THE AWARENESS, PERCEPTIONS AND ATTITUDES OF FACULTY USERS AND FACULTY NON-USERS ABOUT THE ROLE AND PROCESSES OF THE INSTITUTIONAL REVIEW BOARD (IRB) AT ONE 1890 LAND GRANT INSTITUTION

A Dissertation

by

MARCIA COLLINS SHELTON

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

DOCTOR OF PHILOSOPHY

August 2009

Major Subject: Curriculum and Instruction

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ABSTRACT

The Awareness, Perceptions and Attitudes of Faculty Users and Faculty Non-Users about the Role and Processes of the Institutional Review Board (IRB) at One 1890 Land Grant Institution.

(August 2009)

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The primary purpose of the study was tri-fold. The study was conducted to (1) determine differences between faculty users and faculty non-users awareness, perceptions and attitudes about the role and processes of the IRB on one 1890 land grant campus; (2) determine when controlling for status, rank, years of service, and age and the degree to which these variables contributed to the identification of the faculty profile for faculty users and faculty non-users of the local IRB at one 1890 land grant university; and (3) expand scholarly works and empirical literature related to the local IRB's role in human participant's research and its impact upon the university land grant community.

This study was conducted at one 1890 land grant institution located in south central United States during the fall of 2007. The sample group consisted of 50 faculty who were self-identified as faculty users and faculty non-users of the IRB and reported their status, rank, years of service, and age. An electronic survey instrument was used to obtain data for

this study. Secondary data was secured and analyses were conducted to assess the levels of awareness, perceptions, and attitudes about the role and processes of the Institutional Review Board (IRB), using the SPSS analysis package.

Several procedures were employed to aggregate the data: frequencies and cross tabulations, analysis of variances of covariates (ANCOVA), and multivariate analyses of covariates (MANCOVA) to compare specific group mean scores of faculty users and faculty non-users, tenure and tenure track. The significance level was set using an alpha level of .05. The findings revealed (1) that faculty users and faculty non-users had differences between the levels of awareness and attitude; (2) perception remained high among faculty users and faculty non-users; however, (3) when controlling for years of service and age, there were significant differences between the faculty user and faculty nonuser groups.

DEDICATION

To my family, your continual encouragement and unyielding belief in my abilities to persist was remarkable and I am thankful to you for your faith in my success. To my husband, Nathaniel, thank you for encouraging me to, “get my own”, when I was consumed with details. You put this work and me first – constantly above your own. You are my best friend and soul mate. Thanks also to my daughters Delia, Regina, Sierra, and Dolores who have the vision, intellect and ability to change the world for the better. I am so proud of you – you are always in my heart and the inspiration for my being. In honor of my Mother, and in memory of my Dad, J. B.: you two planted the seed for this adventure and have always made me believe that I could scale any peak and given the opportunity go intergalactic to reset the stars. Thank you for this confidence. You gave me my spirit, respect for education and an understanding of the difference between knowledge, wisdom and intellect. This is for my sister Sharon, for her quick wit, constant encouragement and genuine love.

To my paternal aunt Ada Anderson and my cousin Sandra Anderson Baccus for providing the support to sustain the course and their belief in my need to inspire the next generation and defining incarnate the true meaning of family a genealogy and synthesis of DNA that sustains a legacy. In closing, the spirit within is the breath and life force that is resonant throughout the universe and the gift of opportunity must bear fruit or it is without purpose. The fruit of this labor will be borne when it takes the form of advancing human achievement through inspiration and positive change.

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I shall through vision, planning, dedication, scholarship and hard work*:*

"Advance human achievement…through inspiration."-mcs

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CHAPTER I

INTRODUCTION

Chapter I addresses the problem and the purpose of the study. Research questions are outlined, the significance of the study, and key terms as used in this study are defined. To conclude this chapter, assumptions and limitations are delineated and the overall organization of the study is presented.

The 1890 land grant universities have as a mission teaching, research and community service. However, much of the processes related to research regulatory compliance for faculty members that carry out the research component of the mission, more specifically human based research, is often misconstrued or misinterpreted (Mabokela & Thomas, 2004). This study focuses on one 1890 land grant university and the awareness, perceptions and attitudes of its faculty members with regard to the role and processes of the university's Institutional Review Board (IRB). There exists a need to understand faculty users and faculty non-users of the IRB so that the research component of the mission may be executed to the fullest extent while in accord with federal guidelines (Lee, 1998; Leigh, 1998). This execution requires the understanding of faculty users and faculty non-users awareness, perceptions and attitude of the IRB's processes, functions and ethical consideration for human participants in research.

According to Bledsoe, Sherin, Galinsky, Heimer, Kjeldgaard, Lindgren, Miller, Roloff, and Uttal, (2007) land grant universities that receive federal funding to conduct research make a number of pledges or assurances to the U.S. Government. In exchange

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This dissertation follows the style of the journal of *Educational Researcher*

for the privilege of receipt of federal funding, they agree to carry out research in accordance with a plan and to act in a fiscally prudent manner through an instrument termed a Federal Wide Assurance (FWA) or contract with the government which binds the institution to certain tenets of federally mandated standards. When this research involves human participants, institutions agree to ensure that the rights and welfare of the human subjects who agree to participate in research are adequately protected through an ethics review mechanism - the Institutional Review Board (IRB).

An IRB is a committee constituted according to federal guidelines; these guidelines are the Code of Federal Regulations (CFR). Specifically, the principal regulations are found in 45CFR46. IRBs are peer committee review mechanisms and operate similar to that of a journal with an editorial board and likewise its composition is federally defined as a minimum of five or more members. These members possess diverse backgrounds and expertise and review proposed research and examine continuing research to preserve the rights and welfare of human participants. It is the committees' primary task to ensure that no harm is inflicted upon any of the participants (Kerlinger & Lee, 2000). University members are typically a cross section of faculty and staff from the campus and in close proximity to the research sites, scientists or faculty researchers, and to communities of potential human participants. The IRB committee membership is a part of a research organization; however, to be legitimate an IRB must operate independently of its organizational authority. While federal regulations must be adhered to, and IRBs possess the authority to disapprove research, the trend in IRBs leans towards education, and to learn from researchers how to best protect human subjects (Oakes, 2002).

The IRB, in a university setting serves as the federally recognized local governing body for human subjects based research. IRBs have the authority to require changes to methodology and to disapprove research; and they have a responsibility to educate and work with faculty researchers' to best protect human research subjects (Oakes, 2002; Penslar, 2002). The United States Department of Health and Human Services (DHHS): Food and Drug Administration (FDA) (2001) notes that an Institutional Review Board (IRB) is a federally mandated ethics review and oversight committee that monitors the welfare of and provides protection for human subjects recruited to participate in biomedical or behavioral research. The Institutional Review Board on a university campus is the final authority on approval for academic research (DHHS, 1998). However, much of the operation, authority and activity remain misunderstand by the academic community who submit to its governance and oversight (Peckman, 2002). The differences in understanding of the IRB's role and process with human subjects' related research conducted on university campuses suggests that there is a need to examine faculty users and faculty non-users awareness, perceptions and attitudes about the IRB on a university campus.

Statement of the Problem

As resources for state supported institutions dwindle, and research involving external funding is more heavily relied upon to support the institution, there is a need to understand the population of IRB faculty users and faculty non-users. There is also a need to better serve the faculty by building knowledge and enhancing strengths in their understanding of the role and process of the IRB for overseeing the conduct of research in a university setting; however, baseline data are needed. An understanding of the

differences in faculty users and faculty non-users awareness, perceptions and attitudes of the local IRBs' role and process is necessary to begin to create a cultural environment for research regulatory compliance within the university. Thus, the need for awareness and education of the role and processes of the IRB may contribute to faculty involvement in the IRB process and adequate protection for human participants taking part in research.

Purpose of the Study

The study was conducted to: (1) determine differences between faculty users and faculty non-users awareness, perceptions and attitudes of the role and processes of the IRB on one1890 land grant campus; (2) determine, when controlling for status, rank, years of service, and age whether these variables contributed to the identification of the faculty profile of faculty users and faculty non-users of the local IRB at one 1890 land grant university; and (3) expand scholarly works and empirical literature as related to the local IRB's role in human participant's research and its impact upon the 1890 university land grant community.

Research Questions

The overarching research question that guided this study was: What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users of the local IRB's role and processes? In addition, research questions were employed using covariate variables such as years of service, rank, status and age. Thus, the research study responded to the following questions:

1. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users regarding role and processes of the university's IRB?

2. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users by status regarding the role and processes of the university's IRB?
3. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users by rank regarding the role and processes of the university's IRB?
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5. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users by age regarding the role and processes of the university's IRB?

Significance of the Study

The voice of the 1890 land grant university as it relates to behavioral and social research and the ethics compliance review process is limited in the literature. Most references are limited to anecdotes about research however, research evidence is almost nonexistent. In contrast, 1862 land grant institutions which are often classified as leading research institutions, have a plethora of evidence surrounding the study of research regulatory compliance and human ethics review boards. This study makes a contribution to scholarly and empirical literature where the need for further research in this area is evident because there is a profound void.

This significance of this study is centered on the need for baseline data to assess awareness, perception, and attitudes between faculty users and faculty non-users regarding

role and processes of the Institutional Review Board at one 1890 land grant institution. This study generates baseline data to assist in the identification of opportunities for in-service training among faculty members in the area of regulatory compliance as it relates to research involving human participants. In addition, through the identification of faculty by profile characteristics, targeted services may be employed that stimulate a greater segment of the constituents (faculty) to have an understanding of the IRB role and process, as well as to become active protectors of human participants involved in research. This base-line data regarding faculty non-users characteristics can facilitate their conversion to productive and engaged users of the IRB and provide insight into increasing the retention and production of users. Engaged research faculty serve to enhance the 1890 land grant institutions contribution of often distinctive and culturally focused scholarship.

Definition of Terms

For the purpose of clarifying the problem statement in this study, the following definitions for terms as used in this study are provided.

Attitude – an opinion or general feeling about something created by a combination of perception and experiences.

Awareness – having knowledge from observation or experience regarding the role and processes of the IRB.

Faculty – an individual employed at the land grant university with tenure and/or tenure track status; this individual member has teaching responsibilities and may conduct research, outreach and service.

Faculty user – a faculty member with tenure and/or tenure track status that has submitted a protocol to the IRB within the last three years.

Faculty non-user – a faculty member with tenure and/or tenure track status that has not submitted a protocol to the IRB within the last three years.

Human subject/participant - a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or acquires identifiable private information about the individual (OHRP, 2008)**.**

Institutional Review Board (IRB) – a specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research (OHRP, 2008).

Institution – any public or private entity or agency (including federal, state, and other agencies); the traditional location of the IRB within the academic research setting or hospital.

Land Grant Institution – a historically Black land grant university, and is a college or university that has been designated by its state legislature or Congress to receive the benefits of the Second Morrill Act of 1890.

Local IRB – a reviewing ethics committee that is geographically close to research sites, to scientists who conduct the research, and communities of local potential human subjects.

Perception -- the process of using the senses to acquire information about the surrounding environment or situation.

Rank – academic status as it relates to teaching faculty with tenure status.

Research – a systematic scientific investigation or inquiry that may lead to publication or presentation of scholarly findings designed to develop or contribute to generalizable knowledge.

Status – tenured and tenure track faculty.

Years of service – the length of employment with the one 1890 land grant university.

Assumptions

1. Faculty members/subjects participating will provide honest answers to the questions posed on the survey instrument.
2. The electronic survey instrumentation used in this study accurately recorded dependent variables of awareness, perceptions and attitudes between faculty users and faculty non-users, as it relates to the role and processes of the local IRB.
3. Survey instrument scores obtained as measures of awareness, perception and attitudes of respondents in the study were considered valid and reliable.
4. The interpretation of the data collected accurately reflected the participants' responses.

Limitations

1. Findings for this study may not be generalized to any group other than faculty who were employed during the fall semester of 2007 at one 1890 land grant university located in the southwestern region of the United States.
2. Respondents may have felt an inclination to bias answers.

Organization of the Study

Chapter I consists of an introduction of the study including the statement of the problem, research questions, purpose of the study, significance of the study, definitions, assumptions and limitations. Chapter II contains a review of literature pertaining to (1) the history of regulation for human subjects to include events leading to the establishment of the Institutional Review Board (2) university institutional review board processes and functions, (3) the benefits of the IRB to human subjects and to the University faculty in

reducing risks and challenges, (4) case studies of mistreatment of human subjects in research,

(5) relevant studies that examined universities regarding issues such as the faculty users and faculty non-users of the IRB by years of service, rank, status, age, and gender, as it related to the factors of awareness, perceptions and attitudes (APA) influencing faculty users and faculty non-users in their assessment of the function and processes of the local IRB, (6) the legislation that created the land grant college system and chronicles the emergence of the land grant institution and its role in education, research and scholarship, (7) the one land grant institution involved in this study, and (8) the theoretical framework for this study. Chapter III outlines methods and procedures used to conduct the study. Chapter IV contains the analysis of data and discusses the findings of the study. Chapter V provides a summary, conclusion of the study and recommendations.

CHAPTER II

REVIEW OF LITERATURE

This chapter provides an overview of the evolution of the IRB, its functions, processes and responsibility for the protection of human subjects involved in research. The first area of research will chronicle the history of regulation for human subjects to include events leading to the establishment of the Institutional Review Board. The second area discusses the IRB role and processes, the benefits of the IRB to human subjects and to the University faculty in reducing risks and challenges as well as case studies of mistreatment of human subjects in research. An empirical literature review of relevant studies is presented that examined universities regarding issues such as the faculty users and faculty non-users of the IRB by years of service, rank, status, age and gender, as it related to the factors of awareness, perceptions and attitudes (APA) influencing faculty users and faculty non-users in their assessment of the function and processes of the local IRB. In addition, the chapter discusses the legislation that created the land grant college system and chronicles the emergence of the land grant institution and its role in education, research and scholarship, the one land grant institution involved in this study, and the theoretical framework for this study.

Historical Overview of University Regulation for Human Subjects

In recent history, faculty members have faced increasing challenges in the attempt to conduct research that is grounded in ethics and guided by the Belmont Principles (Vanderpool, 2001). This section provides an overview of historical events that have impacted the function and processes of the IRB and reflects on University Misconduct and the IRB.

The current Institutional Review Board (IRB) that serves the higher education community is an outgrowth of the medical model that was established to serve the needs of the doctor and patient relationship (Hunt & Yekel, 2002; Saver, 2004). Medical ethics relating to decisions on patient safety and humane treatment was viewed as the business of doctors and remained unquestioned by any element of society, especially those not aligned with medical care (Annas & Grodin, 1992). Additionally, there were boundaries of professional courtesy where no matter how suspect a treatment may appear, physicians held to a code of silence and did not question another physicians' judgment or treatment protocol. According to Jaeger (2006), the doctors were expected to act on the behalf of their patients, they were considered as the agents of social control. The doctor and patient relationship remained fairly consistent until the world changing events that related to the onset of World War II.

Rothman and Rothman (2006) suggested that prior to World War II breaches in ethics were rare occurrences; on the other hand, there were a number of researchers that suggested that ethical lapses were historically difficult to discern. Rothman also noted that the primary reason was that medical schools did not teach ethics and there were no standards of ethical conduct that were formed. He noted another fiscally related reason often offered was that the federal budget allocations for research involving human subjects were minimal, that the distinction between research and treatment was blurred, and notably that the physician as researcher was not well defined. According to Rothman, the public trust was high with regard to physician's decisions concerning care and in contrast this was complicated by the fact that patients (human subjects) simply did not have the awareness to begin to

differentiate between treatment and research, therefore doctors and researchers had no external compelling force to examine the issue.

In the 1930s and 1940s in the United States, the immutable effects of the Depression as well as World War II featured prominently in the changes that were to impact the nation as well as universities and academic settings. During this era there were two important and defining historical events that precipitated marked changes in human experimentation: [The Report] presented by President Roosevelt and the *Nuremberg Code* (1946).

[The Report] (Landrum, 1999) presented by Roosevelt stressed the need for improved care and the seminal instance of patient mistreatment prior to World War II was identified as the Sulfanilamide Study. The outgrowth of [The Report] was the increased federal funding infusing the hospitals and the education institutions that were associated with teaching hospitals. Concomitantly, there was a movement to address the subtle, yet recurring reverberation for the development of standards or practices of scientific conduct, largely, from evidence that misconduct in human research was an area of incontrovertible concern Gibelman & Gelman, 2001). Issues perceived as problematic, were most exceptional and often stemmed from the concept of informed consent and an unprecedented budding school of thought from within the medical community for admission of the need to protect patients from exploitation and unnecessary abuse in their unequal relationships with physicians (Sugarman, McCrory, Powell, Krasney, Adams, Ball, & Casell, 1999). The doctor-patient power dynamic was challenged as these instances were exposed beyond the inner circle of the medical community and this questioning by

citizens and legislators grew into outcries that set in motion a series of events on the legislative forefront (Koojiman, 1999).

Of all the modern history none more purely portrays the post World War II open and willful exploitation of patients, with complicity from the federal government, the former Public Health Service, as the Tuskegee Syphilis Study (Jones, 1993; Kerlinger & Lee, 2000, p. 440) and in a university setting, the Milgram Obedience Experiment (Blass, 1999; Milgram, 1974). These studies, along with others, desecrated public sensibility and through public awareness evoked emotional responses about involuntary exposure of people, and to large extent vulnerable populations, to harmful medical and scientific procedures without advisement about the true nature of the risks involved (Faden & Beauchamp, 1986). While there were many cases in the historical annals that portray unethical use or involvement of participants as a result of deceptive practices, none led to legislative reform and the ultimate establishment of Institutional Review Boards, as the study that is most related to the similarly situated institution in this study as the Tuskegee Syphilis Study.

The Tuskegee Syphilis Study (Brandt, 1978; Jones, 1993) is named for the location where it took place and not the federal agency, the U. S. Public Health Service, which funded and performed the research on 600 illiterate African American male laborers, 399 with syphilis, and 201 who did not have the disease. According to the Centers for Disease Control (CDC), the study was conducted without the benefit of patients' informed consent. Researchers explained to men (participants) that they were being treated for "bad blood," a colloquial term used to describe several ailments, including syphilis, anemia, and fatigue. The unfortunate reality is that the men never receive the proper treatment needed to cure

their illness. In exchange for participating by deceptive enrollment in a study designed to trace the evolution of untreated course of the bacterial disease, syphilis, the men received free medical exams, free meals, and burial insurance. Although originally projected to last 6 months, the study actually went on for 40 years.

What they received in exchange for willingness to secure consistent medical treatment was a deceptive enrollment in a study designed to trace the evolution of the natural course, thereby untreated course of the bacterial disease, syphilis. The men were told that they were being treated, when in reality they were not. In 1932, medical care in the south for African Americans was more than a luxury because it was out of reach for the average African American and nearly impossible to secure for a poor, illiterate sharecropper or laborer, in light of the social conventions in place at the time. The partnership was one based upon deception.

Throughout the next forty years, symptoms of syphilis were measured and recorded. When the men died, autopsies were performed on each individual after their death and a burial was provided. Even though the American government condemned the social eugenics on the international front that the Nazi's had participated in during the Holocaust, and scientists from this agency were credited with the development of the *Nuremburg Code in 1946,* The Tuskegee study, funded and operated by the federal government proceeded quietly in the United States. The real issue that made it an ethical departure from was that the Nuremburg Code was not applied to the ongoing was that it continued even with the discovery of penicillin in the 1940s: a vaccine that was proven to stop bacterial infection.

