially lead to the participant feeling as if the interviewer agrees with them on an individual matter, which is a false representation that could, later on, leave that participant feeling vulnerable or used. To avoid this issue, I tried to be fully aware of and to not use such words as, "uh, huh", "okay", "right","yeah" when engaging with the participants. Instead, I tried telling the participants to "go ahead" [with what they are

saying] or "please, continue" to ensure that I had not shaped the layout of the conversation. Using these types of words instead will help to promote the participant to speak more in-depth throughout the interview.

Beneficence and nonmaleficence. One of the most important fundamentals when conducting any research study is that the research should produce some identifiable benefit (Atkinson, 2001). The intended beneficence stemming from this study was to gain a better methodological understanding of the cross-cultural ethical dilemmas that exist regarding the consent process and to offer culturally responsive methods of how cross-cultural consent could be negotiated. Non-maleficence is the principle of "avoiding harm, risk, or wrong to those being studied" (Smith, 1995, p. 481). Since through this study, I asked participants to recall and reflect back on their personal experience, this may have evoked some negative emotions. However, the probability and magnitude of the emotions evoked were no greater than those emotional memories evoked in the participants' daily life. Nonetheless, addressing the issue of non-maleficence was in the consent form given to each participant. If I had noticed a member experiencing negative emotions due to the questions asked during the interview process, I had a counseling resource sheet to provide the participant with local and national organizations that could help them (see Appendix C for counseling resource sheet). Fortunately, this type of response never occurred during the study.

Fidelity and responsibility. The APA's ethics code stated, "Psychologists are concerned about the ethical compliance of their colleagues' scientific and professional conduct" (Behnke, 2004, p. 88). In other words, anyone who decides to carry out a research study should stay true to a code of behavior that supports his or her initial

protocol. If another researcher finds that the original protocol is not being upheld and that the breach of protocol could lead to potential harm of a participant or researcher, then that researcher has the responsibility to report the possible violation. The APA's Ethical Standard 1.05 stated that an exception may be made when "intervention would violate confidentiality rights… [the researcher] is then faced with an ethical dilemma that requires choosing between the principle of fidelity and responsibility, on one hand, and confidentiality, on the other" (Behnke, 2004, p.88). While Ethical Standard 1.05 gives priority to confidentiality, I believe the responsibility of the researcher is to report anything that can be used to help protect the public and the participants from any potential harm. In this study, it was my responsibility to ensure that any dilemmas that arose were reported to my research advisor and IRB, as mandated.

Justice. The Belmont Report states that an injustice "occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly" (United States, 1978). Justice of all people having equal access to participation in this study was made by having two different settings in which participants were interviewed. The first interview setting for this study was a face-to-face setting and the second was a computer-mediated communication (CMC) setting. By offering two ways in which the participants can volunteer, I hoped to maximize the number of individuals who may want to participate in this study while also trying to accommodate the various ways in which people may feel more comfortable to participate. By employing two different interview settings, I was hoping to make each participant's interview process different but equal.

Respect for people's rights and dignity. Respect for all individuals, "and the rights of individuals to privacy [and] confidentiality…" (Behnke, 2004, p. 88), was what I strived to do as the primary researcher in this study and as a professional researcher in general. The respect, dignity, and worth of all participants, as well as my fellow researchers, were upheld at all times throughout the study. Conforming to these standards required my assurance not to influence or push any of the participants into disclosing any private information that they may have later regretted. At the beginning of each interview, I addressed this ethical dilemma with the participants and told them to let me know if they felt uncomfortable with any of the questions. I also assured the participants that anything they said would be held confidential, to the fullest extent possible, and that any comments that I planned to use, of theirs, would be reviewed with them beforehand. I also treated all the participants with the utmost respect.

In addition, I think that this respect applies to all of the participants' data that I have obtained. The in-depth interviews from this study generated a copious amount of data to transcribe, and it was of the utmost importance that each participant's data be recorded with the best clarity possible. Making sure that the recording devices were effectively working, and that the participant's and the interviewer's words could be heard clearly during the interviews, was imperative. It is through personal experience as a transcriber that I have learned how important and how disrespectful to the participant this mistake can be. It is so crucial to the study that the interviewer checks to ensure that each interview is being recorded. Each interview is organic and cannot be recreated.

The participant has given up their personal time to speak with the interviewer on a matter that they feel needs a voice. I avoided this crucial mistake by doing a voice check at the start of each interview. Also during each interview, I used two recording devices to ensure that the interviews were recorded.

Showing respect and dignity to all participants can also be shown in how the data is stored. If the data is not protected and personal information on any of the participants is leaked, it shows a disregard for the protection of the participant's information and identity. I avoided this by storing the data on a personal, password-protected computer.

<div align="center">Methodological Framework</div>

Methods

The in-depth interview methodology has become a common way for qualitative researchers to collect data. This approach involves the researcher forming a relationship with the participants that entails trust. If trust between the researcher and participant(s) is not established from the beginning of the study, then an open dialogue, one that involves questions that may lead to a meaningful-conversation, will not take place. Even worse, it may lead the researcher to commit unintentional maleficence toward the participant(s). Again, this study complies with the applicable regulations set forth by the IRB Net as well as the IRB at my University. A letter acknowledging this study's active status and approval is shown in Appendix H.

Interviews. All data collection from participants was collected via in-depth interviews. Interviews remain an "effective way of exploring the ways in which participants experience and construct their lives" (Yeo et al., 2013, p. 182). In-depth interviews are a powerful method for generating description and interpretation of

people's social worlds, and as such are a core qualitative research method (Merriam, 2015). All participants were asked the same structured questions in a semi-structured interview format (Appendix B). I estimated the amount of time for each interview to be approximately 60 to 90 minutes long. The amount of time each interview took depended on the amount of information each participant was willing to divulge. At no point did I probe or pressure a participant into speaking on a matter that they did not feel comfortable discussing. However, I also did not stop a participant from speaking, even if we went well over the estimated amount of time allotted.

Setting. The in-depth interviews took place in two different settings. The in-person interviews were conducted at a mutually agreed-upon time and place that included a specific room in the same public library or in some of the participants' work offices.

Carrying out interviews in-person has been the traditionally preferred mode of conduct. However interviews are also conducted online (Yeo et al., 2013). The second setting was a computer-mediated communication (CMC) setting that took was held at a mutually agreed-upon time. Online interviews can be performed synchronously (using real-time 'chat' platforms) or asynchronously (via email for example, over some weeks) (Yeo et al., 2013).

I conducted the interviews only synchronously via a CMC format in which the interviews were audio recorded. In offering CMC interviews, I hoped to maximize the number of potential participants in the study with the ability to interview people who were long distance as well as accommodate any participant who found a CMC environment more comfortable to participate.

Participants

      Selection criteria and process. Participants were all adults who had conducted or participated in cross-culture or sub-culture human research. I made the initial contact with each participant via an email recruitment letter (see Appendix D). Each participant was recommended to me through my academic mentors or colleagues.

      Sample and participant rates. A purposeful sampling technique was utilized (Merriam, 1998) followed by a replication logic (Yin, 2003). Replication logic requires the careful selection of each case "so that it either (a) predicts similar results or (b) predicts conflicting results but for likely reasons" (Yin, 2003, p. 47). I made the initial contact with each participant via an email recruitment letter (Appendix D). A sample size of 17 participants (i.e., twelve former researchers and five former participants) was obtained. Data saturation was achieved through the seventeen participants interviewed in this study. Data saturation "entails bringing new participants continually into the study until the data set is complete, as indicated by data replication or redundancy" (Bowen, 2008, p. 138). In other words, data saturation is reached "when the researcher gathers data to the point of diminishing returns when nothing new is being added" (Miles & Huberman, 1994). However, "data saturation is an elusive concept and standard in qualitative research since few concrete guidelines exist" (Marshall, Cardon, Poddar, & Fontenot, 2013, p. 11). Morse (1995) stated that saturation is "the key to excellent qualitative work…. [but] there are no published guidelines or tests of adequacy for estimating the sample size required to reach saturation" (p. 147). None of the potential participants were contacted directly by me initially; instead, they were referred to me and were asked if it was all right for me to contact them via email.

Also, I kept a personal contact for each participant after the in-person interviews were completed so that I could follow up for member check purposes. A correspondence with participants via the internet cannot be classified as confidential information due to the internet being considered a public domain; however, all data and materials that I received were treated as such after being downloaded onto my personal computer.

Demographics. In total, 17 participants were interviewed and contributed to the findings of this study. Of the 17 participants, 11 were females, and six were males. Table 2.1 and 2.2, show how the 17 participants were divided into the two method groups (i.e., computer-mediated communication (CMC) vs. in-person interviews), and then by their age and gender.

Table 2.1

Computer-mediated communication participants by age and gender

Age	Males	Females	Total
	N	N	N
< 30	0	1	1
31-50	2	3	5
51-70	0	3	3
Total (N = 9)	2	7	9

Table 2.2

In-Person Participants by Age and Gender

Age	Males	Females	Total
	N	N	N
<30	0	0	0
31-50	4	3	7
51-70	0	1	1
Total (N=8)	4	4	8

Table 2.3 below displays a demographic layout of each participant it includes the participants' education level, and country of origin. The participants' gender and age have been omitted to protect their identity.

Table 2.3

Participants' Demographics

ID	Researcher/ Participant	In-Person/ CMC	Education Level	Country of Origin
P1	Researcher	In-person	PhD	USA
P2	Researcher	In-person	PhD	USA
P3	Researcher	CMC	PhD	Kuwait
P4	Researcher	In-person	EdD	Cuba
P5	Researcher	In-person	Doc Student	Mexico
P6	Researcher	CMC	PhD	Kuwait
P7	Participant	CMC	PhD	South East Asia
P8	Participant	CMC	PhD	Mexico
P9	Participant	CMC	PhD	Palestine
P10	Researcher	In-person	PhD	Iran
P11	Researcher	CMC	PhD	Mexico
P12	Researcher	In-person	PhD	USA
P13	Researcher	In-person	PhD	England
P14	Researcher	In-person	PhD	USA
P15	Researcher	In-person	PhD	Saudi Arabia
P16	Participant	CMC	Artist	USA
P17	Participant	CMC	Artist	USA

Note. Computer-Mediated Communication (CMC). Gender and age are not shown to protect participants' identity

Table 2.3 displays a demographic layout of each participant and includes the participants' education level and country of origin. The participants' gender and age were omitted to protect their identity.

A comparison of the two methods of collecting data (i.e., computer-mediated communication (CMC) vs. in-person interviews) resulted in nine in-person interviews and eight CMC conducted interviews. The average education level for the participants was a doctorate level. Five of the participants discussed their experiences from the perspective of a participant, and 12 participants discussed their experiences from both perspectives (researchers and participants) in a cross-cultural study. It should be noted that all of the participating researchers were very familiar with Western research norms both through receiving advanced degrees from the U.S. and through U.S. IRB training.

Consent forms. Since the basis of this research study was to gain a better methodological understanding of the cross-cultural ethical dilemmas that exist regarding the consent process, the sample of participants represented graduate students and research professors in the social and behavioral sciences who had conducted cross-cultural research or had participated in a cross-cultural research study. I tried to take the opportunity during the interviews to use this study's consent form and the counseling referral handout as a type of interview elicitation device. The use of elicitation devices in the interview process can be a "way to align with positive qualitative methodologies, to gain access to participant beliefs and values, and to highlight the participant voices through their choices of words and visuals" (Richard & Lahman, 2015, p. 8).

The consent form that was presented to the participants included the general requirements, that are included in Title 21 Section 50.20: a) the participants must be voluntary, b) the language contained in the consent form must be written in "language understandable to the subject", and c) no language should be contained within the consent form that "waives any legal rights of the participants or releases the legal rights of the

investigator, the sponsor, the institutions or its agents from liability for negligence" (Code of Federal Regulations, n.d.). After the participants had time to familiarize themselves with the consent form, I asked them some follow-up questions, to answer the research question on how well participants understand consent directly after an interview. A copy of the consent form, as well as the questions that were asked about the consent form, can be found in Appendix E and F, respectively.

Data Collection Methods

There is an element of irony to this study, in that one of the topics of discussion was about how the U.S. IRB process should be more flexible in their methods of obtaining cross-cultural consent from individuals, in particular, their signatures. That being said, I briefed the participants on the nature of the study before the initial interview occurred, and a consent form was presented to them at the start of the interview. I also took that time to inform the participants of their rights as a participant, such as the ability to withdraw at any time and for any reason. If the participant verbally consented to be in the study, then the next step was to start the initial one-on-one in-depth interview with the same structured questions in a semi-structured format (see Appendix B). I asked the participants questions about their experiences as the researcher or participant of a social or behavioral research study, with cross-culturally existing ethical dilemmas when it comes to the consent form. Towards the end of the interview, I reviewed the consent form they signed and the counseling referral handout. I asked questions focused on the federally required content on the consent and cultural understandings of it (see Appendix

B for interview guide). The interviews took 60 to 90 minutes depending on the amount of information provided by each participant. Interviews were held in a mutually agreed-upon time and place.

Participants were asked six interview questions (see Appendix B). Also, note that the in-person interviews were all recorded using the recording functions on my personal recording devices which included a deactivated cellular Samsung Galaxy s5 as well as a cellular Samsung Galaxy s8 that I had put in airplane mode for the duration of each interview. The CMC interviews were all recorded using a Skype recording feature on my laptop as well as my deactivated cellular Samsung Galaxy s5. These data were then downloaded onto a password-protected laptop and transcribed.

Confidentiality of data collection. The data obtained from the in-depth interviews were kept confidential on my personal, password protected, computer, where I was the only one with authorization to access the files. Recruitment emails along with any corresponding documents between the participants and myself were also downloaded and recorded in a personally secured, password-protected, personal computer. Confidentiality of the participants' identification was kept private via pseudonyms provided by the participants. Appendix F that was given to each participant asked the participants to give a fake name to use in the study. At the initial start of each interview, I would ask the participants if they would take the time to fill out the short demographic questionnaire in Appendix F. Furthermore, the name of the institutions that participants were constituents of was held private by using a general geographic description instead of

the organization's name. The personal audit trail of the research study was kept in a locked filing cabinet in my office at my residence. Consent forms will be retained by the research advisor on campus for three years.

Thematic Data Analysis

The data obtained from the structured questions were analyzed using a qualitative thematic analysis. This approach supports the thematic themes that emerged from the interviews. Thematic analysis is a descriptive qualitative method that Braun and Clarke (2006) defined as "a method for identifying, analyzing and reporting patterns (themes) within data" (p. 79). I did, as Creswell and Miller stated, "Enter the informant's world and through ongoing interaction, analyze informants' perspectives and meanings" (2000, p. 128). The collected data were transcribed; a thematic analysis of the interviews was then performed using NVivo© Qualitative Data Analysis software. Next, emerging sets of patterns and common themes from cross-case synthesis were used to evaluate the multiple cases in the study. The logic for using a cross-case synthesis was to "address whether the findings from a set of multiple interviews—too small in number to be made part of any quantitative meta-analysis—support any broader pattern of conclusions" (Yin, 2009, p. 156). As expressed by Simon (2011), in qualitative studies, "there is an ongoing process of categorizing during the data analysis process" (p. 261). A peer review of examining the emerging themes and patterns was conducted by one colleague and by my dissertation chair. The analysis continued until theoretical saturation was achieved, that is, "when no new themes or issues arise regarding a category of data and when the categories are well established and validated" (Simon, 2011, p. 261).

Trustworthiness

Human beings have an innate feeling of curiosity that helps to propel us forward in our learning of knowledge. The reliability of a research study has always been questioned and for a good reason. Regardless of the type of investigation that is being conducted, the trustworthiness of the research study should always be valid, appropriate, and dependable.

Although the differences between qualitative and quantitative research are many, the question as to the importance of the trustworthiness of the research is the same. In both types of research, the concern is, "how well a particular study does what it is designed to do" (Merriam, 1995). In other words, does it answer the research question being asked? Many authors have sought to compare and to address the threats of trustworthiness in qualitative-based research to that of quantitative based research. For instance, as mentioned by Merriam (1995), some qualitative methodologists (Campbell & Stanley, 1963; Cook and Campbell, 1979; Guba & Lincoln, 1981) have directly addressed common threats to internal validity in qualitative studies thus utilizing the standard, positivist approach to validity and reliability while others have sought more conceptualization via examining different criteria (Agar, 1986; Guba & Lincoln, 1981; Merriam & Jones, 1983).

In my experience with conducting qualitative research, following the criteria set forth by Guba and Lincoln (1981) has served as a type of rigorous checklist for assuring that trustworthiness has been established throughout each study. Using this list helps "to ensure the findings are to be trusted and believed" (Merriam, 1995). The essential relevant components are best described by Guba (1981) in an annual review paper in

which Guba broke down the four aspects of trustworthiness into a table, similar to Table A.1 (located in Appendix G). The comparison between the scientific terms and naturalistic terms used allows the researcher to form a clear picture as to the comparisons made between trustworthiness in quantitative (scientific terms) and qualitative (naturalistic terms).