Millions of lives throughout the world were changed for the better as penicillin became readily available. From January to May 1943, only 400 million units of penicillin had been made; by the time the war ended, U.S. companies were making 650 billion units a month (Hughes, 1997). Unfortunately, none was made available to the participants in the Tuskegee Study in Macon County, Alabama. Worse yet, when thirteen participants were found to have sought other medical care and were treated with penicillin, they were replaced with thirteen individuals that were subsequently exposed to syphilis to continue the study. Family members experienced spontaneous abortions and contracted syphilis as well. The study continued until 1972, when public outcries were overwhelming as a result of an article in a newspaper (Rothman, 1982). NIH never made any attempt to halt the study even when it knew that penicillin would have treated the men, thereby willfully and deliberately subjecting the uninformed human participants' to unnecessary risk. Scientists from the government agency that was responsible for the Tuskegee study were involved in the crafting of the *Nuremburg Code*.

The contemporary chronicle of human subjects' protections begins with the *Nuremberg Code* (1946), developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis (Nuremberg Code, 2000, p. 258). The Code imbues many of what are now taken to be the basic principles governing the ethical conduct of research involving human subjects (Freyhofer, 2004). The first provision of the Code states that "the voluntary consent of the human subject is absolutely essential." Freely given consent to the participation in research is the cornerstone of ethical experimentation involving human subjects.

The catalyst for this change was attributed to the active role that universities played in the thrust for scientific collaborative partnerships on projects such as the atomic bomb. The federal government's role in these academic institutions and the scientific collaborative partnerships ultimately led to the establishment of the Office of Scientific Research and Development in the federal government. The tide for funds had been indelibly altered when the federal government became viewed as a viable source for funding the nascent research enterprise on campuses.

Conduct of research and research oversight in universities and their intersection with the federal sector necessitates an enhanced understanding of the role of the IRB in university settings. Academicians viewed the support from the federal government as crucial to the events in the 1950s and 1960s that turned the world on end regarding space exploration and in parallel, the medical advances in disease eradication. The open competition between the Soviet Union and the United States compelled universities to focus on scientific research and increased opportunities for related training were funded by the US federal government (Popovich & Abel, 2002; Starr, 1992). This funding expansion fueled a need for self-regulation to protect the participants.

A system of self-regulation and oversight requires a decidedly developed sense of assurance and accountability from all participants. An implicit expectation for researchers to be forthright, candid and ethical in their conduct of research is a fundamental tenet of scholarly works (Gall, Gall & Borg, 2004; Kerlinger, & Lee, 2000; Lo, 2001). Integrity in scholarship requires confidence in the veracity and accuracy of the information given by an individual or entity. The justice, beneficence, and respect in the treatment of individuals or entities involved in research as elucidated in the Belmont Report (National Commission

for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Sieber, 1992; Vanderpool, 2001) necessitates an assurance that researchers will act responsibly. Additionally, specification of quality standards in the conduct of research is an important function of the institutional leadership. Insistence upon well-conceived and well-conducted research should be evident both in written policies and in actions of institutional officials. Research that is conducted so poorly as to be invalid exposes subjects and the institution to unnecessary risk. Therefore, to take responsibility for research involving human participants makes that person or entity accountable. When an individual possesses integrity, that person becomes responsible for upholding the public or global community's trust.

The IRB review, ethical scientific conduct, and the ability to protect the rights and welfare of human subjects require that the institution address the ideas of trust, integrity and justice as essential components of knowledge related to the application of research (Jaeger, 2006). The Institutional Review Board (IRB) has one primary function for international and national oversight as stated by OHRP (2008), the federal oversight authority, and it is "To protect the rights and welfare of human subjects and to minimize the risk of physical and mental discomfort, harm and danger from research procedures."

In 2008, the Office for Human Research Protections (OHRP) noted that this office is responsible for interpreting and overseeing implementation of the regulations regarding the protection of human subjects promulgated by the Department of Health and Human Services (DHHS). The federal government mandates that each Board that has registered with the federal government is required to establish and maintain communication with the OHRP located within the federal National Institutes of Health (NIH). The decision

rendered by a Board may not be overridden by any member of the university administration. As IRB's respond to their directive to ethically oversee the rising volume of research involving human subjects, they require systematic ways of examining protocols for compliance with best practices. This directive or task of an IRB becomes considerably lighter if researchers are fully aware of such practices and how they can be implemented. By 1979, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (NCPHBBR) issued its report, known as the Belmont Report (1979), mandating the establishment of institutional review boards (IRBs) on university campuses. The OHRP provides broad guidelines to the establishment and operations of the local offices in university settings.

In response to the looming threat of federal oversight, most universities and colleges introduced self-regulation through university guided management processes for research involving humans. Within the past thirty years, ethics review boards began to emerge on campuses to minimally satisfy the federal requirement (Adair, & Davidson, 1995; Leigh, 1998). Federal law enacted in 1985, required universities to develop and implement procedures for approving research protocols and investigating scientific misconduct (Ellis, 1999; Eckenwiler, 2001). In 2000, Shalala (2000) then secretary of the Department of Health and Human Services (DHHS), directed that the federal government impose mandatory education for researchers that involved human participants in research. The guideline was decidedly vague, lending itself to broad interpretation and has led to much discussion on what is vital in terms of coverage to satisfy this guideline. The institutionalization of the process has met with a slow embrace due in large part to the lack

of funding associated with setting up a compliance office to self-regulate human research conducted by faculty in a university setting.

University IRB's Role and Processes

Since passage of the National Research Act by Congress in 1974, local IRBs are required to review and approve all federally funded research involving human participants. Universities sign agreements known as assurances that apply federal regulations to all research conducted by university faculty, staff and students. Irrespective of funding source, the committee reviews every research project conducted across the university that involves interviewing or interacting with human subjects/participants (Bankert & Amdur, 2006). The committee is typically chaired by a tenured professor who has experience in the conduct of research involving human subjects/participants. The federal guideline indicates that an officially constituted committee includes a minimum of five members. Membership includes at a minimum an ethicist, a scientist and a nonscientist, and at least one community member.

The membership composition must demonstrate evidence of an attempt to achieve diversity in gender and ethnicity. Members are characteristically nominated by their respective dean and their credentials are forwarded to the vice president for research who then advances the nominees and recommends appointment to the president. Letters of appointment at smaller institutions are typically received from the university president. However, this may come from the institution official (IO) an individual recognized by NIH with the capacity to obligate the university fiscally. The process for confirming community members is self-nomination or university affiliate nomination and the process is designed to convey the significance of the role of this committee within the university. Members are

typically appointed for staggered terms for a minimum term of three years with no upper limit. The membership roster is forwarded to the federal government as a part of the assurance and updated as changes in membership occur, at least on an annual basis.

As a condition for accepting federal funds for research and other activities, each university in accordance with federal guidelines has established requirements for all research investigators. Order of requirements may vary from university however, in general before submitting applications to the IRB; investigators must demonstrate at a minimum, evidence of satisfactorily completion of an on-line electronic educational tutorial that covers issues related to the rights of the participant. Other requirements include following the IRB guidelines for informed consent documents; obtaining the IRB review before changing previously approved studies; obtaining the IRB review of the on-campus use of sensitive or restricted databases; and immediately reporting injuries or unanticipated problems to the University's Compliance Office.

In summary, the IRB role and process defined by the federal government is designed to be human participant centered in its protection mechanism. However, the process has benefits that extend to the faculty users; faculty non-users are not accorded the benefits.

University IRB Review Benefits to Human Subjects

The university IRB evaluates all proposals based on the ethical principles delineated in the Belmont Report issued by the Department of Health, Education, and Welfare in 1979. These guiding principles include respect for persons, beneficence, and justice. Respect for persons requires that subjects enter into research voluntarily and only after they have demonstrated true understanding of what will be required of them. This principle protects vulnerable groups of research subjects, including children, older people, and people with mental illness, and prisoners, who may not be capable of understanding information that would allow them to give informed consent to participate. Beneficence requires that researchers not only protect their subjects from harm but also actively look out for their well-being. The key to protecting human subjects/participants, according to the report, was to "maximize possible benefits and minimize possible harms." The principle of justice applies to the selection of research subjects as well as to the use of research results. At all times, risks and benefits were to be distributed fairly and without bias.

The Belmont Report (1979) noted that the federal compliance regulations and committee activities are in place for a very good reason: the protection of humans. The university has an obligation to create opportunities of education and awareness regarding oversight and is committed to the proactive oversight of all matters related to human research. The regulations and compliance boards are vital to public confidence in university research.

Generically speaking, the IRB acts as a franchise of the federal government in a campus setting. The benefit of review to a prospective researcher is that the proposed

research is reviewed by a federally constituted body that looks at the merits of the research as it relates to the protection of the human participants. This review provides an insurance policy of a sort if the research is conducted in accord with the approved protocol. A certain level of prophylaxis is provided to the researcher, particularly if there is an unforeseen event or adverse incident, as they have submitted to external review by an independent body and received review by a committee with membership of various areas of expertise. If appropriate, consultants are brought in with specific expertise in the area of consideration with the express intent of identifying issues specific to the population under consideration for the prospective study. The benefit to the institution is that all research undergoes scrutiny to assure humane treatment of human participants so that they avoid or mitigate the legal issues related to poorly constructed studies. The biggest benefit is to the participant and the protection of their rights.

University Faculty's Benefits, Risks and Challenges of the IRB

The benefits to the faculty researchers that submit to the research ethics review or IRB process are an insurance or protective policy (Amdur & Biddle, 1997). By virtue of a peer review of the proposed study, the faculty members' fiscal liability in the unlikely event of an adverse incident and legal action ensues, the associated costs are not borne solely by the faculty member. The financial burden associated with the negligence that results in death may be prohibitive to the average faculty member. In some instances, the IRB often examines methodology and provides constructive comments. This process can be viewed as helpful by new and emerging faculty researchers. In contrast, more seasoned faculty view this same attention to detail, as intrusive and having little merit and the cause for unnecessary delays and may be epistemic to the faculty non-user syndrome.

The challenge to the IRB process is complicated by the lack of checks and balances within the arena of scholarly publications or journals. The federal government assurance with the universities contains language to the effect that all research proposals involving human subjects, whether it is funded or unfunded, must undergo an IRB review as a precondition for the release of funds (Ceci, Peters & Plotkin, 1985). When research is funded through a federal agency, evidence must be provided to the sponsored programs or research funds disbursement office that the proposed research that involves human participants is complicit with the regulatory compliance initiatives. Absent this evidence, funds are not released to the university.

However, the research that is funded through foundations, other sources, or is unfunded does not, as a general rule, possess this inherent auditing mechanism. Tenure, promotion and performance appraisals are intimately intertwined with research productivity and to achieve and satisfy requirements related to fiscal compensation and social stature, publication and presentation is a component of the equation (Popovich & Abel, 2002). When a faculty member submits to a journal or a conference for presentation, the editorial staff and conference proposal reviewers rely upon internal ethical compasses to serve as guides to meet this standard; they are often the recipients of unreliable moral compasses (Bland, Center, Findstad, Risbey, & Staples, 2006).

A study, conducted by Henley and Frank (2006), examined how often research articles reported basic ethical protection offered by the IRB. A retrospective audit of articles published between 1996 and 2001 showed that of the 806 articles reviewed, one out of 2 faculty members (authors) were IRB users. Approximately 48% of the users reported submitting to the research IRB ethics committee approval and informed consent.

It was also purported that faculty from clinical interventions were noted as the highest percentage of IRB users complicity with 58% reported having IRB approval. Faculty users, reporting qualitative methods (30%), chart reviews (17%) and case reports (11%) had the lowest rates of documentation of IRB use. This indicates a trend toward faculty non-users of the IRB in published research articles for qualitative and secondary data.

In summary, challenges related to IRB review of research is met with resistance when faculty users and faculty non-users promotion and tenure are tied to publication. The university cultures do not have a system that guarantees that publication endure the IRB so that faculty become vulnerable when looking at livelihood. The current IRB processes are viewed as overly burdensome to faculty researchers thus, misconduct in research becomes problematic.

University Misconduct and the IRB

Scientific misconduct has been a topic of discussion in research, practice, and policy arenas for decades (Broome, 2003). Scientific misconduct is a grave violation of the fundamental principle that scientists practice truthfulness and fairness in the conduct of research and the dissemination of results (US Department of Health and Human Services [DHHS], 1995). In recent years, the margins of misconduct in research have been extended further than the initial focus on informed consent, risk levels, and coercion (Broad, 1999). The Office of Research Integrity (ORI) located within DHHS defines scientific misconduct, as “fabrication, falsification, and other practices that seriously deviate from accepted standards” (DHHS, 2001).

The most recent proposed definition emanating from the White House Office of Science and Technology Policy illustrates the porosity of the boundaries or margins:

"Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" ("New definition proposed," 1999, p. 4). The definition was notable also in specifying what research misconduct was not: "honest error or honest differences of opinion" ("New definition proposed," 1999, p. 4). The definition applies to research under the auspices of all federal agencies (DHHS, 2001).

The broadened definition and specification of categories of misconduct had far-reaching implications (Steneck, 2006). The integrity of the research protocol itself, as well as the presentation of findings was now within the purview of federal oversight. The charges to IRBs broadened to correspond with the expanded definitions. There was increasing impetus to involve IRBs in reviewing research protocols even when no federal funds were involved. This situation was the result of the growing number of studies sponsored by private sources, including pharmaceutical companies, in areas such as genetic testing (Brainard, 2000).

The growing number of federal regulations regarding how publicly supported research had greater oversight was understandable when viewed within the context of case experience (Monastersky, 2005). It was not a surprise, since the highest proportion of federal funds had traditionally been allocated to biomedical research, given that the majority of scientific misconduct allegations had surfaced. The time for investigations into university related allegations of misconduct involving human participants' research was initiated by a series of high profile cases at prominent research intensive institutions having their federal funds suspended.

According to Hilts (1999), in 1999, a front-page *New York Times* headline decreed:

"Duke Researchers Are Taken Aback by Halt in Studies" and this was the start of a series of IRB related investigations in university settings. The account informed the public of the temporary decertification of Duke University Medical Center as an institution eligible to conduct research with federal funds. Investigators from the Office of Protection from Research Risks (OPRR) discovered a number of ethical and safety rule violations which were not promptly corrected by Duke's researchers. The twenty breaches and violations cited ranged from faulty or absent informed consent documents to the approval of research without complete review by the University's IRB (Hilts, 1999). The federally imposed sanction lasted four days, until Duke officials' agreed to revamp its system for protecting human subjects/participants (Hilts, 1999). The sanctions included the inability to expend or encumber any federal funds, the halt of all federal research, and the institution of training procedures for all investigators to include students and the commitment of adequate resource allocation for the oversight of university regulatory research compliance.

According to Hilts, the action against Duke was not an exclusive instance or event; within a one year period comparable sanctions were imposed upon Rush-Presbyterian St. Luke's Medical Center in Chicago, Virginia Commonwealth University, the Veterans Administration Hospital in West Los Angeles, the University of Pennsylvania, and the University of Alabama (Brainard, 2000; Brainard, 2000; Brainard & Miller, 2000). Comparable sanctions were imposed on the above cited institutions and it was recommended by the OHRP investigation team that more university involvement was needed in monitoring and/or fostering the research integrity process. Simply because 1890 land grant institutions were not identified in the investigations does not mean that they are exempt from activity related to misconduct. Rather the criteria for review stemmed more

from the fiscal value of federal dollars appropriated to institutions.

Steneck (1994) noted that with regard to the research integrity process, at least three justifications for additional monitoring were advanced for immediate action. First, on a practical level, those faculty users of the IRB who were involved in misconduct investigations knew that policies and procedures were best defined before, not during an investigation. Second, as Frederickson, a university researcher and vehement opponent to anything other than tacit federal oversight had argued, universities were in the best position to monitor research integrity and could reasonably be said to have a responsibility to do so. Third, if these positive arguments were not compelling enough, by the mid-1980s it was becoming apparent that if universities did not act, the government would. Steneck also noted that for scientists such as Herman Wigodsky (1984), who believed that "the research community and the institutions must, at all costs, protect the intramural and extramural scientific communities from politicization, "there was no doubt that "the scientific community must look to policing itself and must demand and encourage the high standards of personal integrity required to carry out research using the scientific method".

As Steneck (1994) so expressively stated, it is in moments of ideal reflection, science and universities, on the one hand, and government, on the other, understand that they are partners joined together by mutual needs, expectations and obligations. Each discerns with unequivocal acuity that it has responsibilities for the achievement of common goals. However, in the real world of policy making, budgets, and regulation, a less congenial, more adversarial image dominates. Universities view government as an excessively domineering, controlling and intrusive patron; government reverses the lens and views universities as ungrateful and at times irresponsible recipients of public funding.

According to Steneck (1994), Senator Albert Gore, Jr. stated that the American people's investment in science and technology spoke powerfully of our hopes for the future. As chairman of the subcommittee tasked with investigations and oversight, Gore intended to see that this hope was not misplaced.

As the clients'/investors' representative, Gore posed a series of questions to the research community: "Was science really self-correcting?" "Was the peer review process working adequately?" "Were leading scientists who run large laboratories paying enough attention to the work actually being carried out?" "Had the biomedical research enterprise become too big and too varied to be controlled adequately by research institutions themselves and the informal networks within the professions?" (1982, p. 2). The goal was not to intrude the camel's presence into the tents of scientists; his goal was simply to ask, as any client would, whether the professionals to whom she or he had turned for advice and expert knowledge were acting responsibly.

For universities, 1999 was a year that may most effectively be characterized by a series of unfortunate and unintentional misconducts as the treatment relates to human participants in research. On September 17, 1999, 18-year-old Jesse Gelsinger died after being injected with a genetically crippled virus while participating in a gene therapy trial at the University of Pennsylvania. Less than two years later, a healthy 24-year-old volunteer named Ellen Roche was asphyxiated after inhaling a test chemical during a clinical trial on asthma drugs at Johns Hopkins University. In the aftermath of these deaths, the University of Pennsylvania was sued by Gelsinger’s family, and the U.S. Office of Human Research Protections (OHRP) put an immediate halt to all federally funded research on humans at facilities at Johns Hopkins University.

In summary, university misconduct in human participant research is complex and often related to non-users and users that fail to execute the protocol as it was approved by the local IRB. The costs are high as it relates to the participants the reputation of the faculty researchers, and the funding profile of the university. University faculty awareness of the IRB processes affects the perceptions and attitudes towards the IRB. Perceptual and attitudinal behaviors promote faculty non-users when their behaviors are not corrected and reinforced in the career cycle of a faculty member.

Awareness, Perceptions and Attitudes of University Faculty Users and Faculty Non-users

Studies on the awareness, perceptions, and attitudes of faculty were examined to look at variables that were relevant to the conduct of this study. The investigator reviewed eight studies and purported the summary of findings of this empirical literature. Moreover, limited numbers of studies were found regarding faculty non-users and studies related specifically to 1890 land grant institutions were virtually nonexistent in the literature.

White (1999) examined studies on the effect that gender had on adult moral development of public servants. His study consisted of 252 men and 47 women participants. Even though the study consisted of a small sample of women (9.1%), White observed that there were no differences between genders in the Kohlberg hierarchical scale of moral development between males and females. On the other hand other researchers such as Morris (1997), Bernard (1997), and Wark and Krebs (1996) found different results than White. Morris (1997) conducted a study with 340 school psychologists who found females to score significantly higher than males in ethical beliefs. Bernard (1997) found that female managers also scored significantly higher than their male counterparts. Wark

and Krebs (1996) found that males scored higher in justice orientation, while females scored higher in the area of caring orientation.

Ferraro (1999) focused on attitudes toward, the perceptions of, and experiences with an Institutional Review Board (IRB). This study revealed quantitative data and faculty recommendations were purported from the qualitative open ended questions. A total of 902 surveys were distributed through campus mail with potential respondents coming from 48 departments, whose faculty and students had within the preceding three years, possibly submitted proposals to the IRB. The survey generated three hundred forty respondents for an overall response rate of 38%. Of those respondents, 53% of the faculty members and 39% of the graduate students indicated that they had previously submitted research proposals to the IRB for approval. Overall 48% of the respondents indicated that during their time at the university they had submitted a proposal for review.

Ferraro (1999) noted that three IRB variables were isolated for analysis: faculty academic status, faculty academic field, and graduate student academic field. This analysis schema was an attempt to determine the comparability between the total population surveyed and the samples returning the questionnaire and to mitigate the effects of bias. When the academic status of faculty members were examined no discernible differences in variation emerged. However, within the respondent group of lecturers, instructors, assistant professors and others were slightly under represented. It was also noted that there was an overrepresentation of associate professors, professors and research faculty and staff. In the fields of academic representation of the faculty and graduate students, the greatest variation appeared. Social and behavioral sciences were overrepresented whereas there was a marked under representation in every other academic category to include mathematics,

physical sciences and engineering. Overall, the life sciences and medicine and the social and behavioral sciences categories were the heaviest users of the IRB. Education was the next most frequent user.

Generally, Ferraro's study indicated that the comments from respondents who had submitted to the IRB regarding perceptions of the board were more favorable from graduate students than those with faculty status. Actually, no negative evaluations of the IRB were elicited from the graduate student population of respondents. However, graduate students indicated in greater numbers that they were not as aware of the process for reviewing research involving human participants. Recommendations were presented to the open ended questions and they centered on themes such as the need for speeding up the process; and that this could be achieved by holding more meetings for full board review, the exclusion of survey research, opinion polls, classroom research and education research from IRB review and approval. Finally, the qualitative piece echoed the need for additional training on the completion of the forms, due in large part to their ambiguity.

In a study of scientists' perceptions of organizational justice and self-reported misbehavior, Martinson, Anderson, Crain and DeVries (2006) noted that the issues of integrity of science and the misbehavior of individuals was characterized by the environments in which scientists work. The findings indicated that when scientists believed that they were the recipients of unfair treatment that they were more inclined to behave in ways that compromise the integrity of science. The perceived violations of distributive and procedural justice were found to have a positive association with self-reports of misbehavior among scientists. Within the context of organizational justice literature, procedural justice and distributive justice is central, particularly when people

hold a general regard that the distribution of resources within an organization and the decision processes associated with that distribution are perceived as fair, then the confidence in the organization is in all probability heightened.

According to Martinson, B.C., Anderson, M.S., Crain, A.L. & DeVries (2006), when individuals believe that the distribution or the process, or distribution of resources is unfair, those two believe that they are the recipients of maltreatment will justify this through actions that compensate for the perceived unfairness or inequity. The findings of this research suggest that early- and mid- career scientists' perceptions of organizational injustice are associated with behaviors that may compromise the integrity of science and may lead to ethical, legal or regulatory problems for scientists and their institutions (Martinson et al, 2006).

Keith-Spiegel, Koocher & Tabachnik (2006) examined what scientists wanted from their research ethics committee. A total of 886 experienced biomedical and social and behavioral researchers were surveyed to empirically determine desirable characteristics through the rating of 45 descriptors of IRB actions and functions as to their relative importance. The study found a strong correlation of the prior work in predictions related to organizational justice in other work settings. Essentially, researchers placed a high value on the fairness and respectful considerations of their IRBs. Similarly, recommendations were offered that centered on the need to educate researchers regarding the process and providing greater respect to researchers submitting to the IRB process and fairness in the general treatment. Keith-Spiegel et al (2006), noted that the study's outcome indicated that the ideal IRB appears to be a just body that employs fair procedures, treats researchers with respect, and affords researchers to have a voice when disagreements surface.

In the ethnographic work of Jaeger (1999), institutional review boards were instruments of social control and served as a formal and recognized mechanism for organizations, particularly institutions of higher education, to protect the rights and welfare of human subjects involved in research. His case study examined the decision making behavior of one high risk IRB and the decision processes utilized to determine risk and benefit and issues related to the acceptability of research. The strengths and weaknesses of the process as it related to one institution were presented along the lines of information processing of four IRB meetings regarding the domain of research, problem proposals and the setting of precedents.

Stark (2006) examined the decisions made by IRBs and he posited that they were reflective of a particular form of moral regulation that grew from an amorphous state in the early 1950s to one that was fully codified, replete with penalties and a myriad of loosely interpreted guidelines by 1974. Stark's work emerged from a series of observations of local IRBs in a variety of university settings. Through extensive review of meeting notes, policies, and interviews with a national sample of committee chairs, Stark noted that the virtue of most decisions could be rooted in decisions that followed proper procedure and conformed to abstract principles. While the composition of a board may vary, and the boards did not reach the same judgments in substance, relative to similar proposed work, but that they did render what was thought to be equally sound judgments made by collective individuals using common procedures. Findings were advanced because it reflects much of the current reasoning and that consistency in decision making is unique to each board. Moreover, a pattern was established that makes consistency in decisions on the

same proposal submitted to multiple boards virtually impossible, due to the unique characteristics and patterns of analysis employed by each board.

In a study conducted by Lopus, Grimes, Becker, and Pearson (2007) through a web-based survey administered to economic educators who were posed questions regarding their awareness and attitude towards human subjects' research and the mandated federal protocols that govern such research at most American universities. The survey instrument consisted of 39-question web-based survey instrument. The electronic survey was distributed to all of those that who had published articles in the *Journal of Economic Education* in the previous five years. The survey was completed by 110 respondents', however; no mention is made to the total population sample. It may be safe to extrapolate that this is a relatively small response rate in relation to the number of authors and articles published, which is consistent with small sample size in web-based surveys (Gay, 1976).

Demographic data and descriptive statistics were recorded about the respondent's gender, university position, work-time allocations, and the amount of research conducted and published. The respondents answered questions about their institutions' local IRB human subjects' procedures and how those procedures affected the research of the respondent. The study results revealed that many researchers do not know or understand the prevailing definitions and rules in the federal regulations. In general, there were three recommendations made to create a clear understanding of ethical issues involved in human subjects among researchers. The first recommendation suggested that all economic education researchers should be thoroughly familiar with the Common Rule and the IRB process. The second recommendation was that researchers should be thoroughly familiar with their local IRB policies and procedures. This familiarity with policies and procedures

should include whether or not the board requires certification prior to conducting a project involving human subjects as well as how to submit a project proposal for review. Last, the researcher should factor in IRB review time when scheduling new research projects.

In summary, historical events have provided a chronology for the emerging need for the ethics boards and even mentions briefly, the egregious acts of misconduct involving a longitudinal study that occurred in the shadows of an 1890 land grant institution and ambiguously, bears its name using United States' federal funds. In addition, there are a number of studies that examine gender, position classification, and awareness, perceptions, and attitudes as it relates to the role of the IRB in a local university setting. There is, however, limited research related to 1890 land grant institutions' faculty users and faculty non-users and these variables that surface in the academic literature.

University Land Grant Systems:

The Land Grant Designation and the Morrill Acts of 1862 and 1890

According to Boyer (1990), a land-grant college or university is an institution that has been designated by its state legislature or Congress to receive the benefits of the Morrill Acts of 1862 and 1890. The mission of these institutions, as set forth in the first Morrill Act, was to teach agriculture, military tactics, and the mechanic arts as well as classical studies so that members of the working classes could obtain a liberal, practical education. Over the years, land-grant status has implied several types of federal support. The first Morrill Act provided grants in the form of federal lands to each state for the establishment of a public institution to fulfill the act's provisions. The Nelson Amendment to the Morrill Act provides a permanent annual appropriation of $50,000 per state and territory.

A key component of the land-grant system is the agricultural experiment station program created by the Hatch Act of 1887. The Hatch Act authorized direct payment of federal grant funds to each state to establish an agricultural experiment station in connection with the land-grant institution. The amount of this appropriation varies from year to year and is determined for each state through a formula based on the number of small farmers. A major portion of the federal funds must be matched by the state.

To disseminate information gleaned from the experiment stations' research, the Smith-Lever Act of 1914 created the Cooperative Extension Program associated with each U.S. land-grant institution. This act authorized ongoing federal support for extension services, using a formula similar to the Hatch Act's to determine the amount of the appropriation. This act also requires that the states provide matching funds in order to receive the federal monies.

In 1890, the Second Morrill Act was passed, supplementing by direct appropriation the income from the land-grants. To receive the money, a state had to provide evidence that race or color, was not an admissions criterion for higher education access, or else the State designates a separate land-grant college for Blacks. Thus was born in the then-segregated South a group of institutions known as the "1890 land-grants." Thirty-two years following passage of the Justin Smith Morrill Act of 1862, Congress passed the 1890 Morrill Act creating Black land-grant colleges and universities. Today, the rich legacy of the land-grant tradition remains prominent on the campuses of 17 public Black colleges and universities including Tuskegee University, a private, state-related land-grant institution.

According to the National Association of State Universities and Land Grant Colleges (NASULGC) (2008), of which 18 were Historically Black Colleges and Universities (HBCUs), Black land-grant institutions annually enrolled nearly 40 percent of all students in four-year historically Black colleges and universities up to and through the 1990s. An increase in establishment of doctoral programs in the 1990s at these institutions contributed to the scholarship in a variety of fields. The contributions these institutions made to research and scholarship were significant, yet their voice was silent regarding the awareness, perceptions and attitudes of the IRB process among the academic literature.

The 1890 land grant institutions were competitively awarded federal and private dollars for the conduct of research (West Virginia University Extension Service, 1999). Much of the research at 1890 land grant institutions involved social and behavioral research. Typically, this research involved participation by human subjects. Subjects that must communicate their agreement to participate in the study and the proposed study must undergo an ethics review by a local IRB. There was a void in the academic literature that focuses on the IRB function and processes at 1890 land grant institutions. In contrast there was a plethora of evidence in the literature regarding leading research institutions. There were anecdotes regarding research and the IRB within an 1890 land grant institution but, this had proven non-existent in the academic literature.

An Overview of the IRB Process at One 1890 Land Grant University

The history of the inception of the formalized IRB committee on the one case study institution is brief in its existence. This 1890 land grant institution, located in the southeast region of Texas was founded in 1876, only began to recognize the need for an established federally recognized program for all ethics research compliance programs in July 1997.

This need was driven by two events. The first was the proposed solicitation of funds from federal agencies that required evidence of an operational Institutional Review Board (IRB) program and the second was a petition to the Higher Education Coordinating Board (THECB) to consider an expansion to the institutions' existing table of programs to include doctoral program offerings.

According to Noel, (2007) it was overseen by the dean of the college of arts and sciences. There were neatly handwritten records of deliberations and actions; committee participation was evident related to protocols. Also, there were typed letters of determination all neatly packaged in one manila envelope. While the process was viewed as necessary and valuable, the multitude of responsibilities associated with the largest college by student and faculty measures, presented a challenge to balance the full component of the unit responsibilities with a not often needed human ethics program.

The institution has a history of multitasking and multi-titling and true to form; the responsibility was placed in the hands of the newly created position for director of research and sponsored projects, and the then dean of the graduate school, to make the formalization of the program a reality. In addition to administrative responsibilities, the director taught as many as two graduate level courses a semester and traveled extensively. The assignment was passed on to the newly established position of assistant director for research and sponsored projects. The first few months were spent researching the requirements for formalization of the program and traveling to various seminars to gain understanding of the role and processes of the ethics boards.

In September 1997, the university's application was presented to the then federal governing oversight body, the Office for the Protection from Research Risks (OPRR) and

was formally accepted and provided a federal Assurance in November, 1997. The first year of federally recognized existence, two applications were received and processed. Initially, the numbers grew exponentially, for the first few years, and the annual updates were recorded. The geometric progression slowed to the replication of an additive growth pattern. However, even with the existence of four doctoral programs and forty-five master's degree offerings, many in the social and behavioral sciences, the annual numbers of first time protocol or application reviews has, as of November 2007, or ten years since its federally recognized inception, never exceeded fifty (50) per calendar year. This number of first time applications is defined as a medium range classification by the OHRP.

That is not to say that human participant research does not take place. It is just an indictment of the culture that shrouds the process. The executive administrations over the years have been slow to embrace the process and the resistance precipitates vertically and horizontally across communication lines. While there have been tacit attempts to provide presentations at annual faculty meetings, nothing has so dramatically changed the perceived value of the program institution-wide until the creation of a new position, that of associate vice president for research. With the addition of this voice, there have been marked changes in advocacy and commitment to scholarship that is grounded and has undergone the rigors of a formal review.

Theoretical Framework

Awareness, perceptions and attitudes are based upon experiences, conceptualized opinions, and supported by organizational climate and reinforced by organizational culture (Wharton, 1997). On an individual level, they are also formed by a personal system of values that are developed through ones' interaction with the environment, moral reasoning and ethics. This research study is based on the works of two theorists, Lawrence Kohlberg (1976) and Eliot Turiel (1983). Kohlberg's theory of moral development centers on the framework that people progress in moral reasoning through a hierarchy of stages (Dawson, 2002). The theory emphasizes that one's personal values and ethics are developed from the interaction between the person and the environment, and that moral judgment is characterized according to how a person reasons or structures, rather than according to what the person thinks; or content and that determines moral maturity (Berk, 2007; Kohlberg, 1976). This may be further extrapolated to the cultural or environmental climate of an institution.

According to White (1999), Kohlberg's theory was formed from the prior works of moral development theorist Piaget (1965). Kohlberg, like Piaget, characterizes the stages of moral development in three stages: morality focused on outcomes to one based on ideal reciprocity. Kohlberg proposed that all people in all cultures pass from lower to higher stages of moral reasoning. He offered a model of three moral development levels, each level contained two stages and each represented a progressive shift in moral development.

At the lowest pre-conventional level, egocentric individuals see the value of human life only as a means to their own needs and they exhibited obedience and punishment orientation, an egocentric deference to superior power or prestige, and a trouble-avoiding

attitude. Essentially, behaviors that result in punishment are viewed negatively, or bad, those that lend themselves to rewards are positive or good. At the conventional level, individuals see the value of human life in a concrete sense, through the empathy and affection of communal members. They conformed to stereotypical images of the majority and avoided disapproval and dislike by others, but not for reasons of self-interest. Individuals maintained an orientation toward doing one's duty, respecting authority, and maintaining the social order. This belief in the stasis of the current social system was a means of assuring positive relationships and social order.

At the highest post conventional level, individuals view human life as sacred and a universal right. An individual developed moral autonomy and avoided violating the rights of others. There was an orientation to conscience, not only to social rules but to principles of logic. Morality is defined in abstract terms or principles and values that under gird all situations and social orders or societies. Only at the two highest stages in the post conventional level of Kohlberg's theory do moral reasoning and content merge into an ethical coherent system (Kohlberg, Levine, & Hewer, 1983). There is some agreement among theorists, that the development process of identity, personal or institutional, or in this instance a university, are a part of the same process (Bergman, 2004; Blasi, 1994).

The theory of moral development was expanded by Turiel (1983) using the concept to view the differences between moral values, social conventions, and personal choices. Moral values were categorical, universalizable, and structured by underlying conceptions of justice, rights, and welfare. Turiel posited that social conventions were arbitrary and agreed-upon uniformities in social behavior that were determined by the social system and which were alterable and context dependent. Personal choice issues were those issues

which impacted only on the self. Some issues involved overlap. They were multifaceted issues that raised moral values as well as social conventions or personal choices. He perceived the concepts of moral issues as undergoing development in accord with the cognitive development of the individual or institution, so does the understanding of social conventions.

Many factors are thought to influence moral understanding, including interpersonal relationships, years of service, culture and environment. There is mounting evidence that suggests academic experiences work to challenge awareness, perceptions and attitudes by presenting individuals with cognitive challenges which stimulate them to examine moral dilemmas in more complex ways (Berk, 2007).

Interpersonal interactions among colleagues who confront or engage one another with diverse and differing viewpoints promote moral understanding. When colleagues negotiate and compromise with each other they realize that social life or institutional culture can be based upon cooperation between equals in contrast to authority defined relations (Killen & Nucci, 1995). This study combined the two concepts of moral development of theorists Kohlberg and Turiel by examining the concepts from the internal barometers for moral personal development in its application to individuals and institutions.

This investigator perceived moral development as a social control expressed by the environment and that individuals may operate differently in different settings. On the one hand, moral development was viewed as issues related to values and personal choice and was situational as it relates to awareness, perceptions and attitudes. The development and social control are situational to the extent and context as it related to treatment of

participants in social and behavioral based research and further extended to those faculty users of the IRB that carry this research out in one 1890 land grant university setting. Higher moral development can be attributed to users of the IRB process than those who bypass the IRB process and still conduct research involving human participants.

The culture and environment of an institution may be a contributing factor in moral development of the participants and their awareness, perceptions and attitudes of the IRB's role and processes. As with individuals, not all institutions or universities achieve or aspire to the highest levels of moral development and this must be considered when examining the voices of users and faculty non-users of the IRB and in the development of in-service programs and other systems of rewards.

CHAPTER III

RESEARCH METHODOLOGY

The primary purpose of the study was to determine differences among groups of administrators, faculty and professional staff members' perceptions of the function and process of the IRB on one 1890 land grant campus. The second purpose was to develop a profile of the faculty members who were more likely to be users and faculty non-users of the IRB. Third, this study was conducted to expand scholarly works and empirical literature as related to the local IRB's role in research and its impact upon the university community.

To respond to the research study purpose, five questions were addressed:

1. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users regarding role and processes of the university's IRB?
2. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users by status regarding the role and processes of the university's IRB?
3. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users by rank regarding the role and processes of the university's IRB?
4. What are the differences in the levels of awareness, perceptions and attitudes between and faculty non-users, by years of service regarding the role and processes of the university's IRB?

5. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users by age regarding the role and processes of the university's IRB?

This chapter will provide the research design, population and sample, human subjects' protection, instrumentation, data collection and analysis, procedures and threats of validity as it relates to this study.

Research Design

This investigator employed a one-shot case study, pre-experimental design using a rigorous method of research. According to Yin (2003), the one-shot case study research remains one of the most challenging of all social sciences endeavors, but has been used in many situations that contribute to the knowledge base of science. This design has provided a common base for research strategy in social and behavioral sciences. Yin also noted that this methodology assists investigators with an understanding of complex social phenomena that allows holistic and meaningful characteristics of authentic life events. The characteristics of the study design answers questions that requires exploratory and explanatory or how and why contemporary situations occur for which the investigator has little or no control. This enabled the investigator to find the differences among two groups (faculty users and faculty non-users) within a sample.

Population and Sample

The population of this study consisted of faculty from one 1890 land grant university located in south central region of the United States. Founded in 1876, this university is the second oldest institution of higher learning in the state. According to its states constitution, it is one of the three "institutions of the first class". With an established

reputation for producing engineers, nurses and educators, this 1890 land grant university offers baccalaureate degrees in 50 academic majors, 37 master's degrees and four doctoral degree programs through eight colleges and schools. This institution is the site of the first Army ROTC (1943) and Navy ROTC (1968) programs established to train African-American officers. The university has produced nine flag-rank officers, more than any other single institution. The university has an extension program that has a presence in thirty-eight of the states counties. As part of its mission, it provides a number of outreach services in the areas of agriculture and natural resources, youth and families, and health, finance and nutrition programming targeted to address the needs of low and limited resource individuals.