Using the breakdown presented by Guba (1981), the trustworthiness of a qualitative research study can be represented in four categories: (a) credibility, (b) dependability, (c) transferability and (d) confirmability. Each of these categories contains criteria that were followed to enhance this study's trustworthiness. Methods such as triangulation of data across interviews, peer reviews, and member checks to help establish the credibility, dependability, and confirmability of the study were used. Triangulation of data across interviews means comparing and crosschecking data collected through interviews with people who have different perspectives (Merriam & Tisdell, 2015). Patton (2015) explained, "Triangulation, in whatever form, increases credibility and quality by countering the concern that a study's findings are simply an artifact of a single method, a single source, or a single investigator's blinders" (p. 674). The in-depth interview transcripts and relevant published documents illustrating cross-cultural responsiveness in research were all used to ensure triangulation of the data across interviews had been satisfied. Peer reviews to implement triangulation of the themes that emerged and to help establish the credibility, dependability, and confirmability of the study were performed. Conducting a peer review involves the researcher discussing their research process and emerging themes with neutral colleagues, such as fellow doctoral students, who are either conducting qualitative research currently or have some

experience in conducting qualitative research (Anney, 2014). Given that this was a dissertation, the dissertation chair served as one source of peer review.

Another strategy used in qualitative research to determine the credibility, dependability, and confirmability of the study is the use of member checks. Maxwell (2013) believed that using member checks (a.k.a. respondent validation) in qualitative research "is the single most important way of ruling out the possibility of misinterpreting the meaning of what participants say and do …as well as being an important way of identifying your biases and misunderstanding of what you observed" (p. 126-127).

The credibility of this research was also verified by addressing my biases as the primary investigator, in part through the researcher stance previously presented, and how I minimized the biases through peer reviews. Peer reviews are based on the same principle as member checks but involve the researcher discussing the research process and findings with impartial colleagues who have experience with qualitative methods (Krefting, 1991). Lincoln and Guba (1985) believed that this is one way of keeping the researcher honest, and the searching questions may contribute to a deeper reflexive analysis by the investigator. By using both member checks and peer reviews, I hoped to strengthen the credibility, dependability, and confirmability of this study.

I also used an audit trail to increase the dependability and confirmability of the study. Audit trails, as Richards (2015) stated, help establish "validity from the researcher's ability to show convincingly how they got there, and how they built confidence that this was the best account possible" (p. 143). An audit trail is an account or log of the researcher's journey that an independent reader can then use to track the authenticity of the investigator's findings. In a qualitative study, an audit trail describes in

detail "how and when data were collected, how categories were derived, and how decisions were made throughout the inquiry" (Merriam, 2015, p. 252).

Lastly, the transferability or generalizability of a qualitative research must be addressed. The generalization of any qualitative research is hard to equate to any other qualitative research study. In fact, one basis for choosing to conduct a qualitative research is to find answers to questions that cannot or have not been found by using a more replicable, quantitative, approach. Sandelowski (1998) explained that if an assumption is made at the beginning of a study that the findings are descriptive, then an individual's life history is not relevant for the applicability criterion. If, however, the researcher means to generalize participants' responses, then strategies to enhance transferability are necessary (Krefting, 1991). Krefting (1991) also explained that the difficulty with qualitative research is "situational uniqueness; the particular group studied may not relate to others, and hence conclusions may not be transferable" (p. 220). The intentions of conducting this study were to explore researchers' and participants' experiences with the consent process in cross-cultural human research. A comparison of the characteristics of each participant to the demographic information available on the group as a whole was used to form transferability of the findings of this study. Therefore, a thick description of each participant, as well as the research context and setting, were included to support any generalizability that can be concluded from this research study. As described by Holloway (1997), a thick description refers to the detailed account of field experiences in which the researcher makes explicit the patterns of cultural and social relationships and puts them in context. Lincoln and Guba (1985) noted that the job of the researcher was not to provide an index of transferability but to provide an adequate database to allow

transferability judgments to be made by others. As Merriam (2015) stated, "every researcher wants to contribute knowledge to the field that is believable and trustworthy" and "as in any research, validity, reliability, and ethics are major concerns" (p. 252).

Summary of Chapter III

The purpose of this study was to (a) explore researchers' and participants' experiences with the consent process in cross-cultural human research and to (b) offer culturally responsive methods of how cross-cultural consent could be negotiated. The problem that I have addressed with this study was a lack of flexibility in the current U.S. IRB consent process when it comes to cross-cultural research. Efforts to design or at least negotiate cultural differences on the informed consent process have been made in the medical field. However, an approach to guidelines and standards for cross-culture research becomes increasingly complex across areas of study. Empirical studies on the ethical dilemmas that exist in obtaining consent cross-culturally are limited.

Therefore, the rationale as to why this study was conducted was to gain a better methodological understanding of the cross-cultural ethical dilemmas that exist regarding the consent process. Other considerations besides differences in social norms such as age, gender, and socio-economic status can add to the complexity and difficulty in conducting a cross-cultural research study. Hence, a qualitative approach to exploring past cross-cultural studies' participants' and researchers' views was needed to gain an in-depth, clearer understanding of these ethical issues, and what appropriate measures need to be taken to improve the current informed consent process as it pertains to cross-cultural research. Findings from this study could be useful to researchers who conduct cross-cultural research in areas where Western regulations do not apply.

In Chapter IV, the study's findings are discussed. The seventeen in-depth interviews that were obtained from the participants were transcribed and then used in conducting the thematic analysis. The findings were then further organized into two broad sections: (a) the themes that emerged that answer the research questions and (b) the other salient themes that emerged while conducting the in-depth interviews. The findings are discussed further in Chapter Five, leading to possible recommendations that could be made in an effort to help lessen the ethical dilemmas that occur in cross-cultural research studies.

CHAPTER IV

This piece of paper [the consent form] means different things to different people. It means a form of access to the researcher, it means a form of protection to the University and to the participant, it could mean several different things. One of which is it does not mean anything to me [the participant]. – Jordan

FINDINGS

The purpose of this study was to (a) explore researchers' and participants' experiences with the consent process in cross-cultural human research and to (b) offer culturally responsive methods of how cross-cultural consent could be negotiated. Therefore, the rationale for this study was to gain a better methodological understanding of the cross-cultural ethical dilemmas that exist regarding the consent process. Other considerations besides differences in social norms such as age, gender, and socio-economic status can add to the complexity and difficulty of conducting a cross-cultural research study. Hence, a qualitative approach to exploring past cross-cultural studies' participants' and researchers' views was needed to gain an in-depth, clearer understanding of these ethical issues; and what appropriate measures needed to be taken to improve the current informed consent process as it pertains to cross-cultural research. Findings from this study will be useful to researchers who conduct cross-cultural research in areas where Western regulations do not apply and in near diverse sub-cultures.

Demographics of Participants

   In total, 17 participants were interviewed and contributed to the findings of this study. Of the 17 participants, 11 were females, and six were males. Table 2.1 and 2.2 below show how the 17 participants were divided into the two method groups (i.e., computer-mediated communication (CMC) vs. in-person interviews), and then by their age and gender.

Table 2.1

Computer-mediated communication participants by age and gender

Age	Males	Females	Total
	N	N	N
< 30	0	1	1
31-50	2	3	5
51-70	0	3	3
Total (N = 9)	2	7	9

Table 2.2

In-Person Participants by Age and Gender

Age	Males	Females	Total
	N	N	N
<30	0	0	0
31-50	4	3	7
51-70	0	1	1
Total (N=8)	4	4	8

   Table 2.3 below displays a demographic layout of each participant it includes the participants' education level, and country of origin. The participants' gender and age have been omitted to protect their identity.

Table 2.3

Participants' Demographics

ID	Researcher/ Participant	In-Person/ CMC	Education Level	Country of Origin
P1	Researcher	In-person	PhD	USA
P2	Researcher	In-person	PhD	USA
P3	Researcher	CMC	PhD	Kuwait
P4	Researcher	In-person	Ed.D.	Cuba
P5	Researcher	In-person	Doc Student	Mexico
P6	Researcher	CMC	PhD	Kuwait
P7	Participant	CMC	PhD	South East Asia
P8	Participant	CMC	PhD	Mexico
P9	Participant	CMC	PhD	Palestine
P10	Researcher	In-person	PhD	Iran
P11	Researcher	CMC	PhD	Mexico
P12	Researcher	In-person	PhD	USA
P13	Researcher	In-person	PhD	England
P14	Researcher	In-person	PhD	USA
P15	Researcher	In-person	PhD	Saudi Arabia
P16	Participant	CMC	Artist	USA
P17	Participant	CMC	Artist	USA

Note. Computer-Mediated Communication (CMC). Gender and age are not shown to protect participants' identity

A comparison of the two methods of collecting data (i.e., computer-mediated communication (CMC) vs. in-person interviews) resulted in nine in-person interviews, and eight CMC conducted interviews.

The average education level for the participants was a doctorate level, five of the participants discussed their experiences strictly from the perspective of a participant, and 12 participants discussed their experiences from both perspectives (researcher and

participant) in a cross-cultural study. It should be noted that all of the participants except for two were very familiar with Western research norms both through receiving advanced degrees from the U.S. and through U.S. IRB training.

Findings from the In-Depth Interviews

The study findings are organized into three broad sections. These three sections include (a) the richness of the data collected (b) the themes that emerged that answer the research questions and (c) the other salient themes that emerged while conducting the in-depth interviews.

The themes that emerged from the interviews are organized and presented based on the research questions that the themes are related to or helped answer. Participants' responses to the structured questions were analyzed and grouped by similar responses. The major themes that emerged from the interviews are comprised of similar themes that were of help in examining and conceptualizing each participant's response to the questions asked.

As previously stated, the research questions that guided this study were:

Q1   What are possible cross-cultural implications of participant consent and how might researchers enact informed consent across cultures?

Q2   How are competing ethical values, in human research, negotiated in cross-cultural research?

Q3   When it comes to consent, how should competing ethical values in cross-cultural research be addressed (negotiated)?

Q4   How does the data collection process, experienced during this research study, compare between the in-person method and the computer-mediated method?

Q5   How well do participants understand consent directly after the consent form has been given to them in an interview setting (i.e., computer-mediated communication (CMC) vs. in-person interviews)

Q1. What are possible cross-cultural implications of participant consent and how might researchers enact informed consent across cultures?

Request to participate in a study. How participants in a research study are initially asked to participate differed across the cultures of the participants that were interviewed. For instance, many of the participants that were interviewed shared that the initial approach or decision to participate in a study was a different process than that of what they had experienced in the U.S. as researchers.

John, a researcher from Kuwait, who also has extensive knowledge with how research is conducted in the U.S., explained how the informed consent process is regarded in the Kuwaiti culture:

> In Kuwait, they don't want to ask anything about the concept. They might ask why you are doing this...or where this will be implemented...or how we can make use of this data? But the consent form…it was totally ignored. We are reemphasizing that the work [research] is more important than the signature, so this is a big habit. But… otherwise, the work is more important. They emphasize more power in that than in getting their signature.

When John was completing his dissertation as a student in the U.S., but collecting data in Kuwait, he had issues with obtaining consent from his fellow Kuwaitis and asking them to sign the consent form so that he would comply with the U.S. IRB standards. His experience with this process was that:

> Those that I gave it [the consent form] to…all of them, they didn't even look at the consent form. I give them, they sign it, but they didn't read anything. They said you know us, just give it to me, and I will sign it for you and your university in the United States and from us here we don't need anything.

Again, as John stated, reemphasizing that the research work is more important than the signature has a lot of meaning and value in the Kuwaiti culture as well as many other cultures globally. Sue, a visiting white U.S. researcher to South Africa, shared:

> So we had emic people in the country that were opening doors for us that had already earned the trust of the institutions that we were working with. …gatekeepers opened the door for us, and I remember going through the protocols with consent forms and making sure they read them and making sure they gave us feedback.

The difference in consent forms from culture to culture varies. Leong and Lyons stated ethical codes were not "created in vacuums but are instead contextualized and reflect the culture of the country in which the codes have been developed" (2010, p. 254). However, it is clear Western codes dominate in research.

Denchai, a researcher from South East Asia, explained how the U.S. IRB consent form compared to that of his country's research consent form:

> Simple language is used, the readability should be present and also mostly the consent form in here is like one page, and it talks about the same things like confidentiality, voluntary nature, the protocol that the participant have [has] to do but, when we verbally go through the informed consent normally we will say something like, "This is what I'm interested in, that this is what you have to do, and I will keep the data confidential, if you prefer to use real name, that would be fine as well and any questions at this point?" Also, when going through the consent form verbally, we shorten it, but in writing, I think you can put everything in there.

Lily, an Iranian researcher who has experience conducting cross-cultural and subcultural human research in Iran, confirmed the shortened length of a consent form compared with the U.S. IRB form. Lily recalled:

> …the ones that I have seen before they have been like mostly one or two pages and they were trying to keep that length because they were kind of like "well we don't look at it", and it's kind of like the contracts we sign when we go buy the phone or something, so they don't want to overwhelm people, so they try to make sure that the main points, which is like this is [are] confidential, this is

anonymous, we are not going to share with anyone…so those are the main points that are being bulleted or highlighted. They try to keep it; it's shorter than the ones I see here [in the U.S.].

Lily and John both shared insight into how different cultures behave and act towards consent forms. They were both very truthful in stating the fact that many participants do not even look at the consent form. Many of the participants I interviewed believed the length of the U.S. IRB form was too long and that for many the language needed to be clarified and simplified.

How to ask participants to participate (how consent is gained). The next theme that emerged when discussing how researchers gained consent was how they did so by U.S. IRB standards, (i.e., by legal documentation). Hence, I examined how the participants in this study went through the (a) gaining of the participants trust; (b) signing of the consent form; (c) signing and gaining consent from vulnerable populations; (d) establishing consent over time; and (e) other cultures with IRBs and those without.

Gaining of the participants' trust. Again, the method of gaining the trust of a potential participant is crucial and when the individual is not familiar with the implementation of a human research consent form even more so. The researcher(s) work of gaining trust and getting to know the potential participants beforehand is invaluable. However, how does the researcher go about verbally explaining what is in the consent form that protects the researcher, the participant, and then acquiring a signature?

Adriana an experienced cross-cultural researcher whose research involves translating her work from Spanish-to-English and vice versa explained that with participants from Central America:

> If I frame it in the "it is a requirement that I have" they are much more understanding than if I give them the paper and they think that, "well we already agreed with this, why do we have to sign?" And the reason why they… especially

the people from Central America is that they really distrust… they don't have good relationships with institutions, and so they do not trust anything that an institution gives them…it's not something that they trust.

Lily researched participants who had been affected by chemical warfare that happened during the Iran-Iraq War that lasted from 1980-1988. She recalls her perspective and experience on the comparison of obtaining a signature on a consent form between dealing with Iranian participants who were familiar with such processes to that of the immigrants and refugees to the area.

> "What do you want me to sign off? What is that?" …so you kind of let them know, and it's sometimes easier to just let them know that you know, like "is it okay if we talk to you? …and it's got to be confidential. I'm not going to share it with anyone". …building that trust is hard just because of the things that they have been through, but for the other ones, the ones from Iran it's not a big deal. You just give it to them [the consent form], and they are kind of familiar with it, and they sign it.

Adriana expressed her concern that the language used can be "boring and very formal" and in that formality, we sometimes obscure what our [the researchers] actual goal is, and so I think participants sometimes understate that unless you tell them in your own words."

Adriana is not alone in thinking that the formal consent paper does not provide sufficient information when speaking to people who are non-native English speakers. Adriana explained to me that even though the consent form may be translated into a different language "….it is formatted for English speakers, and so sometime[s] we as researchers create documents that are intimidating."

This brings up a valuable ethical dilemma when it comes to conducting cross-cultural research in that even though the consent form may have been translated into the participants' language; it still may not have been comprehensible to the participants of a given culture making gaining consent problematic.

Signing the consent form. The signing of the consent form can become the "deal-breaker" for so many studies; studies may get terminated or put on indefinite hold because the two cultures cannot agree on how consent should be legally established. Various reasons and circumstances make the signing phase problematic. For instance, as previously discussed in Chapter II, some of the possible implications that make gaining a signature from a participant problematic can be due to the participant's lack of trust in the researcher. The building of trust is discussed in fuller detail further on in this chapter. Some participants may become offended that their physical presence is not enough and therefore they become weary and suspicious of the researcher's intentions. In other instances, the participant may not be allowed to sign for themselves such as for religious purposes and some vulnerable populations such as those with cognitive impairments.

Adriana explained that over the years of conducting cross-culture research if she framed the signed consent as "a requirement that I have… they are much more understanding then if I give them the paper and they think that, 'well we already agreed with this, why do we have to sign?'"

Adriana also alluded to the fact that many participants have a hard time signing their names on the consent form because they do not understand the researcher's full intentions and fear that once they sign their name that they might be bound to something not right. Adriana explained that:

The reason why… especially the people from Central America is that they really distrust… they don't have good relationships with institutions, and so they do not trust anything that an institution gives them, and so either because they know… you know they're used to living in countries where everything is on paper, but nothing is in real life… it's not something that they trust, and so I have to frame it and say this is my requirement and not that I need to seal this deal with [for] you. I know that we're doing this…but I have to do it [obtain signed informed consent].

It seems that gaining the trust of the participants is the key to getting the participant to sign the consent form. Ensuring the participant of the confidentiality in what they say is not something that should be taken lightly in any research.

However, when culture and language are a factor, it seems that ensuring the participant of the confidentiality in what they say becomes more difficult.