The university is a member of a System which has a centralized governance system, comprised of nine universities, seven state agencies, a health science center and central administrative offices in fiscal year 2009. The System was created by the state legislature in 1948 to manage the evolution of a state-wide educational, research and service system. Its roots lie in the founding of what are now the two oldest land grant colleges in the state both founded in 1876: one to educate the state's European American population and the other the African American population. Its role is governed by the state's education code and responsibilities include system-wide planning, coordination and execution of the policies of the System's Board of Regents.

The System's approved budget of more than $3 billion for 2009 funds operations at its nine campuses throughout the state and a medical center. The System educates more than 105,000 students and reaches another 15 million people through service each year. With nearly 27,000 faculty and staff, the System has a physical presence in all but six of

the state's 254 counties and a programmatic presence in every county in the State. Externally funded research brings almost $627 million every year to help drive the state's economy.

The University is dedicated to fulfilling its land-grant mission of achieving excellence in teaching, research and service. In 2002, research was for the first time, inserted into its campus wide mission statement and approved by its governing board. Prior to that, its focus was teaching and service. The university was founded by its state legislature as its first state supported college for African Americans. Situated in a rural community on the periphery of the nation's fourth largest city, the university has approximately 8,000 students enrolled.

According to the 2008 University Fact Book, this institution's research expenditures were $11.6 million dollars for fiscal year 2007. The institution employed 487 faculty members of which 433 (89%) held a terminal degree, 116 (24%) were tenured faculty, 108 (22%) were tenure track, and 263 (54%) were non-tenured. Of the faculty population, a total of 346 (71%) were males and 141 (29%) females.

Sample

The sample group in the original data base consisted of 68 respondents, drawn from a cross section of faculty members who were employed at the institution in the fall of 2007. However, this study sample group consisted of 50 respondents. Due to the nature of the study, random sampling techniques were not employed. Convenience sampling was used to obtain the study sample group. The sample group came from the following self-identified categories: faculty users and faculty non-users, age 18 and above, who were currently employed at the institution of higher education in the fall of 2007. For the

purposes of this focused study, the data were further reviewed and eliminated cases which the respondent had not responded to 60% of the survey questions and those who did not meet the status of tenured or tenure track during the 2007 fall semester. Respondents who provided incomplete information were excluded from the data analysis and the yield for the study sample was adjusted accordingly. Subsequently, the secondary data yielded fifty (50) respondents that met this criterion. The response rate yield was recorded as 22.3%. The faculty members with tenure and tenure track status were further classified based upon their response to a question on the survey as faculty users or faculty non-users. By answering affirmatively to the question on the survey instrument that asked "Have you submitted a protocol application to the local IRB within the past three years?" A total of 17 (34%) of the respondents self- identified themselves as "faculty users". Thirty-three (33) of the respondents (66%) indicated that they had not submitted a protocol to the local IRB in the past three years and were classified for the purposes of this study as faculty non-users.

The rate of return was rather low for these questionnaires – 68/224 (Responses/Total distributed) - only 30.37% of the total distributed to faculty. This low response rate is problematic and the challenge lies in not knowing how the non-respondents would have answered. Hutchinson (2001) notes that "the potential for nonresponse bias is always present when less than 100% of the surveys are returned, with the risk of bias increasing as response rate decreases" (p. 291) (Hutchinson uses the term survey research to include questionnaires and interviews as instruments). Three additional articles suggest that the data is still useful in a study as long as the report indicates the

possibility of bias because of the low response (Data Analysis Australia, 2007; Gay, 1976; Jarrett, 2005).

Protection of Human Subjects/Participants

In accordance with the Department of Health and Human Services (DHHS), i.e., the Federal Policy 45 CFR 46, and the regulations of the Food and Drug Administration, 21 CFR 50, an application was filed with the TAMU Human Subjects Review Committee for review and subsequent approval (Appendix C) to analyze the data collected from the assessment instrument. Based on the information submitted, the IRB made a determination that the study was exempt from further review. Participants read instructions (Appendix B) which outlined the general nature of the assessment. In the letter of information the participants were advised of the voluntary nature of their participation and that no names or linkages to identification were collected or retained relative to the assessment. All of the required language by the IRB was included in the body of the text of the electronic document. Essentially, this communicated the federally mandated guidelines regarding protections for human participants and that submission of the completed questionnaire constituted informed consent to act as a participant in this assessment.

Instrumentation

According to Noel, former dean and current associate vice president for research (personal communication, December 17, 2007); several instruments were reviewed to meet the needs of the institution for an assessment of the role and processes of the IRB. The University research team developed an instrument for on-line assessment and for information to support subsequent training and communication needs after reviewing several existing instruments. The resulting instrument underwent face validity testing.

The Instrument (Appendix D) consisted of 27 items with subscales, which measured perceptions, awareness, and attitudes relative to the IRBs role and processes. The first section of the instrument retrieved demographic data on subjects such as gender (male or female), faculty status - tenured and tenure track, academic rank (instructor, assistant professor, associate professor, professor), years of service, and age. This instrument covered six sections and measured perceptions, awareness, attitudes, preferences, experiences, and demographics; however this investigator examined in this study only the variables awareness, perceptions and attitudes.

Section II of the instrument explored experiences that consisted of twelve questions to include two open-ended items for response. Ten of the questions had a combination of ordinal (number of times submitting) and nominal (Yes or No) response options that were posed to respondents. Section III contained question items related to awareness. Four nominal questions were posed to obtain a Yes or No response. Section IV focused on attitudes of respondents. Four questions used a five point Likert Scale. Sections V and VI consisted of questions on perceptions and preferences to policies that consisted of thirteen questions using a four point Likert Scale and four ordinals and one open-ended response item.

E. N. Noel, associate vice president for research, (personal communication, December, 17, 2007) noted that the questionnaire items were screened and reviewed by members of the research administration assessment committee at the local institution for content, clarity and face validity. After screening and review by the committee, the preliminary survey questionnaire was piloted with faculty and professional staff at the 1890 land grant institution. Respondents were asked to complete all sections of the

questionnaire and to note questions that they had concerning readability, intent of question and format. Also, the length of time required to complete the electronic questionnaire was documented. After piloting the survey instrument, the results from the sample were analyzed and the duration to complete the questionnaire was revised as well as the readability of several questions, based on the recommendations received. Not all questions from the survey were reviewed in this study. Only those questions from the survey instrument that related to demographics (i.e., gender, status, rank, years of service, age) and perceptions, attitudes, and awareness were analyzed. To fortify the analysis of the variable attitude, the variables from experience and perception were combined. An item analysis of questions selected by instrument and content measure follows (Table 3.1).

Table 3.1

Scale Items for Electronic Research Instrument by Awareness, Perception and Attitude from PAAPE Instrument

Variable	Scale Question Items
Demographics (7 items)	Gender
	Ethnicity
	Age
	Years of Service with Institution
	Employment Classification
	Academic Rank
	Tenure Status
	Have you submitted an IRB to the board within the last three years
Awareness (4 items)	Are you familiar with the purposes of the IRB?
	Are you aware that the University has an active IRB?
	Have you ever read the full packet of information provided by the IRB to protocol applicants?
	Was the process for reviewing a research proposal for human subjects'/ participants clear?
	The IRB monitors the progress of each approved in line with federal policy (for example, annual updates)
Perception (6 items)	
	The IRB show considerable evidence that the advancement of science is part of its mission
	The IRB requires members to recuse themselves from evaluating protocols whenever there might be a real or apparent conflict of interest.
	IRB membership is very knowledgeable about IRB procedures and federal policy
	The IRB conducts a conscientious informed analysis of potential benefits against potential risks before making decisions
	The IRB views protection of human participants as the primary function

Table 3.1 Cont.

Variable	Scale Items
Attitude (20 items)	The IRB reviews the protocols in a timely manner
	The IRB gave a complete explanation for any required changes to the protocol
	The IRB includes a complete explanation when it disapproves a protocol
	The IRB invites investigators to present their protocol during a meeting of the board
	The IRB members offer consultation during the development of a research protocol
	The IRB offers investigators opportunities to be educated about federal research policy, through human subjects'/participants electronic training
	IRB offers editorial suggestions regarding informed consent documents and research protocols (e.g., typos, grammar, clarity)
	Have you ever been unable to carry out a research project because of problems with the IRB?
	If you were unable to carry out a research project because of problems with the IRB, what was the issue?
	Do you think the IRB has treated you fairly and equitably when evaluating your proposed research?
	Do you believe that students should have requirements in their classes to conduct research involving other people?
	If a graduate student wants to conduct research involving human participants for a master's thesis or a doctoral dissertation, should the student be required to obtain IRB approval for this research?
	Suppose that a large company wants a faculty member to help test the effects of an experimental medical treatment on patients, as one of dozens of such tests all over the US. Should the faculty member be required to get approval from the university IRB to do the proposed research here?
	Suppose that a private business or government agency wants a faculty member to analyze data on customers or clients that they routinely collect as part of their regular business operation. Should the faculty member be required to obtain approval from the university IRB to do the proposed research?

Table 3.1 Cont.

Variable	Scale Items
Attitude	The IRB reviews the protocols in a timely manner
	Should the faculty member be required to obtain approval from the university IRB to do the proposed research?
	Have you ever submitted a research protocol to the University IRB for approval?
	During your time at the university, approximately how many research proposals have you submitted to the IRB
	Select the type of assessment in which you engage?
	Have you ever served on an IRB Board?

Collection of Data

Secondary data were collected via an assessment distributed through the university global electronic mail system. Data utilized were obtained from an 1890 land grant university, from research staff members, who collected the data employing an electronic survey that anonymously obtained perceptions, awareness and attitudes from a diverse group of administrators, faculty and professional staff members. Permission to access data sets was obtained from the university associate vice president of research, who gave this investigator permission to utilize the data for this educational purpose and related scholarly activities (Appendix A). Faculty members were given an opportunity to review an electronic information form that indicated that this assessment was in preparation for an impending institution-wide reaffirmation of accreditation. Faculty were advised that one purpose of the study was to compile records to satisfy the requirement for self-analysis and further stated, that the data may be used for educational purposes. Interested participants reviewed the letter of information and acknowledged the electronic survey.

The survey was administered within the context of developing a method to assess strengths and weaknesses in the service support area of research regulatory compliance. Data were provided in aggregate form stripped of all identifying information and only demographics supported the data set. Collection methods were such that all responses were anonymous. Elected subjects reviewed the information sheet by pressing an icon affirming their willingness to participate. The icon took subjects to the on-line survey and subjects were asked to complete a battery of questions that assessed variables such as demographic status, awareness, perceptions and attitudes by selecting the appropriate response to set of questions. According to the E. N. Noel (personal communication, December 17, 2007),

the initial numbers were less than optimal and several appeals were made via a number of mechanisms such as meeting with department heads, deans and executive management teams and an inducement was included to increase the number of participants (See Appendix C). The subsequent appeals to the IRB faculty users and faculty non-users netted a modest increase from 7.9% to 22.3% for faculty users and faculty non-users to participate in this study.

Analysis of the Data

The data were analyzed by conducting a quantitative analysis employed to calculate frequencies and percentages for all of the variables of the respondents. Between groups and among variables, the statistical procedures were used to perform the following: frequencies and cross tabulations, independent t-Test, reliability test using a Cronbach's Alpha procedure, an analysis of covariate analysis (ANCOVA), and a multivariate analysis of covariates (MANCOVA) procedure to test the research questions. These statistical procedures were employed to obtain mean scores and standard deviations of variable measures to quantify relationships between faculty users and faculty non-users. Covariates such as status, rank, years of service and age were as also used to determine if there were any statistical significance between faculty users and faculty non-users. Findings were reported using tables and written narrative form. The investigator employed the following procedures to conduct this study (Table 3.2).

Table 3.2

Research Procedures for the Awareness, Perception and Attitude by Faculty Users and Faculty Non-users toward the Role and Processes of the IRB

Steps	Tasks
1.	Collected data via digital media
2.	Examined the data to ensure confidentiality
3	Eliminated cases that provided incomplete responses and identified subjects self identified as tenured and tenure track. 18 cases were removed from the file leaving 50 cases.
4	Computed three new variables (AWARENESS, PERCEPTION and ATTITUDE using the question items. The variable Attitude was formed by using question items PERCEPTION and EXPERIENCE = ATTITUDE.
5.	Reliability Test will be conducted using scale items that formed the variables awareness, perception, experience and attitude; using a series of coefficient alphas (Cronbach's Alpha).
6.	Frequencies and cross tabulations were conducted to obtain the descriptive analysis of the demographic of the sample group.
7.	Analyses were conducted to answer research questions employing an ANCOVA with three dependent variables awareness, perception and attitude. MANCOVA using covariates: Status, rank, years of service, and age with faculty users and faculty non-users.

Threats to Validity

The threats to the validity in this study centered on the secondary data and instrumentation are presented under this rubric. Secondary data analysis has the advantage of greatly reducing the time and cost of doing research and the disadvantage of providing the investigator with little or no control over the data (Hearst, Grady, Barron & Kerlikowske, 2001). This offers a reasonable understanding of the challenges of examining secondary data for content analysis with respect to differences among variables such as faculty users and faculty non-users. Due to the secondary nature of the data and electronic distribution of the instrument, the investigator had no way of knowing whether all surveys were distributed to and received by the potential respondents' because this data was not recorded.

File size limitations on mail systems may have affected this process. Institutions tend to guard resources such as server space, allocated in the form of electronic mail, as a resource tantamount to a nonrenewable resource or the proverbial treatment associated to the protection of highly priced asset. Therefore a premium on the allocation arbitrarily governs the availability, with little regard to the vital communication aspect of the resource. So faculty users and faculty non-users may have the same allotment with vastly differing requirements related to their role within a campus environment. Many potential respondents' mail boxes may have exceeded their capacity and the survey mail was rejected.

Since the survey was conducted independently utilizing a survey generator system and this data was not kept, it is impossible to do anything other than speculate as to the low yield. Another factor is the purging of the mail list. There may have been potential

respondents, that while their addresses were active, they may no longer have had an active affiliation with the institution because of a change in their status as a faculty (tenured and tenure track) or had recently left employment with the institution. It has been noted by other researchers that electronically distributed surveys tend to produce a lower yield than mail out and face to face interviews (Yin, 2003). Just as other electronic generated surveys have low yield it may be safe to extrapolate that this is a relatively small response rate in relation to the number of authors and articles published, which is consistent with small sample size in web-based surveys (Gay, 1976).

CHAPTER IV

FINDINGS AND DISCUSSION

Chapter IV presents the statistical findings and results of the data collected from faculty members who participated in an online survey at one 1890 land grant university.

The primary purpose of the study was tri-fold: (1) the study was conducted to determine differences between faculty users and faculty non-users awareness, perceptions and attitudes about the role and processes of the IRB on one1890 land grant campus; (2) to determine, when controlling for status, rank, years of service, and age whether these variables contributed to the identification of the faculty profile for faculty users and faculty non-users of the local IRB at one 1890 land grant university; and (3) this study was conducted to expand scholarly works and empirical literature as related to the local IRB's role in human participant's research and its impact upon the 1890 university land grant community.

The findings and discussion were organized to answer the following five research questions:

1. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users regarding the role and processes of the university's IRB?
2. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users, by status regarding role and processes of the university's IRB?

3. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users, by rank regarding the role and processes of the university's IRB?
4. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users, by years of service regarding the role and processes of the university's IRB?
5. What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users, by age regarding the role and processes of the university's IRB?

The first section of this chapter provides a descriptive analysis of the sample. Information was collected from faculty responses to the Perceptions, Attitudes, Awareness, Preferences and Experiences (PAAPE) regarding the role and processes of the local IRB instrument. The descriptive analysis is presented by using several selected demographic variables. The second section of the chapter validated the reliability of the instrument. The third section displays the findings and results of the five research questions concerning the respondents' awareness, perceptions and attitudes about the role and processes of the IRB at one land grant institution.

Demographic Characteristics of the Sample Group

A total of 68 respondents completed the online survey. Out of the 68 respondents, only 50 were self identified as faculty members with tenure and rank status, who met the criteria of having completed 60% of the online survey instrument. Therefore, for this study the sample group was comprised of 50 participants. Table 4.1 presents frequencies and

percents of the sample group demographic characteristics such as: gender, ethnicity and age. The response rate for tenured and tenure track faculty was recorded as 22.3%.

Table 4.1 indicates the sample group was comprised of male (*n*=30) 60% and female (*n*=20) 40% respondents. The ethnicity of the vast majority of the respondents were reported as African Americans (*n*=36) 72% and European Americans (*n*=10) 20%. Information on the age range of the respondents was also provided. The sample group reported their ages ranged from 21 to 51 years and older. The category of age was presented in a range or band format. Findings indicate that the majority of the respondents were 51 years and over (*n*=28) 56% (see Table 4.1).

Table 4.1

Demographic Characteristics of the Sample Group by Gender, Ethnicity and Age

Variable	N=50	%
Gender		
Male	30	60
Female	20	40
Ethnicity		
Indian/ Native American	1	2
Asian/Asian American	3	6
African American	36	72
European American	10	20
Age		
21-39	5	10
40-50	17	34
51 and over	28	56

Table 4.2 provides information on the years of service of the respondents to the 1890 land grant institution. The years of service reported by respondents ranged from 1 year to sixteen or more years. The category years of service was presented in a band or range format. A total of 23 (46%) respondents indicated that they were within the service range of 1-5 years and 20 (40%) respondents indicated years of service in the range of 6-15 years. Overall, findings indicate more respondents had 15 or less years of service to the land grant university (see Table 4.2).

Table 4.2

Sample Group Characteristics of Faculty by Years of Service

	N= 50	%
Years of Service		
0 to 7 years	23	6
8 to 15 years	20	0
16 or more years	7	4

Table 4.3 presented frequencies and percents of the respondents by faculty rank and tenure status. The sample group's faculty rank were comprised of a majority of assistant professors (*n*=30) 60% and professors (*n*=11) 22%. The sample group also reported their status by indicating tenured or tenure track. The sample group consisted of fewer tenured faculty members and more tenure track faculty members (see Table 4.3).

Table 4.3

Demographic Characteristics of Sample Group by Faculty Rank and Tenure Status

Variable		N=50	%
Rank			
	Assistant Professor	30	60
	Associate Professor	9	18
	Professor	11	22
Status			
	Tenure track	20	40
	Tenured	30	60

Demographic Characteristics of Sample Group

Table 4.4 depicts the demographic characteristics of the respondents in the sample groups by faculty users and faculty non-users of the IRB process. Frequencies and percents of the characteristics of the sample group of respondents by faculty users and faculty non-users illustrates faculty users comprised (*n* =17) 34% of the respondents, and faculty non-users of the IRB (*n* = 33) 66% of the respondents (see Table 4.4).

Table 4.4

Demographic Characteristics of the Sample Group by Faculty Users and Faculty Non-users of the IRB

Variable	(N= 50)	
	N	%
Faculty Users	17	34
Faculty Non-users	33	66

Table 4.5 details the demographic characteristics of faculty users and faculty non-users by gender. Examining the faculty users and faculty non-users, respondents were comprised of female users (*n*=5) 10% and male users (*n* =12) 24%; and female faculty non-users (*n*=15) 30% and male faculty non-users (*n*=18) 36%. It was noted that male faculty non-users were slightly more prevalent than the female faculty non-users. Also, male users were more representative than female users (see Table 4.5).

Table 4.5

Demographic Characteristics of Faculty Users and Faculty Non-users by Gender

Variable	Faculty Users (N=17)		Faculty Non-users (N=33)	
	N	%	N	%
Gender				
Male	12	24	18	36
Female	5	10	15	30

Table 4.6 illustrates the demographic characteristics of faculty users and faculty non-users by ethnicity. The majority of the faculty users were comprised of African Americans (*n* =10) 20% and European Americans (*n* = 5) 10%. In examining the data, faculty non-user respondents were comprised of a greater representation of ethnicities from African Americans (n =26) 52% and European American faculty non-users (*n* = 5) 10%. European American faculty users and faculty non-users were equally represented in the total sample group (see Table 4.6).

Table 4.6
Demographic Characteristics of Sample Group of Faculty Users and Faculty Non-users by Ethnicity

Variable	Users (N=17)		Faculty Non-users (N= 33)	
	N	%	N	%
Ethnicity				
American/Native	1	2	0	0
Asian American/ Asian	1	2	2	4
African American	10	20	26	54
European American	5	10	5	10

Table 4.7 demonstrates frequencies and percents of the respondents', faculty users and faculty non-users, by age range. The respondents age ranged from 21 to fifty-one years and older. The category of age was presented in a range or band format. The smallest number of faculty user respondents was represented by one (2%) respondent which reported they were within the age range of 21-39. A total of 4 (8%) user respondents indicated an age in the range of 40-50 and 12 (34%) of the faculty user respondents selected the age range of 51 and over, which represented the largest percentage of the user respondent pool of the sample identified as users of the IRB process. Findings indicated that the majority of the respondents (*n*= 33) 66% were faculty non-users. Of the respondents, 17 (34%) faculty non-users and 12 (24%) faculty users, a total of 29 (58%) were 51 years and over.

Table 4.7

Demographic Characteristics of Faculty Users and Faculty Non-users by Age

Variable	Users (N= 17)		Faculty Non-users (N=33)	
	N	%	N	%
Age				
21-39 years	1	2	3	6
40-50 years	4	8	13	26
51 and over	12	24	17	34

Table 4.8 depicts years of service, rank and faculty status of respondents. The category of years of service was presented in a range format. The reported years of service ranged from one year to sixteen or more years. For faculty users (*n*= 17) 34% , a total of 7 (14%) respondents indicated they had one to 5 years of service; 8 (16%) respondents had 6 to 15 years of service and 2 (4%) had 16 or more years of service. A total of 66% (*n*= 33) faculty non-users reported a years of service range of 1-5 years, 16 (32%), 12 (24%) respondents indicated 6 to 15 years of service and only 5 (10%) respondents reported 16 or more years of service.

The faculty users and faculty non-users, respondents' reported their faculty rank as the following: faculty user assistant professors (*n*=10) 20%, associate professors (*n*=5) 10% and professors (*n*=2) 4%. Of the 33 faculty non-users, findings indicated that they were comprised of assistant professors (*n*= 20) 40%, associate professors (*n* =4) 8% and professors (*n*= 9) 18%. The respondents in the sample group reported their faculty tenure status as well. Of the 17 users, the sample consisted of tenured faculty (*n*=5) 10% and tenure track (*n*= 12) 24%. Of the 33 faculty non-users, the sample consisted of tenured faculty (*n*=16) 32% respondents and tenure track faculty (*n*=14) 28% (see Table 4.8).

Table 4.8
Demographic Characteristics of the Sample Group of Faculty Users and Faculty Non-users by Years of Service, Rank and Faculty Status

Variables	Users (N=17) N	%	Faculty Non-users (N=33) N	%
Years of Service				
1-5 years	7	14	16	32
6-15 years	8	16	12	24
16 or more	2	4	5	10
Rank				
Assistant Professor	10	20	20	40
Associate Professor	5	10	4	8
Professor	2	4	9	18
Faculty Status				
Tenured	5	10	16	32
Tenure track	12	30	14	28

Reliability Analysis

A series of Cronbach Alpha tests were conducted with the PAAPE survey instrument which depicts the three variables of awareness, perception, and attitude to determine the reliability of the instrument utilized in the study. These analyses were conducted with the sample group. Table 4.9 illustrates the results of the Cronbach Alpha analyses. The table describes the scales, the number of scale items and the correspondent Alpha coefficient scores. The Alpha reliability coefficient of .70 or higher is considered "acceptable" in most social science research situations (Hays, 1981; Lord & Novick, 1968). According to criteria for measuring internal consistencies for reliability, the PAAPE had respectable measures and were considered as very reliable. The instrument had not been validated for its reliability and internal consistency until this study was conducted. Thus, awareness, perception and attitude scales in the instrument were reported as being highly acceptable and appropriate for this study (see Table 4.9).

Table 4.9

Cronbach Coefficient Alphas for PAAPE's Awareness, Perception and Attitude Scales

Scales	Questions No. of Items	Cronbach's Alpha
Awareness	4	.73
Perception	7	.91
Attitude	27	.95

Analysis of the Research Questions

A series of statistical procedures were used to analyze the data for testing the research questions. First, an independent sample *t* test on the three dependent variables was conducted to test the first research question. The findings and results of the tests revealed the mean scores, standard deviations, *t* test scores and significant levels of each of the dependent variables. It was noticed by the investigator that there were differences between the faculty users and faculty non-users. Second, several two-way ANCOVA were conducted on each of the dependent variables, controlling for status, rank, years of service, and age. This was conducted to compare the group variance between groups. The investigator employed a MANCOVA to determine the difference between subject groups.

The investigator identified directional indicators to assess a high or low level of awareness, perception and attitude. When the mean scores reflected a high score among two of the variables, awareness and perception, this indicated that the faculty users or faculty non-users had a favorable response to their awareness and perception of the IRBs role and processes. When the mean score was low, this was an indicator that the faculty users and faculty non-users exhibited an unfavorable response toward the identified variables of awareness and perception. On the other hand, when the mean score was high for attitude (which was a combination of the variables perceptions and experiences of the IRB); this high mean score represented a negative level of attitude toward the IRBs role and processes. The investigator established a cut off mean score to indicate or set a threshold level for determining high or low awareness, perception and attitude. Mean scores of 20 and above were considered to be a high level of behavior; mean scores of 19

and below were considered to be a low level of behavior (awareness, perception and attitude). The statistically significant level was set for $p \leq .05$ and p=.01.

Research Question 1: What are the differences in the levels of awareness, perceptions and attitudes between faculty users and faculty non-users regarding the role and processes of the university's IRB?

Table 4.10 depicts the differences between the faculty users and faculty non-users awareness, perception and attitude toward the IRBs role and processes. The independent *t*-test analysis was conducted with faculty users and faculty non-users to conduct differences of both groups. For perception, it was noted that the $t = (2, 48)$ -3.59, $p < .01$. The table reflects a high mean score for faculty users' perceptions, M = 26.4, SD = 7.99, whereas the faculty non-users recorded a mean score M= 16.1, SD = 10. Perception between the groups' faculty users and faculty non-users, were found to be statistically significant. Furthermore, perception mean scores for faculty users were above the established set cut off point: mean score 20.Whereas the faculty-non users mean score was below the set cut off point. This indicated that the faculty users had a high level of perception compared to faculty non-users.

The variable attitude was found to be statistically significant at the .05 level for both groups', faculty users and faculty non-users. The variable attitude was reported: $t = (2, 48)$ 5.78, $p < .05$, with M = 44.2, SD =7.43 and the faculty non-users M = 28.2, SD= 10.12. The established set cut off point for the attitude levels were found to be high for both groups, faculty users and faculty non-users mean scores. This was an indicator that both faculty users and faculty non-users had a negative attitude toward the IRB. Thus, those who were deemed to be faculty users of the IRB had a higher mean score than the

faculty non-users, which indicated that the faculty users had a greater negative attitude than the faculty non-users.

Overall, the data indicated that there were significant differences in the levels of perceptions of the faculty users and the faculty non-users. However, there were no significant differences between both faculty users and faculty non-users when controlling for the variable of awareness (see Table 4.10).

Table 4.10

Independent *t*-Test: Differences between Faculty Users and Faculty Non-users Levels of Awareness, Perception and Attitude

Variables	Faculty Users		Faculty Non-users			
	M	SD	M	SD	*df*	*T*
Awareness	7.6	0.71	6.7	0.28	48	-2.56
Perception	26.4	7.99	16.1	10	48	-3.59**
Attitude	44.2	7.43	28.2	10.12	48	-5.78*

*p <.05 **p < .01

Research Question 2: What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users by status regarding role and processes of the university's IRB?

Table 4.11 shows the differences between the faculty users and faculty non-users levels of awareness, perception and attitude toward the IRB role and processes by status (tenured and tenure-track). An analysis of covariance (ANCOVA) procedure was conducted using status (tenured and tenure-track) as the covariate, to find the difference between the faculty users and faculty non-users of both groups. There were no statistically significant differences between groups. Thus, the investigator did observe the mean scores of the faculty users and faculty non-users, which provided a high or low mean score that indicated a negative or positive level for awareness, perception and attitude toward the IRB roles and processes.

Awareness for faculty users and faculty non-users for both tenured and tenure-track status mean scores were low, which indicates a negative level of awareness toward the IRBs role and processes. The means score all fall within range for both tenured and tenure-track faculty users and non-users. There were no significant differences in the levels of awareness between the faculty users and the faculty non-users as it relates to status. For faculty users who were tenured and tenure-track awareness *M*= 7.71 and 7.5, with a SD= .48 and .84; faculty non-users with tenured and tenure-track awareness, *M*= 7.23, SD= 1.09; *M*=6.4, SD=1.3.

Perception, for tenured faculty users and tenured faculty non-users, perception *M* = 27.8, SD = 6.95; *M* = 14.1, SD= 9.13. For faculty users and faculty non-users who were on

tenure-track, perception *M* = 24.28, SD = 9.46 and *M* = 19.07, SD= 11.55. Perception for groups' tenured faculty users and tenure track users, mean scores were above the established set cut off point, whereas the faculty non-users tenured and tenure- track mean scores were below the set cut off point which indicated that faculty users (who were tenured and tenure-track) had a high level of perception, whereas faculty non-users (tenured and tenure-track) perceptions means scores were low and were considered to have a negative perception level.

The variable attitude between tenured and tenure-track faculty users and faculty non- users were found to be statistically significant, *t* = (3, 46) 2.28, p = .05. The variable attitude reported for faculty users tenured *M* = 42.28, SD =8.67 and tenure-track *M* = 45.7, SD = 6.54, thus for faculty non-users with tenure *M*=30, SD=11.64 and tenure-track *M* = 27.05, SD= 9.13. This finding indicated that for tenured and tenure-track status both faculty users and faculty non-user had high mean scores for attitude which means both groups had a significant negative level of attitude toward the IRBs role and processes (see Table 4.11).

Table 4.11

Differences between IRB Faculty Users and Faculty Non-users by Rank, Awareness, Perception and Attitude by Status

	Awareness		Perception		Attitude	
	M	SD	M	SD	M	SD
Faculty Users						
Tenured	7.71	0.48	27.8	6.95	42.28	8.67
Tenure track	7.5	0.84	24.28	9.46	45.7	6.54
Faculty Non-users						
Tenured	7.23	1.09	14.1	9.13	30	11.64
Tenure track	6.4	1.31	19.07	11.55	27.05	9.13

Research Question 3: What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users by rank regarding the role and processes of the university's IRB?

Table 4.12 portrays the differences between the faculty users and faculty non-users awareness, perceptions and attitudes toward the IRB role and processes by faculty rank (assistant professor, associate professor, and professor). An analysis of covariance (ANCOVA) procedure was conducted using rank as the covariate, to find the difference between the faculty users and faculty non-users of both groups. The variable awareness for faculty users and faculty non-users by rank assistant professor, associate professor and professor mean scores were similar in range. Faculty users reported mean scores: assistant professor M= 7.5, SD= .84; associate professor M = 7.9, SD = .44; professor M=7.5, SD= .07. It was reported for faculty non-users, assistant professor M = 6.4, SD= 1.31; associate

professor, M= 6.4, SD = .09; professor, M= 7.44, SD= 1.13. The mean scores were below the established cut off point and this indicated that the awareness levels for faculty users and faculty non-users who were assistant professors, associate professors and the professor rank had a negative level of awareness.

Perception between the faculty users and non-users by rank varied in mean scores. Among the faculty-users who were ranked as assistant professors and associate professors, they had a high mean score, M =27.8, SD= 6.95; M=28, SD =8.57. For full professor, it was reported M= 15, SD = 1.41. Assistant professor and associate professor mean scores were above the established cut off point, which indicated that they had a high level of perception of the IRB role and process. The full professor means score were below the established cut off point which indicated that their perception of the IRB role and process was low or had a negative perception. For faculty non-users, assistant professor, associate professor and full professor mean scores were all below the cut-off point, which indicated regardless of rank among the faculty non-users, each had a low or a negative perception level of the role and process of the IRB.

Faculty users and faculty non-users by rank, attitude levels were quite high and exhibited a statistical significance, t = (5, 44) 2.24, $p \leq .05$. The faculty users assistant professor M = 45.7, SD = 6.55, associate professor M = 45.8 SD 7.66 and professor M = 33.5, SD .07; faculty non-users, assistant professor M = 27.05, SD = 9.13, associate professor M = 27.5, SD = 13.5 and professor M =31, SD = .07. Due to the fact, that the mean scores were above the established set point of 20 and above, this level indicated that the attitude for faculty users and non-users who self- identified themselves as assistant professor, associate professor and full professorship displayed a higher level of attitude

toward the IRBs role and processes. Moreover, the findings show that there was a statistically significant difference between faculty users and non-users by rank in their attitude regarding to the IRBs role and processes (see Table 4.12).

Table 4.12

Difference Between IRB Faculty Users and Faculty Non-users by Rank, Awareness, Perception and Attitude

	Awareness		Perception		Attitude	
	M	SD	M	SD	M	SD
Faculty Users						
Assistant Professor	7.5	0.84	27.8	6.95	45.7	6.55
Associate Professor	7.9	0.44	28	8.57	45.8	7.66
Professor	7.5	0.07	15	1.41	33.5	0.7
Faculty Non-users						
Assistant Professor	6.4	1.31	14.1	9.1	27.05	9.13
Associate Professor	6.75	0.096	17.5	13.4	27.5	13.5
Professor	7.44	1.13	19.17	11.45	31	11.46

Research Question 4: What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users, by years of service regarding the role and processes of the university's IRB?

Table 4.13 displays the differences between the faculty users and faculty non-users, awareness, perception and attitude toward the IRBs role and processes as it relates to years of service. An analysis of covariance (ANCOVA) procedure was conducted using years of service as a covariate to find the difference between both groups' faculty users and faculty non-users.

Examination of the variable awareness findings presented statistically significant differences between faculty users and faculty non-users and years of service, t = (5, 44) 3.30, $p < .05$. The faculty users, with 1 year to 5 years of service M = 7.71, SD= 7.55, 6 to 15 years M= 7.50, SD= 7.55 and 16 or more years M= 7.50, SD = .70; Faculty non-users, 1 year to 5 years of service M = 6.93, SD= 1.18, 6 to 15 years M= 6.58, SD= 1.24 and 16 or more years, M =6.40, SD = 1.81. The mean scores fell below the established cut off point, that indicated the awareness level by years of service were considerably lower for the faculty users and faculty non-users had a negative level toward the IRB role and processes.

For faculty users and faculty non-users by years of service, the perception levels did not exhibit a statistical significance between the two groups. However, the faculty users 1 to 5 years of service M = 25.57, SD = 9.05, 6 to 15, M = 28, SD= 6.88; 16 or more years of service, M = 22.5 SD = 12.2. Faculty non-users with 1 to 5 years, M = 16.87, SD =10.42; 6 to 15 years of service, M = 18, SD= 11.31 and 16 or more years of service, M =8.8, SD = 2.48. Thus, faculty users by years of service had high mean scores that were

above the established cut-off point which indicated that their perception was high. Faculty non-users in the three categories of years of service, mean scores were below the cutoff point of 20, which was a strong indicator that faculty non-users by years of service and perception level was low toward the IRBs role and processes.

The findings for faculty users and faculty non-users by years of service and attitude exhibited a statistically significant difference between the faculty users and faculty non-users, $t = (5, 44)\ 2.90$, $p \leq .05$. The faculty users 6 to 15 years of service M = 45, SD = 6.62 and faculty non-users M = 31, SD =11.11. The established cutoff point was 20 or above to be considered as a high level of attitude. For both faculty users and faculty non-users in the three categories of years of service, the means scores were above the cutoff point. This finding indicated that faculty users and faculty non-users had a negative attitude level toward the IRB role and processes.

Furthermore awareness levels for faculty users and faculty non-users were low and it was found to have a statistically significant difference between two groups. Faculty users and faculty non-users attitude level was also low which indicated a negative attitude toward the IRBs role and processes as it relates to years of service (see Table 4.13).

Table 4.13

Difference Between IRB Faculty Users and Faculty Non-users by Years of Service by Awareness, Perception and Attitude

	Awareness		Perception		Attitude	
	M	SD	M	SD	M	SD
Faculty Users						
1 to 5 years service	7.71	0.76	25.57	9.05	43.71	8.55
6 to 15 years	7.5	0.76	28	6.88	45.62	6.32
16 or more years	7.5	0.7	22.5	12.02	41	11.31
Faculty Non-users						
1 to 5 years of service	6.93		16.87	10.42	28.35	10.18
6 to 15 years	6.58	1.24	18	11.31	31	11.11
16 or more years	6.40	1.81	8.8	2.48	21.4	3.28

Research Question 5: What are the differences in the levels of awareness, perception and attitude, between faculty users and faculty non-users, by age regarding the role and processes of the university's IRB?

Table 4.14 portrays the differences between the faculty users and faculty non-users awareness, perception and attitude toward the IRBs role and processes by age of respondents. An analysis of covariance (ANCOVA) procedure was conducted using age as a covariate to find the difference between both groups' faculty users and faculty non-users.

The covariate age had a statistically significant impact on the three variables awareness, perception and attitude. The findings presented statistically significant differences between faculty users and faculty non-users by age and awareness, t = (5, 44) 5.81, p< .05. The faculty users who were from the 21 to 39 years old reported, M =6.0, SD= 0; ages 40 to 50 year, M= 7.5, SD= .577 and ages from 51 and over, M= 7.75, SD = .621. The faculty non-users who were from ages 21 to 39 years, M =6.33, SD= .577, ages 40 to 50 year old, M= 6.53, SD= 1.61 and ages 51 and over, M= 6.94, SD = 1.08. The mean scores of awareness among faculty users and faculty non-users by age groups were all reported to fall below the established cutoff point of 20. Thus, this indicated that awareness level between the groups by ages were statistically significant, which noted that there was a negative level of awareness between the faculty users and faculty non-users.

For faculty users and faculty non-users by perception and age, the findings also showed a statistical significance between groups, t = (5, 44) 4.58, p $\leq$ .05. The faculty users who were from age, 21 to 39 years old, M = 12, SD= .0, ages 40 to 50, M= 23.50,

SD= 11.09 and ages 51 and over, *M*= 28.50, SD = 5.72. Faculty non-users who were from ages 21 to 39 years old, *M* = 10 SD= 2.64, ages 40 to 50, *M*= 12.76, SD= 8.26 and ages 51 and over, *M*= 19.64, SD = 11.08. The faculty users from ages 40 to 50 and 51 and over, mean scores were above the established cutoff point, which indicated that these faculty users had a high level of perception. Faculty users from ages 21 to 39 had a low mean score that indicated a negative perception level regarding the IRBs role and process. Faculty non-users mean scores were under the established cutoff point, which indicated that they had a negative level of perception of the IRBs role and process.