Gaining consent from vulnerable populations. Gaining consent from other individuals such as older adults, the cognitively impaired and those who are unfamiliar with written word can be a difficult task. So I asked John, a researcher from Kuwait when conducting research that involves participants from vulnerable populations such as the mentally disabled or older adults, what are the Kuwaiti ethical research protocols for speaking with aging adults, mentally disabled, and other participants that might have cognition impairment? Do you have to get special permission to speak with them? John explained:

The elder, in our society we look at them with honor. So, I have an elder woman; I call her Mom, so…I might meet with her, we don't need her son [for the interview information], but he might be there because if I want to speak with his mother, he has to be there to show his respect to his mom and me. But the existence of the men in this situation with his mother is also crucial and sensitive to have, but if he is willing to open his house…it will be sensitive, not like, with older people it's a little bit open we don't need all this restriction. Still there is a restriction, it's his mother.

I asked Zeke, a researcher from Saudi Arabia who has conducted research with parents of deaf children, having researched in both the U.S. and Saudi Arabia if there was a difference between the two cultures when it came to consent and researching parents of disabled children?

> Yes, I think so…you have to consider the country, you have to consider is whether it is [a] sensitive [topic] or not. Sometimes you have a doctor working with a parent with a deaf child for example…the parent already will deny [to everyone in the community] that there is a problem with their child. They don't like to say their child is disabled. Some cultures when you are looking for the culture you may not see these children….and parents won't identify their child as deaf or say like sometimes parents hid [hide], try to hid [hide] their child from the people…they don't want others to know they have a deaf child or a disabled child.

It should be noted that Zeke is not stating that all Saudi parents "hide their [deaf] children" from the public and that this phenomenon of parents keeping their deaf children away from the public occurs outside of Saudi Arabia as well. I asked, "Like, it is embarrassing or something?"

> Yeah, yeah…or maybe they feel angry. They don't want people to know. Maybe in the United States, they are more okay. Even before the terminology, you can say that about your child for example special needs but you do not say handicap. In Saudi Arabia, they think it's a label.

Although giving a 'label' to anyone feels very limiting to whom that person really is, it is a way of helping to identify the special needs support that some of us require. In cultures where vulnerable populations such as deaf children or disabled children go unidentified, it can make it even harder for educators and researchers like Zeke to find not just them but their caretakers also.

Next, I asked Lily, about the Iranian consent process for working with vulnerable participants in Iran. When working with sensitive participants like refugees, veterans,

children, or adults 65 years of age and older do they have to get special permission

through a higher-level ethics board to conduct that kind of research? Lily said that:

> It really depends…so like sometimes it's true that the organization because once people go and get admitted to those places it's kind of like a thing the norm so for example if you were going to some hospital that is being funded by government or something [it is] much harder to get the permission to get those things done. …then sometimes when they are Non-Government Organization's (NGO's) because they are a different levels so first [for some] of them it is easier, for some of them it is harder, and sometimes the person who is managing that special organization might be really strict and put an end to it so…but then you can always go and bring in [a] formal document and follow up and push for it.

Lily also spoke of how difficult the task of obtaining signed consent forms can be

with tribal groups of Afghanistan refugees:

> Well, you kind of try to… sometimes you have to get the consent thing verbally because some of those people like, the ones I have met, those women they can't….write or read so like having that [consent form] in front of them. They cannot even sign some of them, so you want to…help, and it was really hard, and sometimes we were just getting to the point that we would just get their consent verbally like showing a piece of paper to them would just scare them.

Other vulnerable populations such as those who are undocumented residentially

are also researched. So how does one ethically research these populations?

Working with participants' from undocumented populations. There are many

risks in researching populations that are involved in undocumented activities in such

cases, in the U.S., a CoC may be obtained in order to help protect the researcher and the

participants in such cases (for more information on CoCs, please see Chapter II:

Obtaining a Certificate of Confidentiality). I asked Teresa, a white U.S. researcher who

has worked extensively with undocumented immigrant populations, about obtaining a

CoC to conduct research. Teresa explained that:

> The back story for grandparent's raising grandkids is a lot of them do it out of love, but a lot of them do it because the middle generation could be doing something non-legal like, …[and maybe in] incarceration, maybe undocumented

substance use, maybe they kind of technically abandon their kids but not really…. It's not noted anywhere in the system, so it's a population that is at risk. So, the CoC is mostly a research protection. So it just says if we are subpoenaed we can refuse. Eventually, you would have to… The CoC will not prevent you from being brought to court or having to reveal your records, but it makes it harder. So you can fight it more and say 'well we have this CoC, we promise this,' it's a stalling mechanism…and it's a fight. It's protection for the research, getting access to my filing cabinets or my data, my SPSS, it helps to fight that.

In the case of research with indigenous groups, Denchai who sits on the research

ethics board at his University responded that:

We have a few tribal groups, and I have seen research studies that want to be conducted with these participants. The concept of informed consent is foreign to them in a sense that they don't understand why we do this. … When they are suspicious, they normally tend not to participate. So if we go back to the first step, …gaining consent is creating trust, and sometimes we don't [get a signature]... and the researcher did not ask the participant to sign because the concept is very foreign.

In the U.S., there are certain exceptions to gaining written consent. Verbal consent

can be used in lieu of gaining written consent in situations such as when a participant can

understand and comprehend the English language, but who may be physically unable to

talk or write. In such situations, the participant may be eligible to participate in a given

study without a third party witness.

To be eligible for verbal consent the potential participant must be able to (a)

retain the ability to understand the concepts of the study and evaluate the risks and

benefits of being in the study when it is explained verbally, and (b) can indicate approval

or disapproval to study entry (Food and Drug Administration, n.d.). The U.S. Federal

regulations require a waiver of documentation of informed consent that must be approved

by the U.S. IRB to obtain verbal consent from potential subjects (University of California

Office of Research, 2014, par. 5).

Gaining verbal consent with participants from vulnerable populations has been an ethical dilemma for U.S. researchers such as Brad who was involved in a sub-cultural gender and sexuality research project.

Brad is, to this day, is in full support of protecting vulnerable populations. However, he had a profoundly negative experience with an IRB board when attempting to conduct a gender and sexuality research study in a rural community. Brad believes that due to the IRB Board's inexperience in dealing with studies that involved gender and sexuality research the board ignorantly rejected his proposal.

Brad made an interesting and thought-provoking statement when he said:

> I think vulnerability is often times taken too far in what it really means. So like pregnant women or prisoners, they're vulnerable right? …but that doesn't think what most people think it means. I don't think, in my opinion, to the extreme that people take it. So I think there are certain expectations if participants say "Oh I'm so scared to do this because…" You know then sure, in that instance I would say let's not sign. Let's get a verbal consent and figure this out. So I think on a more case by case basis for consent is necessary as opposed to treating everyone in the same way because I think people get classified as a victim often times when they are not.

Brad's proposal was rejected by his University's IRB. The Board ruled that his gaining consent from this population of students or even interviewing them may put them at risk of a hate crime. It should be noted that the population of students were all adults who were publicly open about their sexual identities. Brad suggested that:

> Not even giving them a chance to participate in the study it prevented them from knowing about this study when it may have, not that it would, but it could have saved someone's life. It's like that IRB board deemed these people as un[re]searchable and unworthy of being researched because of the consent in the IRB process. You're taking their voice away.

In my interview with Brad, there was one thing that he said that stood out that I had never considered myself as a researcher and that is "that [there is a] fine line between treating subpopulations as victims and acknowledging their vulnerability."

Establishing consent over time. Checking that a participant continues to be willing to consent to participate in different phases of the research can be termed as process consent. Process consent, as previously stated, is when the researcher checks with participants through the entire study to make sure the participant remains comfortable (Lahman, Mendoza, Rodriguez & Schwartz, 2011). DC, a Mexican researcher, spoke about her experience as an interviewer in an on-going research study where process consent was established over several times throughout the research. DC recalls the study:

> I was a researcher in a study where I was just the interviewer, and I was given an oral survey; I would call participants and ask for their information. The study included four different interviews, the first interview was 45 minutes, and then we have a 15-minute interview, [another] 15-minute interview, and the fourth one was also 45 minutes. It was over the course of…it was almost a whole year.

I asked DC if all of the interviews were conducted in-person, over the phone, or by CMC?

> No, the first one was in-person, the last one was in-person [the second and third were conducted over the phone]. The purpose was to study this group of women, some of them were taking their birth control from Planned Parenthood, and some of them were actually crossing the border to Mexico to buy their birth control. Because over there you can just buy it from a pharmacy. They're not going to ask you for a prescription, and it's cheaper, and you can buy like 12 packages, and you're done. So, I usually tend[ed] to do the second and third interviews which we are supposed to do by phone.

When asked if she had the same participants for each interview, and what she said each time she called them DC replied:

> We were given the whole survey; the survey came with a little script like, "Hello, this is x, from x research, calling from the study on birth control." It was a little more formal, the script, but what happened was that the interviews that we were doing where we were calling… they tended to shorten it. Just "do you remember

this study?" "I do" and "do you still want to participate? It's going to take 15 minutes?" and then they would decide, "yes" or "call me later" or "call me tomorrow" or "stop calling me."

I asked, "So consent was established at each contact with the participant?" DC said:

> It was verbal consent, and some people asked them [us] not to call, and we would just take them out. So, at the beginning of the initial study, they were asked if they wanted to participate, and then they got a consent and then every time you called, or you saw them again, consent was established again.

When I interviewed Teresa, a U.S. researcher who conducts research with older adults, she spoke of when she was working with a population of adults aged 65 years and older whose level of cognition was on a spectrum from entirely aware (i.e., participant understands and comprehends what they are consenting to) to unaware. The level of cognition may also change during a research study. Teresa explained:

> We do work with people who are across the cognitive spectrum so we have a protocol and we have ways that we can consent people with dementia, because we practice person first, right, so it's like you could respond for me, but you don't know what I really think. So we try if at all possible, to consent so we do have procedures. …if we would have had any issues we just stop the interview and then we would have assessed and gone back and kind of see and probably meet and see if that person if we felt that they were… so the ESC (Evaluation to Sign Consent) measure just goes "Can you tell me what this study is about?" "Can you tell me what you need to do be part of the study?" "Can you tell me what you need if you want to leave the study?" "Can you leave the study?" All those questions, it's like five of them, and if the person can answer it, then we feel they are understanding and comprehending as well.

Although it may not be federally required, establishing consent over time is a great aspirational standard for researchers to adopt when conducting research where they are interacting with participants at more than one-time period. It is a way of establishing trust between the researcher and the participant.

Other cultures Research Ethics Boards' standards. Informed consent is a standard practice and regulation for conducting human research in the United States as well as many other countries. However the "focus on an individual's rights to self-determination" is not the norm for all cultures. Denchai, a participant from South East Asia, explained how the Research Ethics Committee Boards are usually designed, and how the informed consent form utilized has similar principals as with the consent regulations and standards in the United States.

Denchai said:

> So in the IRB committee we need to have, you know, diversity in the IRB committee, so we need to have the balance between male and female, you know, balance between different disciplines, different age group…. …We need to have one person who is a doctor, and one person who is a researcher from the social science field even though the IRB is from the science field the social science person has to read that as well so that it goes together. The ethical principles, I would say it's the same in a sense that confidentiality we need to describe the procedure, risk and benefits, voluntary nature, these are the principals that I think are the same.

Denchai also explained:

> The process of submitting for the IRB right now is still, like, paper-based, so it's not through the Internet or anything so once the researcher submits the form we will put the code, like IRB code. For example, humanities and social sciences would be HU, science will be SC something like that and then as...we have the same process as like exempt, expedited, and also full board but mostly the research that has been submitted are [is] in the expedited status. We have a consent form...I think it [is] pretty much the same.

Other complications can come into play when the cultures being studied do not have a research ethics board that sets the standards and regulations. Sue, a U.S. researcher, went to South Africa to conduct research on an HIV project. Sue spoke with me about how the process went for gaining permission to conduct the research and of the ethical problems that can occur when conducting cross-cultural research. Sue recalled:

So we had to get permission from the orphan care center, the project directors of care and orphan house of encouragement, and the school. They didn't really have any [process] on their side that was a developed protocol, and I remember thinking in my mind, when we were going through this, how vulnerable they are…to researchers. I thought if I was an unethical researcher I could totally take advantage of these people. I just remember thinking "how sad, they are so vulnerable" and because I am an ethical researcher, you know, I did the proper protocols I followed our [the U.S.] protocols.

Brad who was a U.S. researcher on a South African project, found the gatekeeper being the stakeholder on the South African side to be a cross-cultural ethical issue.

Brad explained that:

There was what I would call a gatekeeper I think he was a founder or something [of] one of the programs within the orphan care center. So he was the one that we and the directors went through because he is South African, but he is a white male so…so it's still a bit different.

Brad went on to explain that the gatekeeper had the same family name as the town was named:

That felt weird too because it's like okay, this is a very privileged gatekeeper, but it seemed like he really understood everything. Not that that's an excuse or anything, but it didn't seem like he was exerting force or duress. He wasn't making them participate in any way; it seemed to be totally honest, legitimate and entirely in line with what you would hope.

However, as outsiders, Brad's concern was how the research team would be able to assess the power and privilege aspects of the study. Having no local ethics research board appeared to be very problematic. The gatekeeper that Brad worked with was a famous head figure in the community, and even though they had good intentions for conducting the research, the U.S. IRB would find it to be very problematic and unethical to conduct research where the ethical board members on one side of the research are also the gatekeepers.

Q2. How are competing ethical values, in human research, negotiated in cross-cultural research?

As the interviewer, I asked the participants how they thought the U.S. IRB could be more flexible to accommodate the given research contexts in which they had been involved. John, from Kuwait, spoke about how challenging of a difference this can be between the two cultures:

> This is very challenging for us. I had a tough time preparing my IRB…. Some of them [participants]…they don't look at the IRB consent form. They just want to fill [out] the questionnaire or talk. So there is nothing actually we can change a lot, but adding the understanding of the Eastern culture or the Arabic culture…the verbal agreement or the friendship is enough for them.

This is of profound interest because it shows an enormous distinction between the U.S. and Arabic cultures when it comes to trust. As John explained, "from just society culture it [signed consent] doesn't make sense, it doesn't make a big difference for them just to write some signature." One of the challenges John had [while working on his dissertation in the U.S.] was trying to explain to his U.S. doctoral committee how different the consent process can be between Western and Eastern cultures. Unfortunately, John still had to go through the signed consent process with each of his participants to comply with the U.S. IRB protocol. John clarified that "they [the participants] believe that the [relationship between them and the] researcher means more than the [signature] process. So the process is not that important for us here [in Kuwait]".

John experienced one particular dilemma in which he was trying to gain the signature of a participant's husband in order to interview the wife. The husband was not sure why his signature was needed if he had already agreed for his wife to be interviewed by John.

I [John] told him, "no it is not that I don't believe you, I believe that you are the husband, but this is part of my research". He said, "ok" and that I am reconfirming his word that he told me "I'm him", then I told him "sign", he said "why should I sign I told you I am him?", then I explained to him that this is a process [in the U.S.].

This example also underscores a vast cultural difference where in U.S. culture a spouse cannot sign this type of document for their spouse unless they are the legal signatory for some reason such as cognitive decline.

Sue, a U.S. researcher, recalls how difficult it was to get the consenting paperwork to conduct an HIV research study in South Africa. Sue's ethical dilemma was that there was no official ethics research board on the South African side of the research. Sue remembers how hard this dilemma was to get through to her University's IRB (which is in the United States). It came down to the day before the researchers were supposed to start conducting interviews before Sue and her team of researchers was given the final approval to conduct their cross-cultural study.

Sue recalls, "Anytime you are doing cross-cultural research, you are shooting from the hip most of the time, and that's what makes it …where you can have these ethical dilemmas a lot". Sue's cross-cultural experiences as a researcher have taught her that:

> Communication is always the hardest thing about research and I was so glad that I remembered that I had written the IRB to include all kinds of interviews up front because the day of the focus group I had never gotten any confirmation, and in walks the director ministry of education of that whole territory and everybody is running focus groups over here, and I was like, "I'm so glad you are here. Why don't we have a seat?" and I just did an immediate one-on-one non-structured interview. I just pulled him aside because that kind of research…it's very dynamic it's very conversational I didn't have a recorder with me, but I took massive amounts of notes.

Sue's experience emphasizes the idea to write an IRB request for culturally complex research that includes flexibility in the design to the furthest extent possible. Denchai, who now sits on his University's research ethics review board in South East Asia, spoke of his experience in cross-cultural research studies as both a researcher and as a participant, conveying that:

> For me as a participant, I feel like this [consent form] is too long but this is what we have to do from the standpoint of the researcher from the United States. So if you can keep it shortened in length that would be awesome, I think, for cross-cultural research.

It seems that competing ethical values are not being attended to and that it is easier to ignore ethical values that are not the same. If the consent form is unimportant in a given culture than it seems it is easier and appeases the participants to tell them that it is a requirement that you, the researcher, have and why it is important to you that they sign the form. Jordan, a U.S. researcher, believes that consent should be:

> Based on the dominant discourse within the culture. So if the dominant discourses within are primarily oral then that should be their process for consent. If the dominant discourse or the discourse of the culture is one of storytelling then somehow the consent form takes the look of a story to match that what they are used to seeing so that it doesn't come across as some foreign thing. I mean it's going to be foreign anyway especially if it's American versus South African or whatever; and of course, there will be sometimes when the discourse is parallel. This discourse matches the discourse in England, for example. It's a little more formal so, in that case, the discourse matches. It's when there is a mismatch of that discourse is when we need to be concerned and how it looks and does it need to look the same all the time? People who are more visual perhaps will go through one that is more visual or graphics like, like a video, what about a video with someone from their culture talking through it versus me talking through it. Why does it have to be the researcher talking through it? Would it lose value or would gain value because I've actually attended to their needs at that point?