Faculty users and faculty non-users by age and attitude, findings confirmed a statistical significance between the groups, t = (5, 44) 4.88, $p \leq .05$. The faculty users who were from 21 to 39 years of age, M = 31, SD = .0, ages 40 to 50, M = 42.00, SD = 10.51 and ages 51 and over, M = 46.16, SD = 5.33. Faculty non-users who were from 21 to 39 years of age, M = 22.66, SD= 5.0, ages 40 to 50, M= 25.92, SD= 7.66 and ages 51 and over, M= 30.94, SD = 11.82.

Moreover, the mean scores for groups', faculty users and faculty non-users, fell above the established cutoff point, which indicated that both groups had a negative level toward the IRBs role and process. However, faculty users' scores were much greater than those faculty non-users of the IRB. Furthermore, the findings did show a statistically significant difference between faculty users and faculty non-users by age and their awareness, perception, and attitude toward the IRBs role and processes (see Table 4.14).

Table 4.14

Differences Between IRB faculty Users and Faculty Non-users by Age, Awareness, Perception, and Attitude

	Awareness		Perception		Attitude	
	M	SD	M	SD	M	SD
Faculty Users						
21 to39 years of age	6	0	12	0	31	0
40 to 50 years	7.5	0.577	23.5	11.09	42	10.51
51 and over	7.75	0.621	28.5	5.72	46.16	5.33
Faculty Non-users						
21 to39 years of age	6.33	0.577	10	2.64	22..66	5
40 to 50 years	6.53	1.61	12.76	8.26	25.92	7.66
51 and over	6.94	1.08	19.64	11.4	30.94	11.82

Multivariate Analysis of Covariance

The investigator also conducted a multivariate analysis of covariance (MANCOVA) with the three variables awareness, perception and attitude controlling for status, rank, years of service, age, and faculty (users and faculty non-users) as covariates. This procedure was done to check the general linear model (GLM) to determine whether or not the model would reveal the same statistical difference at the .05 level between subject effects (faculty users and faculty non-users). After running the data, the investigator evaluated the robustness of the data, checked for any practical limitations such as univariate or multivariate within-cell outliers at $p = .001$. The results of the evaluation of the assumption for normality, linearity, homogeneity of variance covariates and multicollinearity were also checked. These assumptions were found to be satisfactory. The Box's M test was $p = .000$, which indicated that the robustness was guaranteed.

The Table 4.15 illustrates the general linear model to determine the effect between groups. The results of tests reveal that there were statistically significant differences between the group effects with faculty users and faculty non-users when controlling for age and years of service as it related to awareness, perceptions and attitudes. Furthermore, the other variables did not yield a significant difference.

Table 4.15

MANCOVA with Dependent Variables Awareness, Perception and Attitude of Faculty Users and Faculty Non-users by Covariates Status, Rank, Years of Service, and Age

				Between Subject Effect			
Source		Measure	df	f	SS	P	
Group	Faculty Users and Faculty Non-users X	Awareness	1	0.717	0.867	0.83	
		Perception	1	0.058	4.79	0.89	
		Attitude	1	0.022	1.89	0.94	
Group	Status X	Awareness	1	0.49	0.059	0.4	
		Perception	1	0.02	1.65	0.81	
		Attitude	1	0.005	0.447	0.88	
Group	Rank X	Awareness	1	0.285	0.345	0.59	
		Perception	1	0.261	21.74	0.61	
		Attitude	1	0.107	8.85	0.74	
Group	Years of Service X	Awareness	1	0.99	1.2	0.32	
		Perception	1	7.15	596.64	0.01	*
		Attitude	1	5.56	461.44	0.02	*
Group	Age X	Awareness	1	6.39	7.73	0.015	*
		Perception	1	9.62	802.2	0.003	*
		Attitude	1	27.28	2260.81	0	**
Error		Awareness	49				
		Perception	49				
		Attitude	49				

* $p < .05$, ** $p < .01$

In summary, the investigator established a cut off mean score to indicate or set a threshold level for determining high or low awareness, perception and attitude. Mean scores of 20 and above were considered to be a high level of behavior; mean scores of 19 and below were considered to be a low level of behavior (awareness, perception and attitudes). The statistically significant level was set for $p \leq .05$ and p=.01.

The first research question revealed that perception and attitude showed statistically significant differences between the faculty users and faculty non-users. Awareness was low for both groups' faculty users and faculty non-users. Looking at the second research question the findings revealed that there were no statistically significant differences between groups by status, but mean scores reflect negative and positive awareness, perceptions and attitude toward the IRBs roles and processes.

In research question three, this revealed differences between the faculty users and faculty non-users awareness, perceptions and attitudes toward the IRBs role and processes by faculty rank. The findings reveal that attitude by rank was found to be statistically significant between groups, faculty users and faculty non-users, and rank (assistant professor, associate professor, and professor). The analysis of the fourth research question revealed there was a statistically significant difference between faculty users and faculty non-users by years of service with their awareness and attitude. The fifth research question, findings found a statistically significant level among awareness, perception and attitude between faculty users and faculty non-users by age. However, when the investigator conducted a MANCOVA with the three dependent variables awareness, perception and attitude with the covariates, status, rank, years of service and age, analysis found only age and years of service as being the only variables found to be statistically significant at the $p = .05$ level.

CHAPTER V

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Chapter V presents the summary of the findings, discussion of the study's implications on the theoretical framework, education and policy. The chapter concludes with recommendations for further study and closing comments from the investigator.

Summary

The major purpose of the study was to determine differences between faculty users and faculty non-users awareness, perceptions and attitudes regarding the role and processes of the IRB at one1890 land grant campus. This second reason for this study was to determine if the variables --years of service, rank, status, and age--had a perceptible degree of difference on faculty users and faculty non-users', understanding of the role and processes of the IRB at one1890 land grant campus. The third purpose was to develop of a profile of the faculty members who were more likely to be faculty users and faculty non-users of the IRB.

The five research questions that guided this study were the following:

1. What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users of the local IRB's role and processes?
2. What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users, by years of service regarding role and processes of the university's IRB?

3. What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users, by rank regarding role and processes of the university's IRB?
4. What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users, by status regarding the role and processes of the university's IRB?
5. What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users, by age regarding the role and processes of the university's IRB?

Population and Sample

The population of this study consisted of faculty from an 1890 land grant university located in south central region of Texas. This institution is the second oldest institution of higher learning in the state, founded in 1876 with the charter to educate African Americans. It is situated in a rural community on the periphery of a large metropolitan city. The university has approximately 8,000 students enrolled.

The sample group in the original data base consisted of 68 respondents, drawn from a cross section of employees at the one land grant institution in the fall of 2007. However, only 50 respondents were used for analyses in this study. These 50 respondents met the study criteria of responding to 60% of the questions and with self- identification as a tenured or tenure-track faculty member. Secondary data were used and convenience sampling was employed.

A majority of the sample group consisted of African Americans and European Americans; however, there was representation from other ethnic groups such as Asian

American, and Native American. The greatest numbers of respondents were African Americans and this attribute may relate to the institution having a designation as an 1890 land grant university and the employment practices may be aligned with the mission and primary population served.

Instrumentation

The instrument was developed by the research and development component of the land grant university. The instrument (Appendix D) used in this study was developed by research administration staff using several related instruments found in the literature as a guide. A series of questions were assembled to construct the survey for assessing Perception, Attitude, Awareness, Preferences and Experiences (PAAPE) related to the role and processes of the IRB. The instrument had not been validated for its reliability and internal consistency until this study was conducted. According to criteria for measuring internal consistencies for reliability, the PAAPE had respectable measures and were considered as very reliable.

The study was conducted during fall 2007 and employees were asked to respond to the instrument through an on-line electronic survey. This investigator obtained the data with permission from the associate vice president for research (Appendix A) for the purposes of this educational study. The secondary data was provided in aggregated form thus no names or personal identification could be associated with respondents. The investigator examined the data and eliminated cases that did not meet the criteria. The data was coded using SSPS software applications to determine relationships between and among variables to develop a baseline profile of demographic characteristics of the respondents and measure the levels of their awareness, perception and attitude toward the

role and processes of the local IRB. The levels of awareness, perception, and attitude created a profile for faculty users and faculty non-users of the IRB.

Summary of the Findings

The findings of this study are based on the data analyses and procedures used for determining the levels of awareness, perception and attitude with respondents who participated in the electronic survey. The investigator developed five research questions to assess the variables: status, rank, years of service, and age. These variables were selected to develop a profile of faculty users and faculty non-users of the IRB.

A series of statistical procedures were used to analyze the data. First, frequency and cross tabulations were conducted to analyze the demographic characteristics: status, rank, years of service, and age. Gender and ethnicity were included in this analysis to provide a more comprehensive treatment of the data, however, they were not considered as factors in the development of the five research questions. The research questions were tested and data were analyzed by employing a series of statistical procedures. First, independent sample *t* tests on the three dependent variables were conducted to compare faculty users and faculty non-users awareness, perception and attitude. Second, several two-way ANCOVA were conducted on each of the dependent variables, controlling for status, rank, years of service, and age. Lastly, a MANCOVA was conducted to determine the difference between subject groups. The following findings were noted and discussed.

The investigator identified directional indicators to assess a high or low level of awareness, perception and attitude. The investigator established a cut off mean score of 20 to indicate a threshold level for determining high or low awareness, perception and

attitude. A mean score of 20 and higher was considered to be a high level; a score 19 or below was considered to be a low level.

Research Question 1

What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users of the local IRB's role and processes?

For both faculty users and faculty non-users, the awareness and attitude attributes were high and found to be statistically significant. For the variable attitude, means were extremely high thus indicating a low or negative level of attitude. This connotes that the faculty users and faculty non-users held a negative view towards the local IRBs role and processes. High mean scores for perception were also found among the faculty users and the faculty non-users which were not significant between groups. Furthermore, higher levels of perception were regarded as a positive view of the IRB. The awareness recorded between groups, faculty users and faculty non-users, was low. This is an indication that faculty users and faculty non-users alike held the same negative demeanor toward the role and processes of the local IRB. Findings may be attributed to the manner that information is transmitted through the institution. Word of mouth, opinions, and anecdotal comments are the more respected authority on the role and process in contrast to training or formal communication.

The findings in this study are similar to the findings of the Lopus, Grimes, Becker and Pearson (2007) study regarding awareness and attitude towards human subjects' research. Lopus, et al. (2007) study results noted that many researchers do not know or understand the prevailing definitions and rules in the federal regulations because of a lack of awareness and training in ethical issues involved in human subjects and the federal

guidelines, and a lack of familiarity with their local IRB policies and procedures. The deficit in awareness can be attributed to the limited training available which possibly could have contributed to their negative levels of attitude.

Research Question 2

What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users, by status regarding role and processes of the university's IRB?

When controlling for status, tenured/tenure-track faculty, did not make a difference in the level of attitude between faculty users and faculty non-users. Both groups indicated a negative attitude toward the IRB role and processes and this was noted independent of status. This denotes that the value of research and scholarship are not well communicated in a school or university that has traditionally been a teaching institution and not research focused.

HBCU and 1890 land grant institutions have a history of under resourcing research facilities and not rewarding faculty for performance for research related duties. The faculty teaching work load is great in contrast to institutions that have research intensive designations (Mabokela & Thomas, 2004). While the one land grant institution in this study has a desire to move toward research, they have not yet made the efforts to invest in infrastructure and faculty that are research driven. Phillips (1997) stated that to be competitive in a new era HBCUs and 1890 land grant universities need to position themselves to meet the challenges of the twenty-first century required for major breakthroughs in science and research. Phillips further stated that the land grant system is obligated to adopt an agenda to respond to relevant needs and priorities of the community.

This agenda includes research involving human subjects and participating in IRB processes while understanding its role of the IRB.

Research Question 3

What are the differences in the levels of awareness, perception and attitude between faculty users and faculty non-users as it relates to rank regarding role and processes of the university's IRB?

Faculty rank was used to portray the differences between the faculty users and faculty non-users awareness, perception, and attitude toward the IRBs role and processes. Controlling for faculty rank, there were no results reported as being of significant difference between groups for those who self identified as an assistant professor, associate professor, or professor the faculty users and faculty non-users. Regardless of the rank among the users and faculty non-users, there was negative attitude towards the IRBs role and processes. Ferraro (1999) also noted that rank did not have a marked effect on the variables of awareness, perception or age. Other similarities in Ferraro and this study were that there was an overrepresentation of associate professor faculty respondents. Again, when comparing comments, it is resonant of the need for additional training particularly in the area of completion of forms due to their vagueness.

Research Question 4

What are the differences in the levels of awareness, perception and attitudes between faculty users and faculty non-users by years of service regarding the role and processes of the university's IRB?

Controlling for years of service had a significant impact upon attitude and awareness toward the IRBs role and processes. This meant that it did not matter how long a faculty member was employed with the institution because the attitude was typically negative toward the role and processes of the IRB. The awareness with the respect of years of service of faculty users and faculty non-users was low. This was a strong indicator that there was not enough information communicated about the need and value of the IRB role and processes within the university. According to Keith-Spiegel, Koocher & Tabachnik (2006) regardless of years of service faculty users and faculty non-users could benefit from formalized training. Irrespective of delivery, web based or face-to-face, they will become more confident in the process and this will strengthen their capacity to conduct quality research.

Research Question 5

What are the differences in the levels of awareness, perception and attitudes between faculty users and faculty non-users, by age regarding the role and processes of the university's IRB?

Controlling for faculty users and faculty non-users age regarding their awareness, perceptions and attitudes toward the IRB role and processes, age had a significant impact; however, it did not make a great difference in how users and faculty non-users felt about the IRB role and processes. It appeared that faculty users and faculty non-users who were

51 years old and over had a greater dissatisfaction with the IRB process than any other age group. The age range among the users and faculty non-users and the ranges of age within these group levels of awareness were very similar in agreement for lack of awareness of the processes and role of the IRB. Many of the faculty members who completed the survey were in the age of 51 and over and they possessed the rank of associate- and professor. Because they had been employed longer than the other respondents perhaps their prior contracts, time and their focus was related to teaching and service and not research. The purpose of the university was changed in 2004 to reflect research as one of its primary functions, and tension may exist in the transition of the faculty profile and responsibilities. Faculty users' and faculty non-users perceptions that were in the 21 to 39 and 40 to 50 age categories appeared to be more receptive.

In conclusion, the investigator conducted a more robust statistical procedure to validate the means scores between subject groups, faculty users and faculty non-users and tenured and tenure track. The robust treatment of the data revealed that years of service and age had a great impact upon faculty users and faculty non-users awareness and attitude toward the role and processes of the IRB. Interestingly, the lack of awareness is in direct proportion to level of attitude; there is a direct correlation between awareness and attitude.

Implications to Theory

The implications of theory on this study confirms that awareness, perception and attitudes are based upon experiences, conceptualized opinions, and supported by organizational climate and reinforced by organizational culture (Weigel, Brown, & Martin, 2004). From the perspective of faculty users and faculty non-users, each

possesses personal values that are developed through ones' interaction with their environment, moral reasoning and ethics.

The environment in this case is the university and the pressures exercised to conform within this setting may challenge the values and ethics of a junior as well as a seasoned faculty member (Delva, 2007). This challenge to ethics and values is evident, because the environment has itself not evolved to a level that supports the value of human intellectual capital as much more than a commodity. Kohlberg's (1976) theory of moral development emphasizes that one's personal values and ethics are developed from the interaction between the person and the environment. This may be further extrapolated to the cultural or environmental climate of an institution that has either willingly or not evolved to the highest level of consciousness and as a result its higher education purposes such as research contributions involving human participant research stagnate or perish as well (Eisen& Berry, 2002).

As Kohlberg proposed, all people in all cultures pass from lower to higher stages of moral reasoning. When a faculty user or non-user has to operate in an environment that challenges their belief system they may yield to the pressures of the environment, particularly if geography and external influences limit mobility options. Some faculty may incorporate appropriate measures for protection of human participants, the wrong reasons and vice versa. It is hard to say which is which when you look at the user and non-user respondents data. Ultimately, the real winner is the human participant in the research when ethics are considered and appropriately acted upon (Jones, 1991).

Implications to Education and Policy

Academic research, along with teaching, has long been recognized as a primary responsibility of faculty members. Research and the publication of its results constitute one way in which academics serve the common good (AAUP, 2007). Educational research is an organized professional approach to inquiry (Gall et al, 2003). Higher education is the traditional venue for the preparation of educators with the requisite knowledge base and facility. The educational background of and general orientation of faculty in higher education necessitates that they possess an adequate understanding of the mechanics of the research process (Pritchard, 2002). The command and facility of this process is essential so as to provide the information necessary to equip faculty members with the skills to become competent researchers (Szirony, Price, Wolfe, Telljohann, & Dake, 2004). A fundamental and underlying premise of any research activity is that ethical conduct and specific standards will be observed and applied, during the research process (Lo, 2001).

Martinson, Anderson, Crain and DeVries (2006) noted that the issue of integrity of science and the misbehavior of individuals was characterized by the environments in which faculty members' work. The findings indicated that when faculty members believed that they were the recipients of unfair treatment that they were more inclined to behave in ways that compromise the integrity of science. Within the context of organizational justice literature, procedural justice and distributive justice is central, particularly when people hold a general regard that the distribution of resources within an organization and the decision processes associated with that distribution are perceived as fair, then the confidence in the organization is in all probability heightened. Like the

study by Keith-Spiegel, Koocher & Tabachnik (2006), this study's outcomes indicated that the ideal IRB appears to be a just body that employs fair procedures and treats faculty researchers with respect and affords faculty researchers to have a voice when disagreements surface.

The land grant university, tenure and promotion board should require evidence of all publications involving human participants, listed on the vitae having undergone and IRB review. In addition, journal editors can make advances to assist in the equitable distribution of resources by requesting evidence of a submission having undergone the rigor of an IRB or other ethics board review. This simple request can lend integrity and credence to a process that has the potential to mitigate distribution of compensation associated with publication and other perquisites to faculty non-users of the IRB (Bailey, Hasselback, & Karcher, 2001; Delva, 2007). Training that is relevant and contemporary in nature in subjects such as ethics, the documentation associated with support of these activities and communication should be embedded throughout the cycle of the faculty members' career and the value should be attached accordingly.

Conclusions of the Study

The investigator identified several recommendations for future use for university IRB components based on the findings in this study. The first recommendation suggested that all faculty researchers should be thoroughly familiar with the Common Rule and the IRB process. The second recommendation was that faculty members should be thoroughly familiar with their local IRB policies and procedures. This familiarity with policies and procedures should include whether the board requires certification prior to conducting a project involving human subjects as well as how to submit a project

proposal for review. Last, the researcher should factor in IRB review time when scheduling new research projects.

The term research is used to describe a number of similar and overlapping activities that involve a search for information in a systematic and well defined investigation, that may be designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). The primary objective of research within a discipline is to provide evidence based findings that meet the goals, objectives and purposes of the discipline (Gall, Gall & Borg, 2003). The value of research is the contribution to the relevance and quality of a discipline and that this activity offers insightful and rewarding societal applications. The command and facility of this process is essential so as to provide the information necessary to equip students with the skills that allow them to become competent practitioners and as well as researchers (Szirony, Price, Wolfe, Telljohann, & Dake, 2004, 2001 p.1). A fundamental and underlying premise of any research activity is that ethical conduct and specific standards will be observed, applied, during the research process (Lo, 2001).