Jordan's idea of participants collecting the information from the consent form through the formats in which they are more accustomed to is an interesting notion. For instance, having an individual specifically from the participants' culture who could talk

through the consent form on a video would not be too costly for the researcher to consider. Ideas such as the one posed by Jordan could isolate some of the translation problems encountered during the consent process.

Q3. When it comes to consent, how should competing ethical values in cross-cultural research be addressed (negotiated)?

Jane an elementary public school teacher in Kuwait, with a Ph.D. from the U.S., responded that:

> I hope it to be easier in the U.S. [in the future]. Like, the consent for participants who work with kids or for those who teach like in an elementary school they make the process like two weeks, one month maybe even more and sometimes they want some kind of change to my IRB I hope that like…I think that the approving process takes far too long…well, the one we use anyway. I think this time last year I had gotten approval for like one survey and needed to get 12 more classes [enrolled in the study] to get all my participants.

When Zara, an experienced U.S. cross-cultural researcher who has primarily worked with Mexican immigrants and first-generation Mexican-American citizens, first started to conduct research for a U.S. educational institute along the Mexico-Texas border she noticed that:

> Among the first set of participants, we noticed that many did not understand even simplified versions of consent forms. So I believe it should be presented to a sample to ensure that translation is not only correct but also understood by the local community.

Adriana, an experienced U.S. cross-culture researcher, stressed the importance of cultural responsiveness and awareness when it comes to negotiating ethical values in cross-cultural research believed strongly that:

> As a researcher, you need to know your population well before you ask them to cooperate or ask them to participate and so it may look different depending on the population. So in one population, you can talk about it [signed consent] as a common [process]… you know [to] address it, present it to them, and in another

culture, it may be that even the paper you never even show and you just gain oral consent. So I think... it has to be different depending on the structures of a particular group and what they're used to. So I think you need to treat it differently and really learn about the life of your participants before you present them with a paper.

I asked Denchai, a research ethics board member in South East Asia, how he thought consent should be or could be negotiated better in cross-cultural settings, he replied that:

> I would say gaining consent is not a onetime deal it should [be] ongoing in cross-culture studies and also one thing [that] is very important is that the researcher, ourselves, need to be present in a sense that, if we appear rushed, I think it would be problematic, so we need to be really mindful about what they do in the culture. So go there and see how things work and also verbally appear, come practiced and everything. So that would be the negotiation aspect of informed consent.

Rebecca, who works with minors who are from immigrant families, believes that one cross-cultural dilemma that can be overcome or be negotiated is "being as transparent as one can with your participants and then in the instance or in the case of minors being fully available to the parents or guardians of those minors as well."

Rebecca's statement hits on how important trust between the researcher and participant can be to the study and how ethical values should be addressed in a cross-cultural research. Making a consent form that is not only in the participant's native or home language but also written in the way that the participant's culture interprets that language is crucial in cross-cultural research. How can competing ethical values ever be negotiated when that information (the consent form) is not understandable or comprehensible to the participant?

Jordan who also works on research involving children explained that:

> …it's in the language, you know, and even though we say use participant friendly language and keep out the jargon…the jargon is there. Especially the consent form which is mandatory you know. It's full of it. So how could it be participant

friendly or kid friendly? I mean even within the same culture per se, and this [the consent form] is made for one culture and that would be…the academic culture. There is a good reason why we need to do that but does that reflect the culture that we are going into. No.

Jordan's response rings true in that there are good reasons as to why the consent

form process needs to be conducted. This process was designed to protect vulnerable

participants. Although currently the U.S. IRB consent form process seems forced upon

participants; and if they understand what is included in the consent form or not they are

asked to sign to continue with the study. At some point, you have to stop and ask

yourself, "If the participant is signing this form that they cannot read or they do not

understand. Then by getting them to sign the form who or what is really protected?"

Q4. How does the data collection process, experienced during this research study, compare between the in-person method and the CMC method?

To answer this question, I compared (a) the qualities of the audio recordings of

interviews: CMC method versus In person method and (b) the two methods of

transcribing the interviews.

CMC interviews. For the CMC interviews that included, eight interviews, the

time and availability of being able to conduct the interviews via the Internet helped

considerably and made it possible for me to reach out to prospective participants on a

global scale. All CMC interviews were conducted using the software application Skype.

The CMC interviews were all recorded using a built-in Skype recording feature on my

laptop as well as my deactivated cellular Samsung Galaxy s5. These data were then

downloaded onto a password-protected laptop and transcribed.

Each interview was half an hour to an hour long. The quality of the interviews was decent enough that communication could occur. However, there were many times when the questions that I asked were not fully understood. The interview questions were complex in nature, so the questions had a lot of language sophistication that did not help. This was seen even with the English as a first language speakers. Also, I could see the participants via Skype webcam, but nonetheless the body language to fully help explain my questions was still not there, so it was hard to understand what some of the participants were trying to portray. This lack of understanding for some of the interview questions between the CMC participants and me seemed to stem from the fact that they were all international participants and English was not their first language. I did not speak their first language and found it hard to communicate with some of the participants when I could not use body cues from them to direct the conversation better. Both of these factors seemed frustrating from my perspective as the interviewer**.**

In-person interviews. I found the in-person interviews to be more straightforward to conduct and to yield data that was easier to understand because the participant and I were in the same room and could engage not only using oral language to communicate but also with body language. I did have several non-native English-speaking participants that participated in the in-person interviews; however, the most challenging factor to the in-person interviews was the flexibility in scheduling and meeting in person, which was not too hard to overcome. I only had a few cancellations where we had to reschedule, but that seemed to be the only struggle I had with the in-person interviews. My method of in-person interviews was utilizing two recording

devices that included a deactivated cellular Samsung Galaxy s5 as well as a cellular Samsung Galaxy s8 that I had put in airplane mode for the duration of each interview.

The most significant difference in the two data collection methods utilized in this study was discovered when I started to transcribe the interviews. The computer technology that I have and that I was capable of obtaining at a professional U.S. graduate university is still lacking when it comes to clarity of audio when transcribing recordings.

Method of transcribing the interviews. My first method of trying to transcribe the audio recordings was to use a free NBI (Nero Backitup information) file. The NBI files were decompressed audio recording files. I had the audio files transmitted through my computer using a virtual audio cable. CNET applications made the virtual audio cable application that I used. A virtual audio cable is intended to connect several audio applications in real time. It is like a sound card with hardwired input and output: when an application sends an audio stream to a virtual cable, other applications can record this stream from the other cable end.

The audio files played through this setup into an online Google Docs speech-to-text format. Google Docs cannot be used offline. Therefore, this is a potential breach of participant confidentiality, yet another limitation to my study. However, the fact that I spoke with nearly half of the participants using a public platform (i.e., Skype); and the other fact that member checks use a link to the participant to stay in contact with them throughout the study are all areas with possible breaks in participant confidentiality.

I feel overall that Google Docs was an excellent tool to use for talk-to-text when using it in real time. When using Google Docs as a transcribing instrument, it becomes more difficult for the program to work correctly. There are several features on Google

Docs such as the add-on tools that can help with accents in the text-to-talk. However, when using Google Docs as a transcribing tool, it becomes considerably more difficult for the program to transcribe correctly and became more laborious and time-consuming for me to edit.

The terms of service for using Google Docs states that the writer retains ownership of any intellectual property rights that they hold in that content. Google does not claim ownership of any of the writer's content, which includes any text, data, information, and files that are uploaded, shared or stored in the writer's Google drive (Google, 2018). Therefore, the data that I transcribed using Google Docs was not available to the public nor could it be leaked publicly, yet it still cannot be considered private.

Google Docs translation somewhat worked for the native English-speaking participants in the current study. However, there would be multiple mistakes and have it being conducted on a virtual cable made it hard to go back and edit so for the native speaking participants in which I tried using Google Docs to transcribe. I ended up with a fair amount of single-lined jumble that picked up the exact words periodically. It seems that I wasted more time going back through the dictated transcriptions; and in the end, it was not worth the effort in my opinion. I terminated this method of transcribing due to the transcriptions being so off and time-consuming due to correcting and editing.

I tried two different participants' recordings in Google Docs for the non-native English-speaking participants. One was from Kuwait, and the other was from Mexico. The accent add-on tool that Google Docs offers did have an add-on for Spanish speaking and were somewhat useful compared to how Google Docs transcribed the Kuwaiti

participant's interview. As of the current version, Google Docs does not offer an Easy

Accent Add-on tool. In the end, I stopped trying to transcribe automatically using the

Google Docs talk-to-text tool because it was too time-consuming going back and editing

the mistakes. I transcribed all further interviews using a more traditional method.

The next method I used to transcribe included downloading the software

application known as Express Scribe Transcription Software by NCH Software. This

software with the assistance of a foot pedal was used to slow down the audio recordings

to aid in helping to transcribe the other nine interviews. Given these experiences, in

general, it is safe to say talk to text still has a way to go when it comes to transcribing and

researchers will need to pilot or plan for a trial and error period when determining the

best way to transcribe for the types of languages and accent they have recorded.

**Q5. How well do participants understand
consent directly after the consent form
has been given to them in an interview
setting (e.g., in the CMC setting and
the in-person setting)?**

I wanted to take the opportunity to use this study's consent form and the

counseling referral handout as a type of interview elicitation device. As previously

stated, in Chapter III, the use of elicitation devices in the interview process is a "way to

align with positive qualitative methodologies, to gain access to participant beliefs and

values, and to highlight the participant voices through their choices of words and visuals"

(Richard & Lahman, 2015, p. 8).

I examined the following: Method of how the consent form information was distributed, the idea of understanding versus comprehending a consent form, communication challenges, and the power dynamic between the participants and the researcher to answer this question.

Method of distributing the information on the consent forms. I sent each participant the consent form via email and after the participant had accepted my invitation to be a participant. Therefore, all participants had access to the consent form a few days if not weeks before I interviewed them. During each interview, CMC and in-person, I gave the participants the opportunity to read the consent form by themselves first; then I went over the form with them. After going through the consent form with the participants, I told them of this component of the study and inquired if I could ask them questions about what they had consented to and the counseling referral form. I explained that I had created this elicitation device to explore the difference between the understandings of a consent form versus the comprehending of a consent form.

Understanding versus comprehending a consent form. To understand a consent, form the participants need only know what is required of them, for example, answering interview questions or being observed doing something. On the other hand, a consent form is comprehended if the participant understands such things as what is: the main reason for the study, the rationale, the primary objective of the study, the benefits or risks that may be involved in participating, and what rights they have as a participant. A participant's knowledge of such components is what differs between comprehending a consent form and understanding a consent form; and there are still "no processes associated with obtaining informed consent that is concerned with participants' actual

understanding of their obligation or implications associated with participating in the project" (Leong & Lyons, 2010, p. 255). A copy of the consent form, as well as the questions that were asked of five of the participants, can be found in Appendix E and F, respectively.

Communication challenges. Getting the participant to understand what I was asking them to do for research question five was a challenge. First, there was the difficulty in explaining that I would like to ask them some questions (i.e., give them a little review of the consent form) that we had just gone over together and that the questions that I wanted to ask had to do with my research study. One of the hardest parts in investigating research question five was trying to explain to participants what I was trying to do. It seemed overwhelming to them and was harder to explain then it was worth. In theory research question five would have been great to collect data about; however, the implementation was difficult, and as the prime investigator, I believed it ended up just being an unnecessary confusion for the participants.

I felt like no matter how I presented the questions it was confusing to the participant even though right in front of them, on the consent form, it said precisely the answers to the questions I was asking such as what is this study? The only thing the participant needed to do to answer that question was to look down at the consent form and read the title and the first sentence. This confusion occurred for native English speakers and seasoned researchers.

It seemed that all of the participants understood what they would do during the study, by which I mean they knew that I was going to ask them questions about the consenting process and ethical dilemmas that have occurred when conducting a cross-

cultural research study. However, the reason for the study, why I was doing the study, and what exactly my goal was in conducting it may not have been comprehended; but it was too hard to tell and was too distracting from the primary study. I did have one participant who after I explained the interview question to them in a couple of different ways understood what I was after and in less than a few minutes answered the questions correctly meaning she not only understood the study but comprehended what her role and rights as a participant were. In theory, I believed that this line of questioning to be very simple for a participant to comprehend and answer but the implementation failed as noted previously.

The power dynamic. I also believe that a lot of the confusion and problems stemmed from an underlining power dynamic. In the case of the in-person interviews, I played the role of the researcher in the room and as such directed the line of questioning. Therefore, theoretically playing the role of the researcher I had control because I was directing the participant. I was asking the participants questions that they previously did not know. Therefore, they looked to me for guidance and direction as to what came next after each question. These types of scenarios can be taxing on the participant. The participant may feel anxious about the questions or maybe trying to please the researcher. I witnessed this firsthand with all participants. I had four in-person interviews and one CMC where I asked the questions I had for research question five. What I saw from the in-person interviews is that most of them became flustered and were appeared to be searching for the answers that would please me. It may be as educated scholars and cross-cultural researchers they felt flustered when they had to reflect overly long about what seemed to them to be an abstract question and for myself a concrete one.

What is not widely understood is that the participants are the ones that control the power in the room and the power between the interviewer and the interviewee. Jordan explained that:

> There is power there…the researcher over the participant which is why I choose to do some of the methods I do because it brings the participants into the research versus outside kind of doing it with them. So I think photo-voice and some action research areas or participatory action research. Where the participants are more involved.

In the consent form as written, the participant has the right not to answer any of the questions that they do not want to; or if they want, they can terminate the interview. Therefore, most of the power lies with the participant much like the power struggle that is seen within a classroom between a teacher and a student. The students begin to believe in what their teacher tells them. Nonetheless, students do not realize that they have more control over the power dynamic between themselves and their teacher. The students do not have to listen to the knowledge that their teacher is given them and by no means do they have to believe it. They could get up and walk out at any time if they desired. I believe that this power dynamic was a limitation to the study on research question five in specific and created more questions than it answered. I believe that this question alone warrants its own study.

Section II: Other Themes that Emerged

The other themes that emerged out of the interviews collected from the participants were trust, cultural orientation, cross-gender interaction, ethical dilemmas of cross-research and problems and the different stages of the consent process.

Trust

The trust between the researcher and the participant is crucial in cross-cultural research. So many things depend upon the researcher building a solid relationship with the gatekeepers, participants, and other key individuals that play a role in the conduction of the research.

For trust, I examined the role gatekeepers play as well as how essential building relationships with your participants can be for the research. I spoke with a former participant of a subcultural ethnography study; whose name is Skâll; he described how the interview process was for him. Skâll indicated that the consent form itself "looked way too long and technical" and that he did not feel like he even "wanted or needed to look at it".

When I asked Skâll why he was willing to sign the consent form without reading it first Skâll's response was the following:

> The reason I felt comfortable signing the consent from him [the interviewer of that study] was that I knew very specifically that it wouldn't be misused or misconstrued in any way to make it a negative thing. I trust someone from my community, and I know that they [the researcher/interviewer] are someone from the same subculture. I tend to have more trust for people that are involved in that community specifically because it is something that you have to seek out and it's a family…it's like a big family.

Skâll's trust stemmed from his trust in the researcher being a member of the same subcultural community not from his trust in the study or the consent form process. For many researchers trust and the consent form process becomes two distinguishable parts of the research process, and gaining the participants' trust is not always as easy as in Skâll's case.

For instance, in cases where the researcher wishes to study participants from undocumented populations, in such cases, a researcher may want to obtain a Certificate of Confidentiality. A CoC, as discussed in Chapter II, is to protect the privacy of the participants by restricting the disclosure of identifiable, sensitive information to anyone not connected to the research except when the participant consents or in a few other specific situations (National Institute of Health, 2016).

When I asked Teresa, a professor, and an experienced subcultural researcher, about helping one of her students obtain a CoC in order to interview Latino grandparents. Teresa said:

> My student wanted to do a qualitative project, and her interest is in grandparents raising grandchildren, but her primary interests are in Latino Grand families, really proud Latino grandmothers, we'll see women who will raise grandchildren and… we have had ICE [Immigration and Customs Enforcement] raids in this city, so ICE raids are immigration raids, right, the Illegal Control and Enforcement or something. So, we have had ICE raids, and I have worked with other studies that were bilingual, and people would tell us in Spanish like you're the Government because we are a State school, so you're the Government.

Adriana, a U.S. researcher, originally from Central America, who has experience with and is familiar with working with participants from Central America, explained that:

> Maybe we can say to them "you know I think that this is a problem in your community, is there a project that we collectively can do to maybe look at that problem?" …and so it's not in my study, it's…it's what can we do about this problem that we have identified that we both know is a problem in the community. So they are participants but they're also researchers, and so they take that ownership… I mean that's my take. I want to see them view themselves as researchers as well and we're all collectively trying to figure out this problem.