In conclusion, the culture and environment of an institution may be a contributing factor in moral development of the participants and their awareness, perceptions and attitudes of the IRB's role and processes. As with individuals, not all institutions or universities achieve or aspire to the highest levels of moral development and this point must be considered when examining the voices of users and faculty non-users of the IRB and in the development of in-service programs and other systems of rewards.

Recommendations for Future Research

Other studies identified for future research from this investigation center around awareness, perception and attitude on a broader scale to include all historically Black and other 1890 land grant universities, not only to include faculty members but also to involve extension and agriculture research staff members, because a significant source of funds emanate and opportunities for informed scholarship evolve from the research land grant designation and the unique population it serves. The agriculture components of these institutions have always had research as a component of their mission. Socio-behavioral research is integral to having empirically sound service and outreach programs to fulfill the other parts of their mission. There is an extension and research component within the 1890 land grant system that provides funding mechanisms to engage in research and sponsored project activities, however, these mechanisms are coupled with no restrictions for the conduct of research by classification. The general body may not be aware of their ability to fully engage in research activities involving human participants at this one land grant institution. Expansion of the survey to include all 1890 land grant institutions, HBCUs, Hispanic and Tribal Colleges would provide a more robust sample and enrich the data.

This study sought information on what degree awareness, perceptions and attitude affect IRB participation so as to build a profile of identifying those who are users and not users of the IRB, further research can expand the profile to include other factors. A pretest posttest treatment, to include a training intervention designed to determine whether this training would help ensure better penetration into the faculty community and if it would have an impact on awareness, perception and attitude. The attitude construct was

developed from the combination of perceptions and experiences. The attitude construct may have benefited from a closer examination of the instrument and its structure and assembly of the secondary data. The investigator would improve the instrument by tailoring it to the population and culture and would have designed it with a more closely aligned intent related specifically to the IRB process and role.

REFERENCES

Adair, J. G., & Davidson, R. (1995). The research environment in developing countries: Contributions to the national development of the discipline. *International Journal of Psychology*, *30*(6), 643-662. Retrieved July 12, 2006, from http://dx.doi.org/10.1080/00207599508246592.

Amdur, R. J., & Biddle, C. (1997). Institutional review board approval and publication of human research results. *Journal of the American Medical Association, 277*, 909–914.

American Association of University Professors. (2006). Research on human subjects: Academic freedom and the institutional review board. Retrieved on May 13, 2007 from, http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm#1

Annas, G. J., & Grodin, M. A. (1992). *The Nazi doctors and the Nuremberg code*. New York: Oxford University Press.

Bailey, C. N., Hasselback, J. R., & Karcher, J. N. (2001). Research misconduct in accounting literature: A survey of the most prolific researchers' actions and beliefs. *Abacus*, *37*(1) 26-54.

Bankert, E. A., & Amdur, R. J. (2006). *Institutional review board: Management and function.* (2nd ed.). Sudbury, MA: Jones & Bartlett Publishers.

Berk, L. E. (2007). *Development through the lifespan.* (4th ed.). Boston: Allyn & Bacon.

Bernard, R. A. (1997). An examination of moral development within the public accounting by gender, staff level and firm. *Contemporary Accounting Research*, *14*(4), 653-668.

Bland, C. J., Center, B. A., Findstad, D. A., Risbey, K. R., & Staples, J. (2006). The impact of appointment type on the productivity and commitment of full-time faculty in research and doctoral institutions. *The Journal of Higher Education, 77*(1), 89-123.

Blass, T. (1999). The Milgram paradigm after 35 years: Some things we now know about obedience to authority. *Journal of Sociological Psychology, 29,* 955-78.

Bledsoe, C. H., Galinsky, A. G., Headley, N. M., Heimer, C. A., Kjeldgaard, E., Lundgren, K., Miller, J., Roloff, P., & Uttal, E. (2008). Regulating creativity: Research and survival in the IRB iron cage. *Northwestern University Law Review, 101, 593-641.*

Boyer, E. L. (1990). *Scholarship reconsidered: Priorities of the professoriate.* Princeton, NJ: Carnegie Foundation.

Brandt, A. M. (1978). Racism and research: The case of the Tuskegee syphilis study. *The Hastings Center Report, 8*(6), 21-29.

Brainard, J. (2000, February 4). State of suspensions of academic research spurs questions about federal strategy. *Chronicle of Higher Education,* A29.

Brainard, J. (2000, February 4). U.S. regulators permit research projects to resume at Virginia Commonwealth University. *Chronicle of Higher Education,* A29-32. Retrieved from http://chronicle.com/daily/2000/02/200020204n.htm.

Brainard, J. & Miller, D. W. (2000, January 4). Federal regulators suspend university medical studies in Pennsylvania and Alabama. *Chronicle of Higher Education,* A27.

Broad, W. J. (1999, July 24). Data tying cancer to electric power found to be false. *New York Times*. Retrieved from http://*www.ny**times**.com/**1999**/07/24/us/**data-tying-**cancer**-to-electric-power-found-to-be-false.html - 42k*

Broome, M. E. (2003). Scientific integrity-the cornerstone of knowledge. *Journal of Neuroscience Nursing, 35*(1), 56-59. Retrieved December 12, 2007, from, http://www.aann.org/ce/pdf/jnn

Ceci, S. J., Peters, D. & Plotkin, J. (1985). Human subjects review, personal values and the regulation of social science research. *American Psychologist, 40*(9), 994-1002.

Data Analysis Australia. (2007). *Response Rates*. Retrieved June 8, 2007, from http://www.daa.com.au/analyticalideas/responserates.html

Dawson, T. L. (2002). New tools, new insights: Kohlberg's moral judgment revisited. *International Journal of Behavioral Development, 26,* 154-166.

Delva, J. (2007). The human subjects' protective process: A subjective view. *Journal of Social Work, 52*(*2*), 101-102.

Department of Health and Human Services. (1998). *Institutional Review Boards: A time for reform* (OEI-01-97-00193). Washington, DC: Author.

Eckenwiler, L. (2001). Moral reasoning and the review of research involving human subjects. *Kennedy Institute of Ethics Journal, 11*(1), 37-69.

Eisen, A., & Berry, R. (2002). The absent professor: Why we don't teach research ethics and what to do about it. *American Journal of Bioethics, 2(4*), 38-49.

Ellis, G. B. (1999). Protecting the rights of human research subjects. *Academic Medicine, 74*, 1008-1009.

Ellis, J. R., & Hartley, C. L. (1998). *Nursing in today's world: Challenges, issues and trends.* (6th ed.). Philadelphia: Lippincott-Raven Publishers.

Faden, R. R., & Beauchamp, T. L. (1986). *A history of informed consent.* New York: Oxford University Press.

Ferraro, F. R., Szigeti, E., Dawes, K. J., & Pan, S. (1999). A survey regarding the University of North Dakota institutional review board: Data, attitudes, and perceptions. *Journal of Psychology, 133*(3), 272-280.

Freyhofer, H. H. (2004). *The Nuremberg medical trial: The Holocaust and the origin of the Nuremberg Medical Code*. New York: Peter-Lang.

Gall, M. D., Gall, J. P., & Borg, W. R. (2003). *Educational research: An introduction.* (7th ed.). Boston: Allyn & Bacon.

Gay, L. R. (1976). *Educational research: Competencies for analysis & application.* (2nd ed.). Columbus, OH: Charles E. Merrill.

Gibelman, M., & Gelman, S. R. (2001). Learning from the mistakes of others: A look at scientific misconduct in research. *Journal of Social Work Education, 37*(2), 241-269.

Hays, W. L. (1981). *Statistics* (3rd ed.). New York: Holt, Rinehart &Winston.

Hearst, N., Grady, D., Barron, H. V., & Kerlikowske, K. (2001). Research using existing data: Secondary analysis, ancillary studies and systematic reviews. In S. B. Hulley, S. R. Cummings, W. S., Browner, D. Grady, N. Hearst, & T.B. Newman (Eds.), *Designing clinical research.* (2nd ed., pp. 217-230). Philadelphia, PA: Lippincott, Williams & Wilkins.

Henley, L. D., & Frank, D. M. (2006). Reporting ethical protection in physical therapy r*esearch*. *Physical Therapy, 86(*4) 25-29.

Hilts, P. J. (1999). University forced to pay $1.6 million to researcher. *The New York Times*. Retrieved October 6, 2007, from: http: www. nyt.com.

Hughes, W. H. (1997). *Alexander Fleming and penicillin*. New York: Crane Russak

& Co.

Hunt, B., & Yekel, C. (2002). Moving from compliance to concern, symposium: Compliance or concern: Institutional Review Boards in journalism and mass communication education. *Journalism & Mass Communication Educator, 57*(2), 92-95.

Hutchison, K. R. (2001). Developing faculty use of technology: The Bellevue Community College experience. In R. M. Epper, & A. W. Bates. (Eds.), *Teaching faculty how to use technology: Best practices from leading institutions.* (pp. 93-114). New Haven, CT: American Council on Education.

Jaeger, J. F. (2006). An ethnographic analysis of institutional review board decision making. (Doctoral dissertation), University of Pennsylvania, (2006). Retrieved October 20, 2008, from Dissertations & Theses: Full Text database. (Publication No. AAT 3246172)

Jarrett, C. (2005). *Caroline's corner: Survey response rates? 2% is not good enough.* Retrieved June 8, 2007, from http://www.usabilitynews.com/news/article2528.asp

Jones, J. H. (1993). *Bad blood: The Tuskegee syphilis experiment.* New York: Free Press.

Jones, T. M. (1991). Ethical decision making by individuals in organizations: An issue-contingent model. *Academy of Management Review, 16,* 366-395.

Keith-Spiegel, P., Koocher, G. K., & Tabachnik, B. (2006). What scientists want from research ethics committees. *Journal of Empirical Research on Human Research Ethics, 1*(1), 67-82.

Kerlinger, F. N., & Lee, H. B. (2000). *Foundation of behavioral research* (4th ed.). South Melbourne, Australia: Wadsworth Thomson Learning.

Killen, M., & Nucci, L. P. (1995). Morality, autonomy and social conflict. In M. Killen & D. Hart (Eds.), *Morality in everyday life: Developmental perspectives.* (pp. 32-36). Cambridge, UK: Cambridge University Press.

Kohlberg, L. (1976). Moral stages and moralization: The cognitive-developmental approach. In T. Lickona (Ed.), *Moral development and behavior-theory, research and social issues*. (pp. 78-83). New York: Holt, Rinehart and Winston.

Kohlberg, L., Levine, C., & Hewer, A. (1983). *Moral stages: A current formulation and response to critics.* Basel, Switzerland: Karger.

Koojiman, J. (1999). Soon or later on: Franklin D. Roosevelt and national health insurance, 1933-1945. *Presidential Studies Quarterly, 29*(2), 336-350.

Landrum, R. E. & Chartain, G. (1999), Subject pool policies in undergraduate-only departments: Results from a nationwide survey. In G. Chastain & R. E. Landrum (Eds.), Protecting human subjects departmental subject pools and institutional review boards. (pp. 25-42). Washington, DC: American Psychological Association.

Leigh, W. A. (1998). Participant protection with the use of records: Ethical issues and recommendations. *Ethics & Behavior, 8*(4), 305-319. Retrieved September 15, 2007, from: http://www.questia.com

Lo, B. (2001). Addressing ethical issues. In S. B. Hulley, S. R. Cummings, W. S., Browner, D. Grady, N. Hearst, & T.B. Newman (Eds.), *Designing clinical research.* (2nd ed., pp. 217-230). Philadelphia, PA: Lippincott, Williams & Wilkins.

Lopus, J. S., Grimes, P. S., Becker, W. E., & Pearson, R. A. (2007). Human subjects' requirements and economic education researchers. *The American Economist, 51*(2) 49-60.

Lord, F. M., & Novick, M. R. (1968). *Statistical theories of mental test scores*. Reading, MA: Addison-Wesley.

Mabokela, R. O., & Thomas, G. E. (2004). Black colleges and universities in America and South Africa: Common histories and future destinies. In M. C. Brown, II & K. Freeman (Eds.), *In Black colleges: New perspectives on policy and practice,* (pp. 177-198). Westport, CT: Praeger Publishers.

Martinson, B. C., Anderson, M. S., Crain, A. L., & DeVries, L. (2006). Scientist's perceptions of organizational justice and self-reported misbehaviors. *Journal of Empirical Research on Human Research Ethics, 1*(1), 51-56.

Milgram, S. (1974). *Obedience to authority*. New York: Harper and Row.

Monastersky, R. (2005). Scientific misbehavior is rampant, study of 3,000 researchers. *Chronicle of Higher Education, 51*, A11.

Morris, R. (1997). Demographic and professional characteristics associated with school psychologists' ethical beliefs. Unpublished doctoral dissertation. Tucson: University of Arizona.

National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subject's research*. Washington, DC: National Institutes of Health. Retrieved February 12, 2006 from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

National Association of State University Land Grant Colleges. (1999). Retrieved March 2, 2007 from http://www.nasulgc.org/NetCommunity/Page.aspx?pid=203&srcid=566

New definition proposed for research misconduct. (1999). *Human Research Report, 14*(2), 4.

Nuremberg Code. (2000). *Journal of Power and Ethics, 1*(3), 258. Retrieved September 16, 2007, from: http://www.questia.com/PM.qst?a=o&d=5001205030

Nuremberg Code. (1946). *Permissible medical experiments, trials of war criminals before the Nuremberg Military Tribunals under Control Council Law no. 10(*2), 181-82. Washington, DC: US Government Printing Office.

Oakes, J. M. (2002). Risks and wrongs in social science research: An evaluator's guide to the IRB. *Journal of Evaluation Review, 26*(5), 443-479.

Office for Protection of Research Risks. (1993). *Protecting human research subjects: Institutional review board guidebook.* Washington, DC: National Institutes of Health.

Peckman, S. (2001). Local institutional review boards. In K. Chap, (Ed.), *Ethical and policy issues in research involving human participants* (pp. 349-467*).* Bethesda, MD: National Bioethics Advisory Commission.

Penslar, R. L. (2002). A shared responsibility for protecting human subjects. In R. Amdur & E. Bankert (Eds.), *Institutional Review Board: Management and function*, (pp. 17-21). Boston: Jones and Bartlett.

Piaget, J. (1965). *The moral judgment of the child.* New York: Free Press.

Popovich, N. G., & Abel, S. R. (2002). The need for a broadened definition of faculty scholarship and creativity. *American Journal of Pharmaceutical Education, 66*, 59-65.

Pritchard, I. A. (2002). Travelers and trolls: Practitioner research and institutional review boards. *Educational Researcher, 31*(3), 3-13.

Rothman, D. J., (1982). Were Tuskegee and Willowbrook 'studies in nature'? *Hastings Center Report, 12*(2), 5-7.

Rothman, D. J., & Rothman, S. M., (2006). *Trust is not enough: Bringing human rights to medicine.* New York, New York: Review of Books Press.

Saver, R. S., (2004). Medical research oversight from the corporate governance perspective: Comparing institutional review boards and corporate boards. *William and Mary Law Review, 46*(2), 619. Retrieved September 15, 2007, from http://www.questia.com/PM.qst?a=o&d=5008235303

Sieber, J. E. (1992*). Planning ethically responsible research: A guide for students and internal review boards.* Newbury Park, CA: Sage Publications.

Shalala, D, (2000). Protecting research subjects -- what must be done. *New England Journal of Medicine, 343*(11), 808-810.

SPSS, Inc. (2003). *SPSS user's guide: A complete guide to SPSS language and operations.* New York, NY: McGraw-Hill.

Starr, H. (1992). Democracy and war: Choice, learning and security communities**.** *Journal of Peace Research, 29*(2), 207-213.

Stark, L. J. (2006). *Experience and expertise in IRB decision-making.* Paper presented at the annual meeting of the American Sociological Association. Retrieved November 11, 2007 from, Montreal Convention Center Montreal, Quebec Online http://www.allacademic.com/meta/p10564-index.html.

Steneck, N. H. (1994). Research universities and scientific misconduct: History, policies, and the future. *Journal of Higher Education, 65*(3), 310-330. Retrieved September 15, 2007, from http://www.questia.com/PM.qst?a=o&d=5000268111

Steneck, N. H. (2006). Fostering integrity in research: Definitions, current knowledge, and future directions. *Science and Engineering Ethics, 12*, 53-74.

Sugarman, J., McCrory, D. C., Powell, D., Krasney, A., Adams, B., Ball, E., & Casell, C. (1999). Empirical research on informed consent: An annotated bibliography, *The Hastings Center Report, 29*(1), 1. Retrieved September 15, 2007, from http://www.questia.com/PM.qst?a=o&d=5002314024

Szirony, T. A., Price J. H., Wolfe, E., Telljohann, S. K., & Dake, J. A. (2004). Perceptions of nursing faculty regarding ethical issues in nursing research. *Journal of Nursing Education, 43*(6), 270-279.

Turiel, E. (1983). *The development of social knowledge: Morality and convention.* New York: Cambridge University Press.

U.S. Department of Health and Human Services. (1995). Integrity and misconduct in research: Report of the commission on research integrity. Washington, DC:U.S. Government Printing Office.

U.S. Department of Health and Human Services, Office of Research Integrity. (2001). Federal policy on research misconduct. Retrieved July 13, 2006, from http://ori.dhhs.gov.

U.S. Department of Health and Human Services: Food and Drug Administration. (2001). Code of Federal Regulations: Title 45 Part 46 protection of human subjects.

Retrieved February 10, 2004, from http://www.hhs.gov/ohrp/humansubjects/guidance

U. S. Department of Health and Human Services, Food and Drug Administration. (1998). *Code of federal regulations: Title 21 part 50 protection of human subjects.* Retrieved February 10, 2004, from http://www.accessdata.fda.gov

United States Department of Health and Human Services, Food and Drug Administration. (1999). *Code of federal regulations: Title 21, part 56 institutional review board.* Retrieved February 10, 2004, from http://accessdata.fda.gov/

Vanderpool, H. Y. (2001). Unfulfilled promise: How the Belmont Report can amend the code of federal regulations title 45 part 46 – Protection of human subjects. In *Ethical and policy issues in research involving human participants*. (pp.338-396). Bethesda, MD: National Bioethics Advisory Commission.

Wark, G. R., & Krebs, D. L., (1996). Gender and dilemma differences in real-life moral judgment. *Developmental Psychology*, *32*(2), 220-31.

Weigel, D., Brown, R., & Martin, S. (2004).What cooperative extension professionals need to know about institutional review boards. *Journal of Extension*, *42*(2).Retrieved January 12, 2008, from http://www.joe.org/joe/2004october/tt1.shtml

West Virginia University Extension Service, (1999). *History of 1890 land grant universities*. Retrieved September 15, 2007, from http://www.wvu.edu/~exten/

White, R. D. (1999). Are women more ethical? Recent findings on the effects of gender upon moral development. *Journal of Public Administration Research and Theory*, *9*(3), 459-472.

Wigodsky, H. S. (1984). Fraud and misrepresentation in research-whose responsibility?

IRB: A Review of Human Subjects' Research, 6, 1-5.

Yin, R. K. (2003). *Case study research: Design and methods*. Newbury Park, CA: Sage Publications, Inc.

APPENDIX A

PRAIRIE VIEW A&M UNIVERSITY

A Member of the Texas A&M University System

October 10, 2007

Elizabeth N. Noel
Associate Vice President, Research
Office for Research and Development

Mrs. Shelton:

This correspondence is to address your recent request to review the data collected from the Research Regulatory Compliance Assessment Initiative that was distributed electronically to administrators, faculty and professional staff regarding the Institutional Review Board (IRB). The request is granted for use of this data, which will be provided in aggregate form, with the condition that we receive a copy of any materials generated and acknowledgement in any publications, presentations or scholarly works.

Office for Research and Development

P.O. Box 519; MS 1200 Prairie View, Texas 77446

Phone (936) 857-4494 Fax (936) 857-2255

APPENDIX B

PRAIRIE VIEW A&M UNIVERSITY

A Member of the Texas A&M University System

Members of the University Community

FROM: Marcia C. Shelton
Office for Research Regulatory Compliance
Research and Development

Elizabeth Noel, Ph. D.
Associate Vice President
Research and Development

Willie F. Trotty, Ph. D.
Vice President
Research and Development

RE: Research Regulatory Compliance Assessment Initiative: Human Participants

Prairie View A&M University is dedicated to excellence in teaching, research and service. It is committed to achieving relevance in each component of its mission by addressing issues and proposing solutions through programs and services designed to respond to the needs and aspirations of individuals, families, organizations, agencies, schools, and communities – both rural and urban. Prairie View A&M University is a state-assisted institution by legislative designation, serving a diverse ethnic and socioeconomic population, and a land-grant institution by federal statute. [Excerpts from University Mission statement, 2005-07 University Catalog, p. 25.]

To help ensure accomplishing key elements of the University mission, nine priority goals have been defined. Four of these priority goals have been highlighted as having specific implications for the work of the Office of Research and Development. The institutional goals aligned with the research component of the University mission are as follows: 1) increase applied and basic research; 2) strengthen the quality of academic programs; 3) promote programs that contribute to student success; and 4) increase and enhance the visibility and awareness of the University to the community/All Stakeholders.

Prairie View A&M University is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools to award Bachelor's, Master's and Doctoral degrees. "The concept of quality enhancement is at the heart of the Commission's

philosophy of accreditation as reflected in the *Principles of Accreditation* as follows: The Commission on Colleges expects an institution to dedicate itself to enhancing the quality of its programs and services within the context of its mission, resources, and capabilities, and to create an environment in which teaching, public service, research, and learning occurs." (p. 3). Therefore, "The institution engages in ongoing, integrated, and institution-wide research-based planning and evaluation processes that incorporate a systematic review of programs and services that (a) results in continuing improvement and (b) demonstrates that the institution is effectively accomplishing its mission" (p. 9). [Excerpts from Resource Manual for the Principles of Accreditation: Foundation for Quality Enhancement, 2005.]

In order to help document the effectiveness of the Office of Research and Development, the Research Regulatory Compliance component of the Office has outlined a **Research Regulatory Compliance Assessment Initiative** as a part of the ongoing, integrated, and institution-wide research-based planning and evaluation processes. The Office of Research Regulatory Compliance has outlined this initiative to assess the perceptions of the University Community relating to the effectiveness of the varied regulatory compliance committees utilized by the Office to monitor adherence to the institutions' Federal-wide Assurance (FWA) regarding the responsible conduct of research.

The Assessment Initiative will be conducted in a minimum of three phases. This is Phase One of the Assessment Initiative and it focuses on the Institutional Review Board (IRB). The IRB reviews all University research, including sponsored projects/programs and service/continuing education/service learning activities, involving human participants. As mandated by federal law, the University is in compliance with the Department of Health and Human Services (DHHS), Office of Human Research Protection (OHRP) when, according to University procedures, all such research, funded or not, conducted by University personnel or students, or otherwise sponsored by the University, and having human participants, has been reviewed and approved by the Institutional Review Board (IRB) prior to any activity beginning on the project.

The Office of the Vice President for Research and Development, in conjunction with the Institutional Review Board for the Protection of Human Subjects (IRB), wishes to expand their collaboration with researchers to help ensure this end by establishing the Assessment Initiative. As part of the IRB Quality Assurance Program, the Assessment Initiative is meant to serve as an educational, as well as an assessment tool for both researchers and administrators and will give researchers an opportunity to provide their perception of the IRB process. As a result of this initiative, administrators will learn first hand of the concerns researchers encounter when conducting human subjects/participants research, and take the resulting concerns into account as policies and procedures are refined and developed. Through an open dialogue regarding the federal requirements, researchers will continue to improve their understanding of the expectations for human subjects' research. It will improve the human subjects program at Prairie View A&M University for researchers, administration and most importantly, the people who participate in the research. It is only by working together that we can achieve this important goal.

Congress has declared that conducting research is a privilege, not a right. We should be very proud of the Human Subjects Research conducted at Prairie View A&M University and must protect the privilege of engaging in research for all investigators at Prairie View A&M University. Unfortunately, during recent years, the Office of Human Research Protection (OHRP), Department of Health and Human Services (DHHS), has stopped *all* human subjects work at several institutions. We never want that to occur at Prairie View A&M University. This Assessment Initiative helps fulfill Prairie View's obligation to self-monitor the human subjects program in accordance with our Federal-wide Assurance agreement with the Office for Human Research Protections (OHRP). Your cooperation in this joint venture is much appreciated.

The Office of Research Regulatory Compliance and the IRB look forward to working together with you in our continuing efforts to create a strong program of human subjects' protection at Prairie View A&M University. The Office of Research and Development understands how valuable your time is and certainly does not wish to make your willingness to respond to this quality check of our federal-wide assurance compliance burdensome. Therefore, we have designed the assessment to be user-friendly and concise. However, the success of this initiative is dependent upon your cooperation and participation.

Thank you for your cooperation. We could not fulfill this federal requirement without your full participation. Our office welcomes any questions. Please direct your questions and/or comments to: Marcia Shelton, Regulatory Research Compliance, at mcshelton@pvamu.edu or 936.261.1588; Elizabeth Noel, Associate Vice President for Research and Development at ennoel@pvamu.edu or 936.261.1589; or Willie Trotty, Vice President for Research and Development at wftrotty@pvamu.edu or 936.261.1550.

APPENDIX C

TAMU IRB APPROVAL LETTER

TEXAS A&M UNIVERSITY
DIVISION OF RESEARCH AND GRADUATE STUDIES - OFFICE OF RESEARCH COMPLIANCE

1186 TAMU
College Station, TX 77843-1186
1500 Research Parkway, Suite B-150

979.458.1467
FAX 979.862.3176
http://researchcompliance.tamu.edu/

Institutional Biosafety Committee | Institutional Animal Care and Use Committee | Institutional Review Board

DATE: 11-Apr-2008

MEMORANDUM

TO: SHELTON, MARCIA C

FROM: Office of Research Compliance
Institutional Review Board

SUBJECT: Initial Review

Protocol Number: 2008-0204

Title: Administrators, Faculty and Professional Staffs' Perceptions, Attitudes and Awareness of the Institutional Review Board at One 1890 Land Grant Institution

Review Category: Exempt from IRB Review

It has been determined that the referenced protocol application meets the criteria for exemption and no further review is required. However, any amendment or modification to the protocol must be reported to the IRB and reviewed before being implemented to ensure the protocol still meets the criteria for exemption.

This determination was based on the following Code of Federal Regulations:
(http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)

45 CFR 46.101(b)(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Provisions:

This electronic document provides notification of the review results by the Institutional Review Board.

APPENDIX D

PAAPE IRB Assessment Instrument

Instructions: We appreciate your efforts regarding completion of this assessment. The information obtained from the completion of this assessment will help PVAMU improve procedures and service delivery to administrators, faculty, professionals and students that conduct research, sponsored programs, education, and training that involves human participants/subjects. Please complete all parts of the survey. Once again, your participation is greatly appreciated.

Demographics

1. Gender

☐ MALE ☐ FEMALE

2. Your Ethnicity:

☐ AMERICAN INDIAN OR ALASKAN NATIVE

☐ ASIAN

☐ BLACK OR AFRICAN AMERICAN

☐ WHITE OR CAUCASIAN

☐ HISPANIC

OTHER

☐

3. Age:

☐ under 21 ☐ 33 - 38 ☐ 51 - 56

☐ 21 - 26 ☐ 39 - 45 ☐ 57 - 62

☐ 27 - 32 ☐ 46 - 50 ☐ over 62

4. How many years have you worked at PVAMU?

☐ 0 - 3 ☐ 12- 15 ☐ Not an employee

☐ 4 - 7 ☐ 16 - 19

☐ 8 - 11 ☐ 20 - more

5. What is your employment classification?

☐ ADMINISTRATOR ☐ FACULTY ☐ PROFESSIONAL STAFF ☐ N/A

6. What is your academic rank? (Please Select One)

☐ LECTURER

☐ INSTRUCTOR

☐ ASSISTANT PROFESSOR

☐ ASSOCIATE PROFESSOR

☐ PROFESSOR

☐ RESEARCH ASSOCIATE

☐ GRADUATE STUDENT

☐ ASSOCIATE RESEARCH SCIENTIST

☐ RESEARCH ASSISTANT

☐ RESEARCH SPECIALIST

☐ PROGRAM SPECIALIST

☐ N/A

☐ OTHER

7. Please select your tenure status.

☐ non-tenure track ☐ tenure track ☐ tenured ☐ N/A

8. Are you full time or part time?

☐ FULL TIME ☐ PART TIME ☐ N/A

9. Are you a Master's student at PVAMU?

☐ YES ☐ NO

10. Are you a Doctoral student at PVAMU?

☐ YES ☐ NO

11. If no, are you enrolled in graduate study at another institution?

☐ YES ☐ NO

12. Select your academic field from the list below (select one):

☐ Agricultural Sciences
☐ Biological Sciences
☐ Computer Sciences
☐ Engineering
☐ Environmental Sciences
☐ Mathematical Sciences
☐ Medical Sciences
☐ Physical Sciences
☐ Psychology
☐ Social Sciences
☐ Arts and Humanities
☐ Business Administration
☐ Education
☐ Law and Public Administration
Other Sciences - Please specify
☐

13. Do you supervise graduate work?

☐ YES ☐ NO

14. If yes, answer all that apply:

☐ Chair ☐ Committee member ☐ Advisory

15. Do you teach a research methods course?

☐ YES ☐ NO

16. Do you offer ethics in any of your courses?

☐ YES ☐ NO

Awareness

17. Are you familiar with the purposes of the IRB?

☐ YES ☐ NO

18. Are you aware that PVAMU has an active IRB?

☐ YES ☐ NO

19. Have you ever read the full packet of information provided by the IRB to protocol applicants?

☐ YES ☐ NO

20. Was the PVAMU process for reviewing a research proposal for human subjects/participants clear?

☐ YES ☐ NO

Experiences

21. Have you ever submitted a research protocol to the PVAMU IRB for approval?

☐ Yes ☐ No

22. During your time at PVAMU, approximately how many research proposals have you submitted to the IRB for approval?

☐ 0 ☐ 1 - 3 ☐ 4 - 5

23. Do you have an existing active protocol?

☐ YES ☐ NO

24. If yes, is the protocol for

☐ research

☐ teaching

☐ sponsored programs

☐ service/community outreach

☐ N/A

25. Do you engage in assessment?

☐ YES ☐ NO

26. Select the type of assessment in which you engage:

☐ Direct

☐ Indirect

☐ Programmatic

☐ Course

☐ Individual

27. Have you ever served on an IRB Board?

☐ YES ☐ NO

28. The statements below reflect your experience(s) with the IRB. Based upon this experience, respond to the following statements by selecting yes or no.

	YES	NO	N/A
The IRB reviews the protocols in a timely manner	☐	☐	☐
The IRB gave a complete explanation for any required changes to the protocol.	☐	☐	☐
The IRB includes a complete explanation when it disapproves a protocol.	☐	☐	☐
The IRB invites investigators to present their protocol during a meeting of the board.	☐	☐	☐
The IRB members offer consultation during the development of a research protocol.		☐	☐
The IRB offers investigators opportunities to be educated about federal research policy, through human subjects/participants electronic training	☐	☐	☐
The IRB offers editorial suggestions regarding informed consent documents and research protocols (e.g., typos, grammar, clarity).	☐	☐	☐

Perceptions

29. Based upon your perception of the IRB, rate the following statements by selecting a number on the following 5 point scale:

5 = Outstanding, 4 = Very Good, 3 = Good, 2 = Fair, 1 = Poor, 0 = Unable to Rate

	5	4	3	2	1	0
The IRB monitors the progress of each approved research protocol in line with federal policy (for example, annual updates).	☐	☐	☐	☐	☐	☐
The IRB shows considerable evidence that the advancement of science is part of its mission.	☐	☐	☐	☐	☐	☐
The IRB requires members to recuse themselves from evaluating protocols whenever there might be a real or apparent conflict-of-interest.	☐	☐	☐	☐	☐	☐
IRB membership is very knowledgeable about IRB procedures and federal policy.	☐	☐	☐	☐	☐	
The IRB conducts a conscientious, informed analysis of potential benefits weighed against potential risks before making decisions.	☐	☐	☐	☐	☐	☐
The IRB views protection of human participants as its primary function.	☐	☐	☐	☐	☐	☐
The IRB takes timely and appropriate action whenever scientific misconduct is alleged.	☐	☐	☐	☐	☐	☐

30. Have you been unable to carry out a research project because of problems with the IRB?

☐ NO ☐ YES ☐ N/A

31. If you have been unable to carry out a research project because of problems with the IRB, what was the issue?

- ☐ DISAPPROVAL
- ☐ PROCESS TOOK TOO LONG
- ☐ ALTHOUGH APPROVED, CONDITIONS TOO RESTRICTIVE
- ☐ N/A

OTHER PROBLEMS/ISSUES (Please specify):

32. Do you think the PVAMU IRB has treated you fairly and equitably when evaluating your proposed research?

☐ YES

☐ N/A

☐ NO

IF NO, WHY NOT?

33. Do you have any recommendations regarding the organization and processes of the PVAMU IRB?

34. Do you believe that PVAMU students should have requirements in their classes to conduct research involving other people?

☐ YES ☐ NO

35. If a PVAMU graduate student wants to conduct research involving human participants for a master's thesis or a doctoral dissertation, should the student be required to obtain IRB approval for this research?

☐ YES ☐ NO

36. Suppose that a large company wants a PVAMU faculty member to help test the effects of an experimental medical treatment on patients, as one of dozens of such tests all over the US. Should the PVAMU faculty member be required to get approval from the PVAMU IRB to do the proposed research here?

☐ YES ☐ NO

37. Suppose that a private business or government agency wants a faculty member to analyze data on customers or clients that they routinely collect as part of their regular business operation. Should the PVAMU faculty member be required to obtain approval from the IRB to do the proposed research?

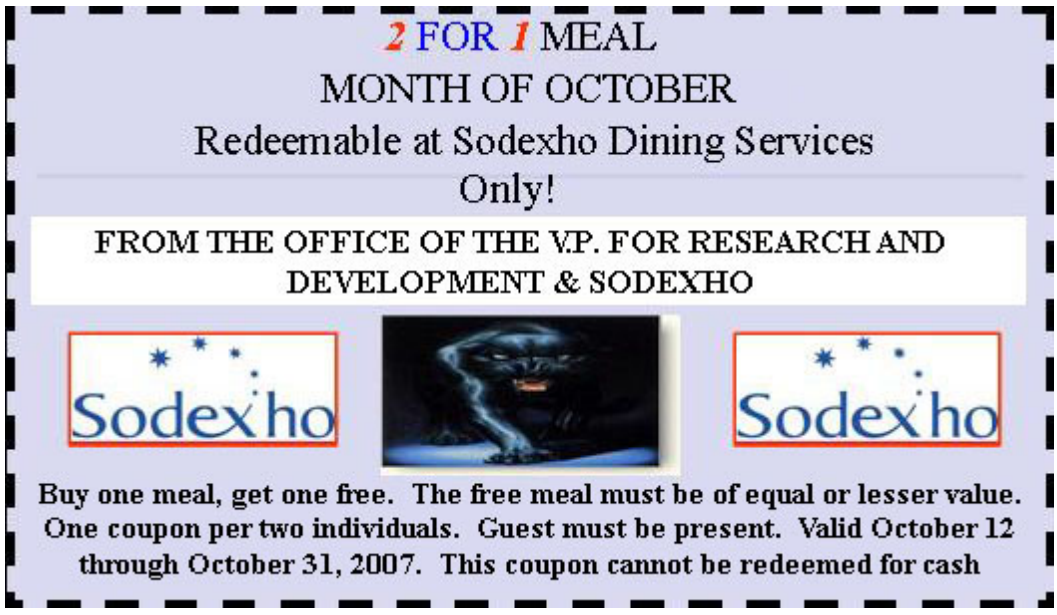
☐ YES ☐ NO

Thank you for investing time and effort in this assessment.

Thank you for your cooperation, as a token of our appreciation we would like to give you a buy-one-get-one-free certificate! Please print this page and come by our office located on the 2nd floor of the Drew Memorial Complex, Suite 202 (above Pardus) to pick up your official certificate for a free lunch for your guest. Again, thank you for your participation and bon appetite!

The Office of the Vice President for Research and Development, with the generous support of SODEXHO, are providing a certificate that offers a free meal with the purchase of a meal in the Cafeteria located in the Memorial Student Center or at Pardus.

The certificate is valid during October 12-31, 2007. The coupon must be presented with the guest. Photocopies will not be accepted.



VITA

Marcia Collins Shelton
mcshelton@pvamu.edu

Anderson Hall, Suite 104 Prairie View, TX 77446 v. 936.261.1588 f. 936.261.1599

Licensure Licensed Professional Counselor (LPC) - Texas # 257041
Certification(s) Credentialed Alternative Dispute Resolution Mediator – State of Texas
Clearance – Top Secret –federal
Honors and Awards NASA Graduate Student Research Program (GSRP) - Fellow

EDUCATION

Institution/Location	Degree	Year	Field
Tuskegee University, Tuskegee, AL	B.S. ChE	1982	Engineering
Tuskegee University, Tuskegee, AL	M.S. ME	1986	Engineering
Prairie View A&M University, Prairie View, TX	M.S. CnsL	1998	Education
Prairie View A&M University, Prairie View, TX	L.P.C.	1999	Education
Texas A&M University, College Station, TX	Ph.D.	2008	Education

PROFESSIONAL EXPERIENCE

09.06-present	Director, Regulatory Research Compliance	Prairie View A&M University Prairie View, TX
08.03 – 08.06	Officer, Regulatory Research Compliance	Prairie View A&M University Prairie View, TX
07.97 – 08.06	Assistant Director, Research and Sponsored Programs	Prairie View A&M University Prairie View, TX
10.96 – 07.97	Special Assistant, to the President - PVAMU	Prairie View A&M University Prairie View, TX
08.93 – 05.95	Director, Religious Education	Wiesbaden Air Base Wiesbaden, Germany
12.89 – 07.93	Senior Chemical Engineer	US Department of Defense Chemical School (USACMLS) Anniston, AL
08.86 – 12.89	Quality Assurance Engineer	NASA - Marshall Space Flight Center (MSFC) Huntsville, AL
05.83 – 08.86	National Graduate Research Fellow - Materials Engineering	NASA - Marshall Space Flight Center (MSFC) Huntsville, AL
09.83 – 05.83	Graduate Research Assistant Mechanical Engineering	Tuskegee University Tuskegee, AL
08.82 – 08/83	Tribological Engineer	Gulf Oil Corporation Columbia, SC