Adriana was able to build trust with her participants in a short time by asking the participant to collaborate with her, the researcher, on a given project that was meaningful to both of them. Another way that a researcher can build trust is by going through a gatekeeper or someone in which the participant(s) trust.

Gatekeepers. Finding and becoming familiar with gatekeepers or the individuals who are familiar, enough with the potential participants to provide access to them and research settings (DeRoche & Lahman, 2008) is the only way to start a cross-cultural research study. Sue who worked on an HIV research project in South Africa explained that:

> The way cross-cultural research is done is you work with your gatekeepers. So we had emic people in the country that were opening doors for us. That had already earned the trust of the institutions that we were working with. So our gatekeepers opened the door for us.

> Of course, the preliminary phase of any cross-cultural research study begins with a game of who-knows-who however, one must consider that some gatekeepers hold different and more power than others do. Brad recalls the gatekeepers for the HIV South Africa research program were white South African males with high social and economic statuses.

I asked Brad if it felt as if the South African founder gatekeepers helped with the resources but not the legality part of the study. Did he believe that to be correct? Brad said:

> Right, so we didn't really know anyone there. Even if we did there, [the South African] IRB is not like ours. I think we were told they don't even have one… so there was literally no one there whom we could put on here [pointing at contact piece of consent form] who could be a reasonably safe contact, but I…we were approved anyway.

Denchai, from South East Asia, believes that:

> The most important part of the cross-cultural content in the sense that let's say the principal at the school is the biggest authority there, so we normally go there. If the principal understands our context then I think everything should be fine, there is no like harm or risk. The participants tend to volunteer to participate.

It is clear from Denchai's statement that knowing someone who has authority at the research site (a gatekeeper) is vital to initially starting a cross-cultural study. Denchai explained that:

> So for example if we go to the school, right, I normally go there and hang out first, you know gaining trust, but normally the school that we go, I kind of know someone there so that, we I kind of be there to building trust and everything and gradually trying to explain what I'm interested in through the gatekeeper.

Lily, an Iranian researcher, advised that:

> Having one person who is both Americanized and also has their own culture and knows about it… like it's coming from the culture, not someone who was born here or something…they wouldn't know exactly about all of those details about the culture probably, so it's good to learn about their culture through somebody who knows.

Lily also made an excellent point about how the gatekeeper and networking coincide, "So if you go talk to someone who is from that community they would also know that group of businessmen so they can put you in contact with them." She also spoke of how knowing a gatekeeper can help in gaining the trust of not only the potential participants but for all those people that may be involved with the study. Lily explained:

> Even if they [the potential participant] won't trust you at the beginning because they trust this person from their community… they trust you to because you're coming through this person and so it can increase the sample size and also it can increase the response rate. So it's good to build up a friendship or professional relationship, a personal level with one of them that is kind of like more open to conducting research and saying "Well I am trying to reach out to this community and these people with this culture so what do you think is the best way to approach them?"

Rebecca also pointed out the importance of gatekeepers saying she was:

> Fortunate enough to be able to engage with refugee students and some of their families, but I [Rebecca] would never have been able to do that had it not been for the teachers of these students. They were trusted members who were considered actively close to the families.

Rebecca believed going through the gatekeepers…"that piece is very central and respecting and understanding… that kind of a little bit of humility on our parts, as researchers."

Building Relationships. Sue explained that "All research is always about relationships, that's how you get access. It does not matter if you are doing quantitative or qualitative. It's all about relationships; it's not a random assignment."

Brad stated, "You could read a million things and still not be prepared, so the next most important thing…is really to spend time building rapport in your participants' lives or wherever you are at." Brad believed that during his research in South Africa, he did not have adequate time to build as much of a rapport with the participants as he would have liked.

> Because we were there for three weeks and we were there to do research that had to be done in that amount of time, so we had to leave after that. That's not an excuse, but I don't think their consent is necessarily completely valid until you become known to those people.

Brad's take on his experience and on being a cross-cultural researcher, in general, is both intriguing and valid. Brad said:

> I don't think it means you have to necessarily go to their house and have tea and get to know them because it did have an ethnographic component, but it was not ethnography. We didn't have time to immerse ourselves in the culture for months and get to know them, but I do think more rapport was needed.

When I asked Brad what he would have done differently, he replied, "In this particular case going to the orphan care center maybe for a week, beforehand, just to get to know them… but not to do any active note taking or interviews or recordings".

Brad learned that a better rapport might have been built if the research team could have been there for a longer duration of time to:

> Volunteer to help, do lots of participant observation…do the dishes, whatever you [they] need [you] to do…and we did some of that, but we mixed it with the immediate data collection which is what we had time for… so I think that was one of the most important things.

Brad believes that one of the most critical things in conducting cross-cultural research is:

> To make sure you are welcome…rapport leads to becoming a welcome member of that community. I have no idea to this day if I was welcome among all of the people. I know the children, of course, but they weren't active participants. Adriana explained that before even presenting the consent form or speaking to her

participants about the IRB and the consent form process:

> I'm very interested in looking at how they [the participant] view their experience. So basically, I talk to them about the idea or point of their research project. So now I am approaching them with an idea, and so I say something like "do you think this is a worthwhile idea to pursue?" and so then I wait and they always say, "Oh yes, it's a great idea." So then I say "okay, so then I will get together everything that I need and then we can start working on this project."

Adriana explained that by building a trusting relationship with research participants (i.e., adolescent students) and their parents then "by the time I talk to them I've already started working on the IRB process, and then I finalize all the IRB."

Cultural Orientation

The next section contains a review of the themes of cultural awareness, reflexivity, responsiveness, and cross-gendered interactions that were identified as major themes in the data. Attentiveness to these themes at the prior and throughout a study support researchers in conducting culturally aware research.

Cultural awareness. Becoming aware of the culture that is being studied is a big part of why cross-cultural research studies are conducted. Awareness starts with a standard link, making something that is foreign in one society more common and familiar. One of the main ethical dilemmas is how to get the word out to the public or in other words disseminate the findings to the public. To inform the public of the situations that are going on around them that they could help with if they were more aware of the situations.

For example, Lily from Iran who was conducting research that involved speaking with Afghanistan refugees, mostly women, had an ethical dilemma in gaining the trust of the refugees enough that they would feel safe to speak about their experiences. When I asked Lily, what was one of the hardest things that she experienced as a researcher of Afghanistan refugees her answer reflected that it was the gaining of the participant's trust, speaking with them, and then trying to disseminate the findings into Iran (her home country). In other words, letting the Iranian people know just what these Afghani refugees were going through, how people could help, and what community resources could be set up and provided.

In one of the research studies, Lily helped conduct, she interviewed the refugees about what they had experienced in their country and now as refugees in Iran. She explained that just listening to their stories and disseminating that information out into Iranian society was hard to do. Lily explained:

> Letting the society know about the problems that they [the refugees] are going through, the circumstances that they have rights here [in Iran], and then trying to provide help for them. Societies are always having judgment like being all judgmental about… what difficulties they have to go through especially because of their culture. Letting society know, kind of like educating both sides about the circumstances and the situation that they are going through... So they were like,

there were some like really difficult cases that we had to deal with that I would just sit down and cry after those interviews. It is hard trying to bring awareness to these types of situations and in helping the refugees and providing resources for them.

Beyond trust, one of the ways that a researcher can demonstrate that they are trying to become more aware and knowledgeable of the prospective participants' culture, beliefs, values, and set of ideas would be to gain awareness of the culture to the extent possible beforehand. Adriana explained that what occurred in her classroom when she became aware that there were inter-gender issues for some of the students (i.e., the women will not speak if a male from that culture is present; the females sit separately from the males). Adriana spoke of how when two of her Pakistani women students:

> …kind of realized that I really wanted to learn and that I was really genuine and sincere in my wanting to learn [to become aware], so they were wonderful to me…. and then I got a lot of information [on Pakistani culture], read a lot.

Gaining awareness of the other culture before conducting a cross-cultural study is vital, and aids in preventing the researcher from offending the people from the other culture.

Such was the case for Sue also when she was conducting HIV research in South Africa. Sue informed me that, as is standard protocol, she had some of the gatekeepers they worked with in South Africa go through the consent forms beforehand to make sure that the consent forms would make sense to the participants. However, Sue recalls that:

> One of the terms we used was key informant…and in Black Post-Apartheid South Africa that word [key informant], is not used the same. They [the gatekeepers] were like, "do you know if you were a key informant they used to disappear, and they never came back. So you have to change that word." It was like I didn't even think about it but the ethics about cross-cultural research is very rich and important and critically important to have ethical research happening.

The term informant is being used less frequent methodologically due to the negative connotation that is attached to that word (Lassiter & Campbell, 2010).

Reflexivity. Brad brought up an excellent point for anyone who collects data with humans. The notion of observing, writing researcher notes, and reflexive journaling is a big part of the research process. One of the things Brad wished that he could have done more of while researching in South Africa was to, "Be reflexive and reflective within yourself so journaling or just thinking actively about how you're fitting into the culture."

Brad spoke more about how researchers can and should be present while collecting qualitative data:

> What did you do during this hour, or during this day that might have come off as a faux pas… or something that you did good or did bad or… how was your interaction with people and if it felt good, why did it feel good?

Keeping a journal while researching can document not just your observations but also can give the researcher a chance to reflect on how that interaction felt. Brad believed that:

> Just making sure that you are being respectful, making sure that you are treating them as an equal, or even more than that because they are really doing you a favor. Even though you always, and especially here [in the U.S.] you think you are doing an evaluation so you think "oh, I'm doing something for them" but this was really kind of invasive in nature, I would say, so making sure that you are respecting them, making sure that they feel dignified I guess and not indignant, I guess.

Responsiveness. For a researcher to become culturally responsive, they must become aware of the participants' cultural traditions, rituals, and customs. This requires the researcher to educate themselves, beforehand, of the participants' way of living. Lily who conducted research in Iran recommends, "Trying to study their [participants']

culture before starting. …the word can get around among them if one of them [a participant] doesn't have a good experience… [such as] getting scared of [some aspect of the research]. …they're going to let the others know." Lily was a student at the time of this interview and was studying in the U.S.

She knew firsthand what if felt like to be part of a small-immigrated population, in this particular case she was recognized as a person in a Persian community in a Western U.S. city. In my interview with Lily, she explained that:

> If one of them [a participant] has a bad experience with an organization or something they would talk about it. Even if they don't mean to inform you... they are getting together for a party and then you are chatting, and they might say something.

This would be a negative consequence for the given study and may indeed put the whole study in jeopardy. Lily highly recommended speaking with a person of that community (e.g., gatekeeper, emic) "to one of them that is more educated or more familiar with American culture so they can help breach between the two cultures."

Rebecca who has worked extensively with minors from other cultures believes that:

> …our job as researchers is to be very mindful of the participants that we're working with and what their cultural backgrounds are. I think we need to be respectful of the home environment, of the condition of minors because not all minors are necessarily in a traditional or a stable living condition. In fact, I have worked with several who are not living with their parents, it's an aunt or uncle or another extended family member with whom they are staying. So, first of all, we need to understand who are the individuals, the participants that we are potentially planning to engage in a research project.

Rebecca believes that it is the cultural responsiveness of the researchers to "communicate directly with participants and their adult family members in that first

language or that there is a gatekeeper who has the trust of the participants and their

families with whom the researcher also has a very trustworthy relationship."

In the interview with Sue, she explained how before starting the HIV research

project she had her group of researchers engage with the emic individuals, many of

whom were also the gatekeepers of the community, in a cultural responsive training

program. One of Sue's goals, being an evaluator, was to involve the emic people in

helping to conduct the research ethically so that they may continue the research after Sue

and her research group left South Africa. Sue said:

> It was a responsive evaluation, so we want them [emic] to be able to collect their
> own data, so we did a two-day training that included ethics. You know, doing
> research, what are the protocols…we taught them how to do that as part of the
> project and then they did focus groups. We taught them how to do good focus
> groups, we had the emic people run the focus groups, and then our researchers
> just took notes.

During the interview, Sue also shared:

> The big lesson…cross-culturally is I should have done much more team building.
> I did all research methods stuff instead of things like team building that I could
> have anticipated. I totally underestimated the need to do massive amounts of team
> building as a part of the research methods prep for a cross-cultural study because
> so much is unpredictable. We also had a team on this side [the U.S. side]
> supporting us while we were there, so it was a really nice model. It was a good
> life-learning lesson.

Brad was a U.S. Researcher on an HIV project in South Africa. His experience, as

he recalls, began well before they arrived in South Africa. Brad recalls that "this [the]

project started in the Advanced Evaluation course and so that whole entire semester was

spent planning or designing what we would do when we got in the country." Brad

received some culturally responsive training by gatekeepers, guest speakers, who came

into the classroom and told them about the culture that they would be interacting with

while in South Africa. What was interesting was how Brad does not recall a guest speaker ever talking about the way the consent process would be conducted on the South African side of the project. Brad recalls:

> We had a guest speaker come in and kind of tell us about the culture… what to do, what not to do to make yourself stand out, but we never, I don't think we ever talked specifically about how consent appears in that culture let alone how it's gained.

Brad concluded that the culturally responsive training the U.S. research team, received was:

> Very much in an American or Western way which was where…you give it [the consent form] to them, you go through it, and they sign it. Whether or not that is welcomed in their culture or frowned upon, I don't know because we don't even know if consent is really a thing that they are aware of. We kind of imposed it, possibly, on them and just, "hey this is what we do, so this is what you are going to do because our board requires it and our ethical boundaries do.

When Adriana was getting ready to teach a group of teachers from Pakistan, she read a lot about the Pakistani culture first. Adriana said:

> I needed to make sure that I structure the program in a way that was successful so… we had a Pakistani student at the University at that time, and I asked her if she could work with me on the project, and then there was a person in the community that also was from Pakistan, and I asked her. So they gave me a lot of information.

Cross-Gender Interaction

Another possible implication that must be considered when conducting cross-cultural research is the cross-gender interaction. While all research that is cross-gender has cultural implications, it is apparent from the data the more removed the cultures are from each other the more gendered interactions needed to be attended to. This was an area of questions asked of the participants in the study to see how, if at all, cross-gender interaction interfered with the consent process.

John explained that cross-gender research might be different depending on the type of interaction the researcher has with the participants. He shared the following within the context of Kuwaiti culture:

> It is the most challenging participants to find in research. There are two ways I believe, the first way if I am talking to an employee and like government based institution I can go directly to the female manager there. She will accept meeting me with no concerns or limitations or reservations because it's a government based.

Next, I asked John, "What if it is not government based, what if it is a private business or a participant from a private sphere?" John responded that:

> Even if it's a private business, let's say…I will go to the head. I cannot go directly to the employees because here [cross-gender interactions] might be seen differently [in one of those settings]. But I have to go, but I'm a male, I am talking, female-to-female…it is easier than male.

When I asked him what happens if the head is a female because you are a male? John stated:

> I have to go to the manager or the top position employer, there, and…if I can interview the employees. She will tell me if she can take the… questionnaire. She will take the questionnaire, and she will distribute and then collect it back to [for] me. This is one way she will go through it, sometimes if the number is big or I have to visit specific people or if I want to interview [female employees} she might let me, she might say "let me ask them first," and then you can talk…[if they] accept, I will send you to them or them to you or meet in the conference room. So this is one way to go through the process.

John went on to explain that if the research participant were from a much more private sphere, such as someone who does not work for an organization, there would be a lot more reluctance. John explained how:

> If I'm talking to like people [females] that are not working, let's say government…those people also they have limitations, they will say, "you know, we don't want to talk to a male." This is one of the challenges, most of the time they will refuse…. But sometimes if I, like say that I know the person, the women and I desperately want to talk to her or want to interview her. I can talk through her husband. I call, find his number through friends, and he [the friend] will give

it to me, and I will talk to him, and he might accompany her during the interview. So we will do it in public most of the time. If it's private, definitely he will be there.

I asked John to explain how it works for female researchers in Kuwait to conduct cross-gender interviews:

> It goes either way; it depends on the research if she is [an] open-minded researcher. I have to clarify something now. Kuwaiti society is a little bit open-minded…more than Saudi Arabia, UAE (United Arab Emirates), Qatar; most of the populations are more conservative then Kuwaitis. Kuwaitis are the most open-minded, and even we have a modern American lifestyle in Kuwait. Our females [are] a little bit more open to it than other females, but my responses would be a little bit open, more than if you asked someone from Saudi Arabia. You will have more restrictions; if you have Saudi Arabia participants or UAE, you will find them more conservative because they are still under the more conservative culture or society.

Then, I asked John does a female researcher need to be accompanied by her husband or other male family members? Would a female still talk to a male that was the head of business? Would she talk to him about talking to the employees or would she have to get a male to talk to him first? John explained how:

> If a female, like my wife, would like to interview in the same situation, I can go with her to support her or she can go through the female. She can go…because she is a researcher also, she asked, and she went by herself, she contacted them, she texted them, even the males. She can meet with anybody. So from my perspective, it's okay. Kuwaiti perspective you will find half will agree with this, the other half, which is conservative, they would say no. They will never give the chance for a female to contact a male. If it's proper conservative family, which they are rooted to Saudi Arabia because Kuwaiti society is basically divided into two, half of them come here from Saudi Arabia as their root heritage. So those people will never, never accept females to contact them.

Basmah is a researcher who was born in Palestine and raised in an Arab culture where students were split by gender. There was a school for the boys and another school for the girls to attend. Basmah pointed out that: "this custom is starting to change in some places but not everywhere. For example, some private schools have boys and girls

learning together in the same classroom, but not in public schools". When I asked

Basmah about conducting research that included cross-gender interaction Basmah's

response was:

> First off, you would just ask someone if they wanted to participate in your study. In most cases, you do not need a form for them to sign. Their word is enough. However, no cross-gender studies in some areas or in some families are allowed, either because they are very strict on girls, or because of their religious beliefs. For instance, in those areas or families woman could not go up to a man and ask him if he would like to participate, but a female could ask a female. However, the male's opinion in the family overrides the female's opinion. For example, if her husband, father, grandfather, or brother does not want her to participate in a research, usually she would not, only in order to avoid problems with him. Arab culture is biased toward the male against the female. The Arabic culture and societies are male dominant. The male is the boss who controls his wife, sister, daughter, and sometimes his own mother. The males in the Arabic world even changed the Islamic laws that came in the Quran in their courts in order to benefit the male and detriment the female more and more.

However, as John from Kuwait expressed, non-cross-gender interaction in

research is not necessarily true for all Middle-Eastern cultures. When Lily, an Iranian

woman conducted research around various regions in Iran she experienced no cross-

gender interaction problems. It is important to note Iranians are often Persian and not

Arabic. Arabs comprise only around two percent of Iran (DaBell, 2013). Lily's research

was also in urban areas. Lily recalls:

> Actually no they just say "You go, girl!" I mean you are doing that study, and it's really good. …I mean I talked to many people, and lots of them were men, and I never experienced any problem. There was just one time that I needed to conduct a study, and it was kind of like [in] a ghetto area, and it was like really, I mean it was late at night, and it was ghetto, so I went with my dad, so he just drove me there, but he sat outside.

Adriana, who conducts cross-culture research, has worked with many different

groups of teachers such as teachers from Pakistan, Latin America, and the Caribbean and

has been able to compare their education system to that of the U.S. Education System.

Adriana clarified that even when in a U.S. classroom setting with students from gender-

segregated cultures such as her Pakistani students:

> Their [the Pakistani students] tendency was to sit separated [by gender], and one of our goals was…for us to promote conversations inter-gender conversation so that they can go back and collaborate, and so we had had to explain it to them [the Pakistani students] and almost get their permission. In class, we like to work with groups, and sometimes that includes gender, mixed-gender, and so they were agreeable to that…. So it was just a process of taking your time and learning about how to program your instruction, and your work, and your research in ways that are not going to be intimidating or break some rules that they have said they still want to try.

Ethical Dilemmas of Cross-Cultural
Research ("Consequences")

On Sue's HIV research study in South Africa, she noticed that the children who

were not orphans did not get the same attention as the orphan children. Sue explained

that:

> They see all the resources going…and that's what we heard from the schools is that, yeah, the unintended consequence of the orphan care project is that now others students want to be orphans because…they see all this fantastic stuff…. So that's another ethical thing because it's another unintended consequence that you try to monitor.

Sometimes the incentive to participate can be too enticing for the participants to

pass up. Although this may be a good way of collecting participants, the data produced

by such participants may not be as rich, or as truthful, like that of participants whose

agenda for participating was not driven by the incentive. DC recalls her experience as a

survey researcher:

> This participant just didn't want to answer anything, and the more I think about it I think that she was really a big heroin user, and that's why she didn't want to answer any of the questions, but she did like want to get the vaccine and the TB test, and they were getting like a reward, like a $5 value reward. …for every person they referred they would get another $5 dollars. So yeah, she didn't want

to answer anything, she said the questions were stupid…I lost my temper, and the interview ended, but she did allow them to collect a blood sample from her….

On another similar research project, DC noticed that:

…it was like $25 for the first interview, and then $10 for the next two interviews, and then another $25. So it's like payouts. I always felt like that was very enticing. …some of the questions were very repetitive because we were trying to triangulate I guess. But, like they [the participant] would be in their jobs, they just want to get their gift card so they would just answer really quickly.

DC explained some questions that she asked participants were of a sensitive

nature. DC recalled:

I would have to ask them some sensitive questions such as I would say, "on the second interview you said you were pregnant and in the third interview, you said you were not. Can you tell us what happened?" Actually, another researcher person had a situation that she called during a time when…the participant's husband was being very abusive and, like, we were not told how to handle that kind of situation.

I asked DC, "How was that situation handled?" DC responded that, "…I don't

think she said much…. She was actually really sad about that, but just stayed with her on

the phone until she stopped crying, but I don't know what I would have done."

**Problems at Different Stages of
the Consent Process**

I reviewed some of the problems, in this section, such as compromised data,

confidentiality, and issues with the consent protocol that occur at various stages in the

consent process.

Compromised data. Compromised data can occur at various stages throughout

the research study (i.e., during the interviews). Qualitative data is based on the richness

and quality of the conversations that go on between the researcher and the participant.

The richer the data is, the better the analysis becomes. An ethical dilemma arose on the

HIV evaluation research trip in South Africa in which Sue was primary researcher. Sue

recalls how she and another researcher felt when one of the translators was not translating

word for word what the participants were saying:

> I remember we had the same thought when I saw the translator go between the interviewer, the translation back to the Grannie, back to the translator. It was like, the interviewer would say one thing, it would get translated, and the granny would say, "oh…blah, blah, blah" then stop and it would be like translated back in two lines. So I know we lost a lot of data. We were all really frustrated about the loss of data due to the translation. Because the Grannie would go on and on and on and then the translator would say three sentences and one of our researchers was like, 'no, I know there is more,' and he was so frustrated cause he couldn't say anything.

Brad brought up an excellent point when it comes to the collection of qualitative

data. Brad recalls that the South African people with whom he was working:

> Speak it [English] very well, but we don't know how well they read or write it. How do you judge that or how it translates into Western lingo and concepts? And so would translating it into another language be appropriate or does it not translate and how do you gauge that the translation is appropriate because we didn't have anyone to translate it or whom we could trust to translate it thoroughly and appropriately.

So having a trustworthy translator is vital in enhancing the reliability of the data

that is being collected during a cross-cultural interview in which there is a language

barrier. Case in point, Adriana who told how data could be compromised by getting "lost-

in-translation" if the culture is not easy for the researcher to interpret and share; even sub-

culturally, these misinterpretations happen. Adriana said:

> So I think in interpreting the results as researchers…in order for you to be able to interpret what other people are telling you, who may not share your same culture, you almost have to understand the way they interpret the world so there's always the risk in going cross-culturally and doing research, because you may not interpret the results, what they're telling you, in the same way, that they meant to. This is why this going back and member check, and "is that really what you meant?", or you know asking colleagues that are/ share the same culture or even asking participants who are similar because I think there's a great risk in misinterpreting what people tell us, I mean we do it within our own cultures.

Confidentiality. Research ethical issues surrounding confidentiality occur when the information that is given can be used to identify the individual. In qualitative research, this information may be in the form of a quote or comment in the researcher's write-up. The ethical research issues that can occur when dealing with a cross-cultural participant's identity can be found to be atypical by U.S. IRB standards. Denchai, who sits on his University's research ethics board, had an interesting ethical dilemma when it came to using one of his participant's real names instead of pseudonyms. Denchai said:

> From a participant perspective, I can see that in the United States they would be very comfortable understanding the informed consent…but the participant from [the] cross-cultural context I can see that might be problematic. So in some cross-cultural context, the participant wants to be acknowledged so sometimes they don't want to use a pseudonym. Sometimes they want to use their real name because they feel that they want to be acknowledged. For example, the participants here may say, "I don't understand, why do I need to use a fake name, is it going to be dangerous?"

Illustrating an opposing concern is an experience that occurred during John's dissertation research. He had one participant that was concerned with the confidentiality. John remembers:

> What he said about the data because he was a coach in a club. I did tell him once…he trusted me, but he was worried that his opinion about the club [soccer] would be exposed. He was totally secured I told him, I follow the American procedure, I was not following the Kuwait procedure…. We have to provide all the information, so this was only the coach… he asked about the confidentiality issues and in his opinion would he be exposed from our relationship, because he knows a little bit about how our culture over here [in Kuwait] how it works... I told him to trust me this is something. I don't know anybody in the club. And this is all confidential, and it's the American system. And he answered, very well, my questions; he was very good at his responses.

A common ethical issue that occurs at the data collection stage is that the

participant has some type of identification that links them to their data, which is a breach

of confidentiality. DC noticed such a breach when working on a massive research study

for a state university:

> I was mostly in charge of collecting the data but when I was in the [study] with the birth control…what we would do is we would scan the survey because the PI's were in [another city]. So they would analyze the data there because they wanted us to focus on collecting the data. What I did notice in that study is that sometimes we were supposed to keep the information separate from the survey data, so they're not supposed to be linked and that turned out to be really hard sometimes. So you could see a trail or link on what participant filled out the study. It was easy to follow who like F29 was in that study especially because we also had to send them gift cards.

Issues with the consenting protocol. Several of the issues with the consenting

protocol came from the consent form itself. The length, the language used, and the

requirements that stem from an individual's culture that must be addressed in the U.S.

IRB are problematic. For instance, Lily a researcher from Iran spoke of how long the

length of the U.S. IRB form can be and how deterring that could be for a potential

participant**.**

> I really do think that these consent forms are necessary everywhere because I know there are some places where they don't do it at all, and it hurts the population of people and the information that the people provided has been used against them, so it's very important to have it. It's just like how to do it in a more efficient way, and that is the part that is the problem. So I mean I think that trying to keep it efficient, shorter, making sure that all the areas are being addressed, and the participants are being informed about all those things because I'm sure once we conduct our research we care about finishing up that research and they say "well, I'm never going to share it with others.", but I mean you never know what's going to happen to the data, and so I think it's very important to consider the rights of the participants, especially when they trust people and they want to contribute to the body of the research.

Rebecca whose research involves studies with bilingual youth spoke to me about

two issues with the consenting protocol:

> First, you're dealing with minors, so you need a consent form first in English that is accessible enough for an adolescent to understand and then you probably also need a consent form for parents in Spanish as well. So we would always do both consent forms in English and Spanish. I'm proficient in Spanish so I would always do those translations as well, in Spanish. Interestingly, there is nobody in IRB that can tell whether those consent forms are actually legitimate or not.

> Next, I asked Rebecca, "So you're saying there is nobody looking at it saying, 'hold on there?'" Rebecca replied that:

> We don't have any institutional…as far as I know, pretty certain we don't, and any institutional capacity to check the veracity of what's in a consent form in a language other than English and that might be an issue.

In all likelihood, many IRBs do have bilingual professors on their review boards

and certainly in their employment, such as the one at my university does. The point is that

it is not part of the federally mandated review process to check the translation. However,

Rebecca does make an interesting point that there is no sure way to ensure that those on

the review boards are capable of making sure that the consent form not only translates

into the second language correctly but that the context of the language fits culturally. An

even greater issue is that the majority of U.S. IRB review boards have such small and

limited budgets that languages that are more uncommon in the U.S. have no one on the

review boards that can check that the language is appropriate which leaves the accuracy

and the appropriateness of the language contained in the consent form entirely on the

researcher.

Due to Sue's issue of having no research ethics board on the South African side of

the research to work with, Sue had a difficult time trying to get her University's IRB to

understand her research situation and to accept her proposal for the study.

> I remember specifically that the consenting protocols were so hard to get it through IRB that it was like the day before we were supposed to [conduct] the interviews we finally got our approval. I mean we were sitting in South Africa trying to get the email back from the Associate Vice President of Research back at our University right before we were supposed to start our interviews.

Like Rebecca, Adriana finds that the translation of the IRB consent forms from English into another language has no validation from the University's IRB board. Adriana believes that:

> When you're speaking to people who are not speakers of English and the way that we go about translating or sometimes also makes it a lot more disconnected from their world so that the nature of how we have to follow this IRB… format, it's a foreign format for many people…it is formatted for English speakers, and so sometimes we as researchers create documents that are intimidating."

Denchai agrees that when he has been a participant in a cross-cultural research study "if it is too long [the consent] it's...for me as a participant I feel like this is, like too long but this is what we have to do from the standpoint of the researcher from the United States, so if you can shorten the length that would be awesome, I think, from cross-cultural research."

The findings from the in-depth interviews delivered valuable insight into some of the issues that currently exist within the U.S. IRB consent form process. Participants from this study offered global-wide responses as to how the consent process works in their home countries compared to in the United States. Along with emerging themes trust, cultural orientation, cross-gender interaction, and the consequences that result from conducting a research involving human participants were presented. The findings and themes that emerged from these in-depth interviews are discussed further in Chapter V along with concluding remarks and recommendations.

Summary of Chapter IV

In Chapter IV, the study's findings were discussed. The seventeen in-depth interviews that were obtained from the participants were transcribed and then used in conducting the thematic analysis. The findings were then further organized into two broad sections: (a) the themes that emerged that answer the research questions, and (b) the other salient themes that emerged while conducting the in-depth interviews.

Themes such as the Gaining of the Participants' Trust, Signing the Consent Form, Gaining Consent from Vulnerable Populations, Working with Participants' from Undocumented Populations, and Other Cultures Research Ethics Boards' Standards emerged from Research Questions 1 – 3. The other salient themes that emerged were Trust, Cultural Awareness, Reflexivity, Responsiveness, Cross-Gender Interaction, Ethical Dilemmas of Cross-Cultural Research (Consequences), Problems at different stages of the consent form, Problems at Different Stages of the Consent Form.

These findings are discussed further in Chapter Five, leading to possible recommendations that could be made in an effort to help lessen the ethical dilemmas that occur in cross-cultural research studies.

CHAPTER V

CONCLUSION

Chapter V addresses (a) the richness of the data collected, (b) the discussion of major findings from each research questions and the other themes that emerged, (b) conclusions, and finally (c) recommendations for change and future research.

The aim of this study was to explore the shared experiences of researchers and participants as to the cross-cultural ethical dilemmas that exist when it comes to the informed consent process. A qualitative in-depth interview methodological approach was taken to offer insight into the development of more culturally responsive methods of negotiating cross-cultural consent and on how to establish and maintain positive rapport cross-culturally.

Therefore, the rationale as to why this study was conducted was to gain a better methodological understanding of the cross-cultural ethical dilemmas that exist regarding the consent process.

Based on the literature review and theoretical bases on individuals' perceptions and interpersonal interactions, I attempted to answer the following research questions:

Q1   What are possible cross-cultural implications of participant consent and how might researchers enact informed consent across cultures?

Q2   How are competing ethical values, in human research, negotiated in cross-cultural research?

Q3   When it comes to consent, how should competing ethical values in cross-cultural research be addressed (negotiated)?

Q4   How does the data collection process, experienced during this research study, compare between the in-person method and the computer-mediated method?

Q5   How well do participants understand consent directly after the consent form has been given to them in an interview setting (i.e., computer-mediated communication (CMC) vs. in-person interviews)

Discussion of Major Findings from each
Research Question

Richness of Data Collected

The richness of the data collected during the interview stage is highly dependent upon the interviewer's approach. If the interviewer is not found to be open, inviting, and interested in what the participant has to say, then the participant will not feel as inclined to divulge as much information on a given subject. Like Merriam stated, "In-depth interviews are a powerful method for generating description and interpretation of people's social worlds, and as such are a core qualitative research method" (2015). Therefore, when collecting the data, I utilized an in-depth interview methodology that relied on the effectiveness of the interviewer as well as the technology used. During the current study, I felt that it was harder to engage with the CMC participants. Even though the participant's face was visible on the computer screen, and we both were respectful in giving our undivided attention to one another, I still found that it was harder to interact with the CMC group of participants. Body language says a lot, especially when talking with individuals. These types of cues may be even more important when the researcher and the participant do not speak the same first language. So when asking some of the more abstract questions I found that it was hard to tell if the participants understood what

I was asking. Whereas with the in-person group of participants I could tell if some of the questions were not understood and could then ask the question again in another way that helped to clarify my question.

Interestingly, the length of time it took to interview the CMC participants was approximately the same length of time as it took to conduct the in-person interviews. Therefore I concluded that the amount of data collected from both types of interview methods (e.g., the CMC interviews and the in-person interview methods) was approximately equal. After conducting the analysis using NVivo, the data collected utilizing the CMC method was found to be as rich in data saturation as the in-person method. Therefore, one of my findings was that the CMC interviews felt awkward for the interviewer, more distant and not as connected, but this had little effect on the outcome of the data collected.

Research Question One

Enacting informed consent across cultures involves gaining the participant's trust. For most participants, gaining trust between researcher and participant is more important than signing their name on the consent form. When it comes to the signing of the consent forms, various cultural reasons and circumstances make the signing phase problematic. It is important for Western researchers to understand not all cultures engage in signing paperwork as frequently as they may have experienced. For instance, as previously discussed in Chapter II, some of the possible implications that make gaining a signature from a participant problematic can be due to the participant's lack of trust in the researcher.

Checking that a participant continues to be willing to consent to participate in different phases of the research can be termed as process consent. Process consent, as previously stated, is when the researcher checks with participants through the entire study to make sure the participant remains comfortable (Lahman, Mendoza, Rodriguez & Schwartz, 2011). Consent over time is one way of establishing trust in the informed consent process in cross-cultural research that requires more than one interaction between the researcher and the participants.

Signing and gaining consent becomes even more problematic when the research involves studying participants from a vulnerable population. As presented in Chapter Four, participants from vulnerable populations can be difficult to find (Roche et al., 2018).

The other issues that were presented by the participants that were problematic were such things as stakeholders being gatekeepers and working with participants who were doing something illegal in which a CoC was needed.

Research Question Two

Focus on the culture of the participant should be the priority when conducting a cross-cultural study. This means that gaining informed consent from cross-cultural participants should be focused on their understanding of their rights as a participant, any foreseeable risks for participating, and finally what the study is asking of them. As discussed previously in Chapter II, (Ruiz-Casares, 2014a) stated that the value of verbal agreements often outweighs that of written consent, and the very act of requesting signatures could create mistrust and the misperception that participants are entering into binding agreements in which they will not be able to withdraw.

Several participants from the current study discussed that in their cross-cultural studies, their participants do not even bother with looking at, let alone reading, the U.S. IRB consent form. They signed the form only because of their trust in the researcher. This means that the consent form, regardless of what is written in it, becomes a symbol of trust, not a contract that means the participant necessarily understands and consents. So with that understanding, what does the consent form actually represent? Who is it actually for and what meaning does it represent?

Making the U.S. IRB more accommodating and suitable for the culture in which the participants are from would bridge the gap between the participants' understanding and the researcher confidently gaining consent. Distinctions between cultures can become more flexible and accommodating by learning how consent is gained in the participants' culture and honoring that, such as in Eastern cultures where verbal agreement and verbal understanding of the study is more important than what is written in the consent form. Therefore, the reading and signing of the consent form should be second to the researcher verbally describing to participants what the study entails and gaining the verbal agreement of their understanding before proceeding in asking them to sign the required IRB consent form. The same accommodations should be made for sub-cultures such as participants that are visual learners. By making the consent process visual, such as in a video, the researcher could help the participant in their understanding of their rights as a participant, any foreseeable risks, and the main objective of the study.

As was described in Chapter II, there are various research studies that have shown the depictions of research aims, methods, and procedures through the use of photographs, pictures, diagrams, and even film to help render the research coherent, ethical, and to give full contextual ways that augment written documentation (Adams et al., 2007).

Research Question Three

When it comes to the consent form in cross-cultural research that involves different languages, not only should the consent form be translated into the participants native language, but it should also reflect the participant's cultural influences such as regional backgrounds, ethical beliefs, and other aspects that make up how the participant understands and converses with the researcher. The consent form should be understandable and written for the participants' culture, not for the 'Academic Culture'. Just as described in Chapter II, Bhutta (2004) stated, "Even in regions with adequate literacy, there may be a poor understanding of the nature of the research" (p. 273).

Research Question Four

When I compared the quality of the audio recordings of the CMC interviews to that of the in-person interviews, I found the quality of the CMC recordings to be subpar to that of the in-person interviews. The CMC interviews were all recorded using a Skype recording feature and on my personal recording device, a deactivated cellular Samsung Galaxy s5 with a recording function.

The computer and other technology (i.e., digital audio recording devices) that I utilized for the CMC interviews were not the best to work with and slowed down the transcribing process. Even so, I found the additional Skype recording applications

(i.e., mp3 Skype recorder and Irecorder) not to be reliable. During the CMC interviews, I utilized one of the additional Skype recording applications named above as well as using a recording device on a deactivated Samsung Galaxy s5. The Skype recording application failed to pick up each interview clear enough to transcribe the interviews using the Google Docs talk-to-text tool.

Research Question Five

The understanding versus comprehending of the consent form could be broken down into two observations that I made when I asked the participants questions about the consent form and about this specific study. All of the participants understood and were familiar with their rights as a participant and the benefits or risks that may be involved in participating. However, when I asked questions specific to the study such as "why am I conducting the study" the communication challenges became apparent.

As previously stated in Chapter II, Leong and Lyons (2010, p. 255) reminded scientific audiences that there are still "no processes associated with obtaining informed consent that is concerned with participants' actual understanding of their obligation or implications associated with participating in the project".

There was difficulty in explaining that I was asking questions regarding my research in particular, such as, why is this particular study being conducted? This question was confusing to the participants even though it was on the first page of the consent form that was given to them. They could still have looked at the consent form, and they were either seasoned researchers or people with a high level of research training. In theory, I believed that this line of questioning to be very simple for a participant to comprehend and answer, but the implementation failed.

The power dynamic between the researcher and the participant appears to be where the researcher has control. The researcher asks the participants a line of questions and the participant looks to the researcher for guidance and direction on the questions asked. In the current study, it seemed as though most of the participants consented to be in the study without thoroughly reading the consent form. It was also obvious from the way participants responded to this line of questioning that they were looking to me for cues as to the correctness of their response.

Other Themes That Emerged

Other frequent themes that emerged out of the data included trust, cultural orientation, cross-gender interaction, ethical dilemmas of cross-cultural research (consequences), and problems at different stages of the consent process. These themes are broken down and discussed in the following sections.

Trust

The trust between the researcher and the participant is crucial in any research. In order to find participants that fit the sample criteria, researchers must find and become familiar with gatekeepers for access to participants. The findings from this study suggest that the researcher should keep in mind that gatekeepers hold different levels of power within the community and that gaining consent does not happen without first gaining the participants' trust. Every institutional ethics board differs, as we saw with the South African example where one of the gatekeepers was also a stakeholder.

Cultural Orientation

Cultural orientation includes three categories, including cultural awareness, reflexivity, and responsiveness.

Cultural awareness. Awareness in cross-cultural research includes becoming aware of the participants' cultural values, ethical standards, and how they conduct research. As cited in Chapter II, the knowledge a researcher must possess needs to go well beyond the "mere awareness of, respect for, and general recognition of the fact the ethnic groups have different values or express similar values in various ways" (Gay, 2002, p. 107).

Reflexivity. The notion of reflexivity includes observing, writing researcher notes and reflexive journaling and can help the researcher become self-aware of thinking actively about how they are fitting into the culture. Journaling while researching can help document not just the observations of the researcher, but also can give the researcher a chance to reflect on how interactions felt.

Responsiveness. The researcher can become more culturally responsive by becoming aware of the participants' cultural traditions, rituals, and customs. Responsiveness requires the researcher to become educated on the participants' way of living beforehand (culturally responsive training). As discussed in Chapter II, cultural responsiveness requires an affirming attitude toward cultural differences (Villegas & Lucas, 2002).

Cross-Gender Interaction

It was apparent from the data collected that the more removed or foreign the cultures are from each other, the more to which cross-gender interactions needed to be

attended. Researching with cross-gender interactions might be different depending on whether the interaction is between a professional or in a professional setting or the participant is in a private sphere or population group.

As discussed in Chapter II, there are several reasons why women in cultures where the male must give permission for their wife to participate would want to participate but cannot sign the consent form (Marshall, 2008; Molyneux, 2005; Ngare, 2007).

**Ethical Dilemmas of Cross-Cultural
Research (Consequences)**

Some of the participants spoke about how their own research caused ethical dilemmas that were not apparent to the researchers until after the study had been concluded. The consequences include incentives to participate that were too enticing for the participants to pass up. Thus, the data produced may be more agenda driven than accurate. In addition, resources brought in by the researcher(s) may be disrupting and isolating to others in the community. For example, the research that was conducted in South Africa on HIV orphans brought in resources that were only given to the orphan children being observed in the given research study, isolating the non-orphan children who were not in the study.

**Problems at Different Stages of the
Consent Process**

As cited in Chapter II, ethical dilemmas that make gaining informed consent from cross-cultural participants problematic include issues of confidentiality, the pressure to

participate in the research, lack of comprehension and understanding of the consent, and language and literacy barriers (Killawi et al., 2014). All of these ethical issues came up in the interviews I had with the participants in this study.

One of the topics of main concern involved ethical issues that affected the richness of the data. Based on the quality of data collected from the participants, the richer the data is, the better the analysis can become. One such ethical issue that was discussed that can jeopardize the quality of the data collected is when an untrained translator is used. A trustworthy translator is vital in enhancing the reliability of the data that is being collected. However, there is still no foolproof way of telling that the translator has translated all of the information between the two parties.

Another ethical issue that can occur at the data collection stage is when the participant has some type of identification that links them to their data, which is a breach of confidentiality. As pointed out by Denchai in Chapter IV, in some cultures the participants want to use their real names because they want to be acknowledged for their contribution. Although using one's real name in research is uncommon, participants should be and are allowed to use their real names.

Issues with the consent form such as the length, the language used, and the requirements that stem from an individual's autonomous culture that must be addressed in the U.S. IRB are problematic. In U.S. IRBs, the language used in the consent form is very formal, and in that formality, we sometimes obscure what is the actual goal. Participants understate what is included in a written consent form when it is too long in

length and the writing is too formal. Even when the U.S. IRB consent form is translated into another language, it is usually still formatted for English speakers, making the consent form seem intimidating or confusing.

As previously stated in Chapter II, in September of 2015, a revision to the Common Rule suggesting a shorter informed consent form was proposed (U.S. Dept. of HHS, 2015). Currently, I believe that the Clinical Trials Transformation Initiative (CTTI) is working on an Informed Consent Project that is still in development. Yet even with a shortened consent form, many times there is not anyone on the IRB board who can read the consent forms to check for interpretation accuracy when they have been translated from English to the participants' language. So errors in translation and interpretation will still go unchecked unless the IRB develops a way of checking the consent form has been condensed properly into two pages, and not only has it been transposed into the participant's first and primary language but with the participant's cultural and regional language influences attended to also.

Conclusions

The concluding remarks directly related to the findings from the research questions and other major themes are presented. These remarks also relate directly to the significance of the study.

Findings from the Research Questions

Question One. Enacting informed consent across cultures involves gaining the participant's trust. Building a relationship beforehand with research participants can help

in building rapport and trust, but requires a lot of resources. Time and money drive all research, and relational research is time-consuming, even more so when culturally complex.

Question Two. Focusing on the culture of the participant should be the priority when conducting a cross-cultural study and when creating the consent form. The limitation in cross-cultural studies that was discussed the most in the interviews was the length of the U.S. IRB consent form. Many believe that all that is needed can be written in two pages or should have a limit of two pages. It was also evident from speaking with the participants that more often than not participants are speaking with the researcher as a favor to the researcher, not because they are adamant about the study itself. Researchers should keep this in mind when conducting cross-cultural studies and should give incentives that are attuned to the participants' culture.

Question Three. The consent form, even when translated into the participants' language is still written from an academic culture context. The consent form should be understandable and written for the participants' culture, not for the 'academic culture'. The first interaction with participants should be speaking to them about how the researchers appreciate how they are willing to speak with them, and giving the participants some context to why their contribution would be invaluable to the study. This could occur in a short oral summary of why the study is important, and then if the participant would like to contribute.

Question Four. The quality of the audio recordings was best with the in-person interviews. As for the method and technology, there was no real difference in the data quality. This study's findings indicated that the CMC interviews felt awkward for the

interviewer more distant and non-connected, but had little effect on the outcome of the data being collected. The researcher's recording technology made the in-person recordings easier to transcribe than the CMC interviews.

Question Five. All of the participants understood and were familiar with their rights as a participant, and the benefits or risks that may be involved in participating. However, when they were asked questions specific to the study, such as the reason the study was being conducted, the communication challenges involved in consent became apparent. Establishing consent is not as critical as the relationship that is established between the participants and the researcher. In the power dynamic, participants quickly assume the supporting role and take direction from the researcher. What is not widely understood is that the participants are the ones that control the power in the room and the power between the interviewer and the interviewee.

Other Major Themes

Trust, cultural orientation, cross-gender interaction, ethical dilemmas of cross-cultural research (consequences), and problems at different stages of the consent process were the other major themes that emerged through the findings in the data.

Trust. The trust between the researcher and the participant is crucial in any research. The findings from this study suggest that the researcher should keep in mind that gatekeepers hold different levels of power within the community and that gaining consent does not happen without first gaining the participants' trust.

Cultural orientation. Cultural orientation includes three categories, including cultural awareness, reflexivity, and responsiveness. Cultural awareness involves becoming aware of the participants' cultural values, ethical standards, and how they

conduct research. Reflexivity includes the notion of observing, writing researcher notes, and reflexive journaling, and can help the researcher become self-aware of thinking actively about how they are fitting into the culture. Cultural responsiveness requires training the researchers before they interact with participants on the participants' ethical standards, values and anything else pertinent to conducting the consent and interview processes. Culturally responsive training should include the way the consent process is conducted in that culture. It is essential that the researcher be well trained in these three categories before starting the cross-cultural data collection process.

 Cross-gender interaction. Findings from this study indicated the more removed or foreign the cultures are from one another, the more cross-gender interactions needed to be attended. I believe that special circumstances should be given in cases where the male of the household must sign for their wife to participate. Let the husband's signature suffice for his wife's written consent while gaining her oral consent, or let the wife consent without having to sign. In Western culture, we see this as an opposing factor and feel that the participant's willingness to be in the study may not be voluntary. However, this is still a Western problem to an Eastern approach; if we can find a way to justify why it is okay to collect signed consent from a cognitively impaired individual, or from a parent without the assent of their young child, then I believe we can find a way to justify collecting from spouses in cultures with opposing values to that seen here in the U.S. (This would allow additions to IRB guidelines on documentation of informed consent in 45 CFR 46.117.)

Ethical dilemmas of cross-cultural research (consequences). Cross-cultural research can cause post-research ethical dilemmas. These consequences include incentives that disrupt and isolate those who are not in the study, or that are too enticing to pass up. The consequences derived from these ethical dilemmas can have an effect on the data collected. The data produced may be more agenda driven than truthful.

Problems at different stages of the consent process. Breaches of confidentiality, an ethical issue that occurs at the data collection stage, is that the participant wants to keep their real name, a breach of confidentiality. In some cultures, they participants feel honored to contribute their experiences or opinions in a research study, and therefore want to use their real name to be acknowledged. I believe that participants have the right to use their own names if they would like, but I believe that measures should be taken to ensure that the participants have no other links to identify them. Issues with the consent form such as the length, the language used, and the requirements are all problematic areas. The U.S. IRB consent form uses primarily 'Academic Culture' language, and in that formality, we sometimes obscure what is the actual goal of the consent form. In particular, we obscure that it is a contract representing the participant understands their rights as a research participant. Unfortunately, from the findings of this study, it seems that most cross-cultural participants would rather sign without reading the forms. So how does getting them to sign really demonstrate that they understand?

Recommendations for Change

Funding for IRB in institutions is minimal, yet the requirement for research institutions to have IRBs are mandatory when conducting research that involves humans.

This puts a lot of stress and responsibility on review board members that also hold full-time positions outside of being on their institution's review board. These are professors and University staff that make the time to give back to their campus community. I fully believe that if there was more funding for board members to add additional checks and balances within the IRB process, then some of these recommendations would be given more consideration for change.

Recommendations for change concerning the issues with the consent form such as the length and the language follow, as well as recommendations for resolving conflicting cross-cultural research values and issues between the researchers and participants. Finally, recommendations for changes to the U.S. IRB process and methodology are presented.

Length. The length of the consent form should be limited to two pages for easier readability. Two pages in simple language should be adequate for presenting the participants with a brief description of the study, benefits, risks, confidentiality, the voluntary nature of the study, contact information, and statement of consent.

Language. The consent form should not only be translated into the participants' language but also composed with the participants' cultural and regional influences in mind. Academic culture language should be strictly avoided for any study that is not of high-level academics.

Even when translated into the participants' language, the consent form is still written for an academic culture. Much of this language is required to be in the consent form; therefore, I believe a brief summary of how the researcher intends on explaining the consent form orally to the participant should be included.

Research values. The data indicated the more removed the cultures are from one another, the more cross-gender interactions needed to be attended to. I believe special circumstances should be given in cases where the customary culture is that a male spouse or father must sign for their female participant. In scenarios where the participant(s) would like to use their real names, I believe that this should be allowed, but the researcher should take extra measures to ensure that other identifying characteristics be stricken when it comes to these participants, such as their location.

Issues between the researchers and participants. It is essential that the researcher be well trained through cultural orientation before starting the cross-cultural research data collection process and should be made a requirement.

I. Cultural Awareness- Starts with a standard link, making something that is foreign in one society more common and familiar.

II. Cultural Reflexivity- Such as keeping a journal while researching can help you to document not just your observations but also can give the researcher a chance to reflect on how that interaction felt.

III. Cultural Responsiveness- Requires the researcher to educate themselves, beforehand, of the participants' way of living.

IV. Cross-Gender Interactions – The more removed the cultures are from one another the more gender interactions need to be attended.

Changes to the United Stated Institutional Review Board process. IRBs approve research studies but seldom check on a study. Where is the reliability that studies are being carried out in accordance with what their IRB has accepted? There should be

some check that consent forms have not only been translated into the participants' native language but also composed taking the participants' cultural influences on language into consideration.

Methodology recommendations. The quality of the audio recordings was best with the in-person interviews. As for the method and technology, there was no real difference in the data quality, although I firmly believe that a researcher should use two recording devices when conducting an interview. So many factors can complicate the sound of audio recordings. For example, in-person interviewers should ensure that the audio recording device(s) are close enough to both the participant and interviewer so that a clear audio sound is recorded. Sound checks of the room or environment in which you wish to record in should be conducted before meeting with the participants. If possible, using the same location and room for all in-person interviews can decrease the chances of environmental factors affecting the audio recordings. CMC interviews follow much the same line. Using the same location can decrease the chances of environmental factors affecting the recordings. Technology challenges are the main concern when conducting CMC in-depth interviews. Making sure that the microphone is working correctly before each interview should be mandatory to decrease complications during the interview.

In addition, sound checks should be conducted before each interview to ensure that the recordings device(s) can pick up the participants' voice enough that it is coherent during the transcribing phase of the study.

Transcribing takes the most time in an in-depth case study process. To date (2018), there are several different transcribing software packages on a wide price range

(e.g., $$-$$$$). I used free transcription software (Express Scribe Transcription Software) that allowed me to slow the participant's words on the audio recording down while I transcribed manually.

Furthering Culturally Complex Research

There is much to learn about culturally complex research. Studies on the topic of cultural complexity should be of importance to any researcher wishing to conduct research involving human participants. It is important that the horrendous events that have plagued the history of human-based research remain in the past (Landram, 2018). Such historical events as the Nuremberg Trials after World War II, the Tuskegee Syphilis Experiments that went on for decades in Alabama, and the misuse of the Havasupai Indian Tribe's blood samples should be used as examples as to what constitutes bad research practices of the past.

Future endeavors that may stem from this study would be in the areas of understanding how to gain true consent from research participants. Certain aspects discussed in this study were directed towards notions of how and when do we know true consent has been gained from the participants. Participants seem to trust in the individual more than they do in a given institution especially individuals who are unfamiliar with a research consent form. This was a general response heard from many of the participants of this study. Therefore, a closer examination of this phenomenon should be conducted. How cultural orientation fits into the practice of cultural humility is another area of interest in which I wish to pursue. Culturally complex research practices such as the ones mentioned above are all aspects that a cultural competent researcher should possess. Such aspects can help contribute constructive and critical knowledge for a greater cause. The

findings and recommendations from this research, as well as similar research studies that examine the cultural complexities that exist, can help to further cultural responsive research practices the impact of which could, someday, result in a wider span of such knowledge being taught to novice researchers. To think that one-day social researchers just starting out could be trained in the practices of cultural responsiveness, cultural orientation, as well as cultural humility is a large step forward in the right direction.

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APPENDIX A

DEFINITION OF TERMS

Definition of Terms

Common Rule - The basic ethical principles of conducting human research are collectively known as the 'Common Rule' (Federal Policy, n.d.).

Culture - is the beliefs, customs, arts, etc., of a particular society, group, place, or time.

Cultural Competence – is a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals and enables that system, agency, or those professionals to work effectively in cross-cultural situations (Cross, Bazron, Dennis, & Isaacs, 1989, p. 13).

Cultural Relativism - is the view that all beliefs, customs, and ethics are relative to the individual within his own social context. In other words, "right" and "wrong" are culture-specific; what is considered moral in one society may be considered immoral in another, and, since no universal standard of morality exists, no one has the right to judge another society's customs.

Cultural Responsiveness - when the researcher is aware of and responsive toward their own and the participants' traditions, rituals, ways of life, and customs then they are considered to be (Lahman, Geist, Rodriguez, Graglia, and DeRoche, 2010).

Data Saturation - entails bringing new participants continually into the study until the data set is complete, as indicated by data replication or redundancy (Bowen, 2008, p. 138).

Ethical Imperialism – is an ideology that there is one universal moral standard, regardless of location or culture (Schermerhorn, Hunt, & Osborn, 2000).

Ethics – is a system of moral principles or rules of conduct recognized in respect to a particular class of human actions or a particular group, culture, etc..

Member Checks - a technique that consists of continually testing with participants the researcher's data, analytic categories, interpretations, and conclusions (Lincoln & Guba, 1985).

Morals – refers to the generally accepted customs of conduct in a society, and to the individual's practice in relation to these customs.

Peer Reviews - are based on the same principle as member checks but involve the researcher discussing the research process and findings with impartial colleagues who have experience with qualitative methods (Krefting, 1991).

Social Norms – Pattern of behavior in a particular group, community, or culture, accepted as normal and to which an individual is expected to conform.

True Informed Consent - True informed consent can only be obtained when the researcher can ensure that the participant understands as well as comprehends: (a) the context of the research; (b) that the participant has not been pressured by anyone else to participate; (c) the appropriate protocol for obtaining their consent has been approved by both culture's overseeing research review boards; and lastly, (d) that the participant has given ongoing consent throughout the research process.

APPENDIX B

STRUCTURED INTERVIEW QUESTIONS

Structured Interview Questions

Thank you for your participation in this qualitative study in which the main interest is to gain a better understanding of the informed consent process. In a typical study, we would start with the consent form and proceed with the interview questions after gaining your signature, marking your agreement to participate. However, due to the nature of this study, I would like to go over the consent form with you at the end of our interview session. After which I would like to ask you some follow-up questions on the consent form itself.

If it is okay with you then I would like to start the interview questions, now, starting with any background information, you feel like sharing, with me, on your experiences in research (if you have a lot of experiences please focus on the ones that you consider to be cross-cultural).

- If I realize I need to explain what cross-cultural is then, I will say, the researcher is from a culture which is different from the participant.

For example, people may be different culturally due to nation, race, ethnicity, religion and many other reasons. This may be in the same country such as a white, US researcher and a participant who immigrated from the Horn of Africa or two different countries.

1. Please share with me:

For former researchers ask:

- o Type of study- was it a qualitative or quantitative study, what method was used?

- o What was the purpose and rationale of the study?

- o Please describe your sample? (N, demographics, etc.)

- o setting (e.g., geographic, cultural, economic status of participants)

For former participants ask:

      a.   Was the study based on interviews or did you fill out a survey?

      b.   What information were you given on the purpose of the study? Such as why were the researchers doing the study?

      c.   Do you know what the researchers were trying to achieve from conducting the study?

      d.   Where did this study take place? (e.g., geographically, culture of participants)

2.   Can you please describe to me how consent from participants was gained? If I realize I need to explain what consent refers to in this instance, I will say, it is the permission given by an individual or on the individual's behalf to do something. For example, agreeing to take part in a research study.

For former researchers ask:

- How did you go through the consent process with each of your participants?
  - …did you read it to them?
  - …hand it to them to read?
  - …or other?
- Did you gain consent from each participant before, during, or after their participation?
- Did you have the participant(s) sign the consent form or did you gain consent in another way?

For former participants ask:

- Did the researcher explain what was on the consent form to you?

    o If yes- was it before, after or sometime during your participation?

- Do you remember what information was on the consent form?

- Did you understand the information that was on the consent form?

- How did you consent or agree to participate in the study? (Signature,

someone else's signature, verbal agreement, etc.)

3. How is consent established in your culture?

    o For example, through signature, verbal consent, another person

- Does another person consent for others in your culture (e.g., women,

elderly, severely mental handicapped)?

- When it comes to consent, are you aware of any differences that exist in

    your culture that differ culturally from this one?

    o For example, what is the age of consent for marriage, age of

    consent to legally sign documents, can women consent?

4. Are you aware of when you first became mindful of this existing difference

between your culture and others?

5. How are cross-cultural research issues dealt with in your culture?

    o Specifically, cross-cultural consent issues…

- Can women interview men?

6.   How do you think consent should be negotiated cross-culturally in research?

Thank you this concludes the line of questions that I have for you. Is there anything you would like to add before we proceed to the consent form?

APPENDIX C

COUNSELING RESOURCE SHEET

UNIVERSITY OF NORTHERN COLORADO, GREELEY
Counseling Resource Sheet

We appreciate your time and efforts as a participant in our study. We hope that you found your experience as a participant pleasant. However, we acknowledge that some of the questions we asked are of a sensitive nature. Thus, we understand that you may have experienced some psychological discomfort during the study. Please contact the lead researcher, Suzanne Landram, at xxx-xxx-xxxx or xxxxxxx@gmail.com, if you have any other questions or concerns. Also, below is a list of resources that are available at low or no cost. * Referenced and modified from the University of California, Irvine, retrieved from http://www.research.uci.edu/forms/docs/irb-forms/9_CounselingResourceSheet.doc.

UNCO COUNSELING CENTER
Available for: UNCO Students, Faculty, and Staff
Location: Cassidy Hall, Second Floor
Hours: 8 am to 6 pm, Monday -Thursday
8am to 5pm, Friday
Closed, Saturday and Sunday
Phone: (970) 351-2496
Website:
http://www.unco.edu/counseling-center/services.aspx

NORTH RANGE BEHAVIORAL HEALTH EMERGENCY LINE
Available for: All Study Participants
Location: Walk-In Center at 928 12th Street, Greeley, Colorado (open 24 hours day/7 days a week/ year-round)
Phone: (970) 347-2120
Hours: 8 am to 5 pm, Monday through Friday

ASSAULT SURVIVOR ADVOCACY PROGRAM (ASAP) CONFIDENTIAL RESOURCES
Available for: UNCO Students, Faculty, and Staff
Location: Cassidy Hall
Hours: 8am-5pm, Monday through Friday
Phone: (970) 351-1490
24 Hour Hot Line: (970)351-4040
Website: http://www.unco.edu/asap/

ROCKY MOUNTAIN CRISIS PARTNERS
Available for: All Study Participants
Hours: 24 hours a day, seven days a week
Toll-Free: 1 (844) 493-TALK (8255), or
Text: "TALK" to 38255, to receive immediate and professional help
Website:
http://www.metrocrisisservices.org/

NATIONAL ALLIANCE ON MENTAL ILLNESS (NAMI)
Available for: All Study Participants
Hours: 10am-6pm, Eastern Time, Monday through Friday
Phone: 1 (800) 950-6264
Alternate Phone: 1 (888) 600-4357
Alternate Phone: (949) 646-4357
Website: http://www.nami.org/Find-Support/NAMI-HelpLine

NATIONAL SUICIDE PREVENTION LIFELINE
Available for: All Study Participants
Hours: 24 hours a day, seven days a week
Phone: 1 (800) 273-TALK (8255)
Website:
http://www.suicidepreventionlifeline.org/default.aspx

APPENDIX D

RECRUITMENT LETTER

Recruitment Letter

Hello, my name is Suzy Landram, and I am a Ph.D. student in the Applied Statistics and Research Methods Department at the University of Northern Colorado.

I am currently recruiting participants to interview on the ethical dilemmas that occur in cross-cultural research settings when trying to gain informed consent.
I am hoping to gain a better understanding of the ethical issues that may occur during the informed consent process. Potential participants include:

- ☐   former researchers who have conducted extensive cross-cultural human research
- ☐   former participants who have participated in cross-cultural human research

I would be delighted if you considered being a possible candidate in my study. All that is required of you is a one-time in-person interview in which I will ask you questions that pertain to your research experience.

If you choose to participate in this research, you will have the choice between:

- ☐   face-to-face interview
- ☐   online interview

During the write-up stage, any comments or direct quotes that I plan on using, of yours, I will check back with you, the participant or member of this study beforehand.

If this study interest you and you would like to be a part of it, please contact me, at the phone number or email address provided below.

If you know anyone who would be a good candidate for this research study; please feel free to forward this information to them.

Thank you for your time.
Sincerely,
Suzanne V. Landram, M.S.
Ph.D. Program
Applied Statistics and Research Methods
University of Northern Colorado

email: xxxxx@gmail.com   phone number: xxx-xxx-xxxx

APPENDIX E

CONSENT FORM

Consent Form

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Title: **A methodological review of the cross-cultural ethical dilemmas that exist within the informed consent process: When ethical considerations in human research differ**

Researcher: Suzanne V. Landram, College of Education and Behavioral Sciences
Phone: xxx-xxx-xxxx   E-mail: xxxxx@gmail.com
Research Advisor: Maria Lahman, Ph.D., College of Education and Behavioral Sciences
Phone: 970-351-1603 E-mail: maria.lahman@unco.edu

Introduction:
You are invited to participate in a research study exploring how obtaining consent from potential participants should be negotiated in cross-cultural human research. The purpose of this study is to:

(a) Explore researchers' and participants' experiences with the consent process in cross-cultural human research

(b) Offer culturally responsive methods of how cross-cultural consent could be negotiated.

This study is being conducted to gain a better understanding of the cross-cultural ethical dilemmas that exist regarding the consent process. Findings from this study could be useful to researchers who conduct cross-cultural research in areas where Western regulations do not apply.

This study is being conducted by Suzanne V. Landram, a graduate student in the Applied Statistics and Research Methods program at the University of Northern Colorado. If you have any questions please, do not hesitate to ask.

_____
   (Please initial here)

Background Information:
Many researchers, globally, agree to the added value of having some investigators' ethical regulations and or guidelines to follow when seeking consent or assent from participants in human research. However, many researchers' and former participants state a need for better standards, guidelines, and cross-cultural sensitivity protocols from research ethical committees (e.g., IRB) when it comes to cross-cultural studies.

Procedures:
The interviewer aims to ensure your trust by not probing too far into any question that you are not comfortable with answering, please feel free, at any time during the study, to decline any questions you do not want to answer. The interview will be audiotaped and should take approximately 60 - 90 minutes to complete. Interviews will be held in a setting and time that is convenient for you.

Risks and Benefits:
There is no anticipated risk and no direct benefits to you for participating in this research. Since the study is asking you to recall and reflect back on your personal experiences, this may evoke some negative emotions. However, the chance and extent of the emotions evoked are no greater than those emotional memories evoked in daily life. If such an instance does arise, please refer to the counseling referral page that I have provided along with the consent form.

Confidentiality:
Any information obtained in connection with this research study that could identify you will be kept confidential. In any written reports or publications, pseudonyms will be used to protect your identity. Furthermore, the names of the institutions in which the data is collected from will be kept private.

I will maintain the research results in a password protected computer in the privacy of my home. Only my dissertation chair and I will have access to the records while I work on this project.

During the write-up stage, any comments or direct quotes that I plan on using, of yours, I will check back with you, the participant or member of this study beforehand. In order to do this, I will have to have some personal way (email/telephone) of staying in contact with you after all the interviews have been completed.

Please note that all audio recordings will be accessible only to me and will be erased or destroyed three years after the study has been completed. For those corresponding by email, please note that while I will make every effort that your information stays private, confidentiality cannot be assured due to the internet being considered public domain

_____ (Please initial here)

Voluntary nature of the study:
Participation in this research study is voluntary. Participants can refuse to answer any of the interview questions if they choose. If you decide to participate, you are free to stop at any time, and no further data will be collected.

Contacts and questions:
If you have any questions, please feel free to contact me, Suzanne at xxx-xxx-xxxx, xxxxx@gmail.com. You may keep a copy of this form for your records.

Statement of Consent:
Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Sponsored Programs, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

I consent to participate in the study, and I agree to be audiotaped for interviewing purposes.

_____
Signature of Participant   Date

_____
Signature of Researcher   Date

If any comments or direct quotes of yours are used in the final write-up I will check with you, the participant/member of this study beforehand, please provide an email address or telephone number where I may reach you below:

Email _____

Telephone number _____

Please place a check next to your preferred method of contact:

Email _____   Telephone_____

APPENDIX F

QUESTIONS ABOUT THE PARTICIPANT'S DEMOGRAPHICS

Questions about the Participant's Demographics

Now that you have read the informed consent, or had it read and explained to you, and you understand the information please help answer the following questions:

Participants Demographics:

Age: _____

Gender: _____

Education Level: _____

Profession: _____

Country of Origin: _____

Pseudonym (fake name):_____

Questions for Participants on the Consent Form:

1. Why is this research study being conducted?

2. What is the goal of the research?

3. How is this research going to be done? (explain any steps that you can remember)

4. What is the selection of participants based on?

5. From what we discussed, if you decide you do not want to participate can you ask

   not to be included in the study?

6. Does any part of the research seem confusing?

7. Do you have any suggestions for the researchers? (pertaining to the consent form)

8. How might it feel to a participant to receive a counseling resource sheet?

9. Do the resources given to you on the counseling sheet seem reasonable?

- For instance, do the resources seem adequate to you?

- Does it seem like something you would use?

APPENDIX G

FOUR ASPECTS OF TRUSTWORTHINESS

Four Aspects of Trustworthiness (Guba, 1981)

TABLE A.1

Scientific and Naturalistic Terms Appropriate to the Four Aspects of Trustworthiness

Aspect	Scientific Term	Naturalistic Term
Truth Value	Internal Validity	Credibility
Applicability	External Validity Generalizability	Transferability
Consistency	Reliability	Dependability
Neutrality	Objectivity	Confirmability

APPENDIX H

INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

DATE:	October 25, 2016
TO:	Suzanne Landram, B.A., M.S.
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[970300-1] A methodological review of the cross-cultural ethical dilemmas that exist within the informed consent process: When ethical considerations in human research differ.
SUBMISSION TYPE:	New Project
ACTION:	APPROVAL/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	October 25, 2016
EXPIRATION DATE:	October 25, 2020

Thank you for your submission of New Project materials for this project. The University of Northern Colorado (UNCO) IRB approves this project and verifies its status as EXEMPT according to federal IRB regulations.

Suzy-

Thank you for your patience with the UNC IRB process. Your materials are clear and thorough. The protocols and materials provided are verified/approved exempt and you may begin participant recruitment and data collection.

Best wishes with your study.

Sincerely,

Dr. Megan Stellino, UNC IRB Co-Chair

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

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