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Analysis of Faculty Knowledge of Human Subjects Protections in Research

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Abstract

Institutions of higher education are continually engaging in human subject research at the faculty and student level. It is extremely important that all research involving human subjects is in compliance with the United States (U.S.) *Federal Policy for the Protection of Human Research Subjects.* If faculty and students are not following the guidelines for the ethical conduct of human subject research, their institution will be at risk of losing any federal funding acquired through these studies and risk the possibility of having all research shut down. The lack of faculty knowledge in the area of human subjects research protections has been considered non-compliance for human subjects research. The purpose of this study was to determine if a significant relationship exists between the areas of faculty research experience in higher education and knowledge of the Total Governing Principles of U.S. Codes and Regulations. The study sought to find if faculty experience in research could predict their knowledge of human subjects research protections. In order to test each hypothesis, two statistical tests were conducted. A Multiple Linear Regression (MLR) was utilized as well as a One-Way Multivariate Analysis of Variance (MANOVA). Findings indicated that there is no statistical significance between the amount of faculty experience in research and their knowledge of the U.S. Codes and Regulations for human subjects research protections.

Keywords: human subjects research, institutional review board, higher education research, governing principles of human subjects research

Introduction

Human subjects research (HSR) has long played a role within academia. Institutions of higher education continually encourage faculty to pursue research studies and apply for federal funding in order to see these projects through. Some faculty are in need of these research opportunities for professional growth which includes publication requirements set forth by their institutions. Human subjects research misconduct has occurred in institutions as recent as 2016, and continues to occur. According to the United States Department of Health and Human Services (HHS) *Office for Human Research Protections* (OHRP) (2016) website, eight institutions of higher education have already been issued determination letters for reports of noncompliance with HHS regulations for the protection of human subjects (45 CFR part 46) from January through May 2016. For this reason, it is extremely important that higher education institutions and their faculty remain in compliance and keep abreast of the rules and regulations regarding HSR protection practices.

Many research studies involving human subjects at higher education institutions are federally funded and therefore fall under the purview of the United States Policy for the Protection of Human Subjects (USPHS) (Garfinkel & Cranor, 2010). Institutions that violate federal policies protecting human subjects are at risk of having their research shut down as well as their university as a whole.

Institutions of higher education are continually participating in HSR, and therefore should be guided by HHS' *Code of Federal Regulations (45 CFR part 46)* and the *Federal Policy for the Protection of Human Subjects* or the *"Common Rule"* in order to ensure the safety and well-being of all human subjects in research. All U.S. federal agencies as well as institutions utilizing federal funding for research studies, must follow the ethical codes outlined by HHS. Unfortunately, despite these regulatory structures, researchers in some higher education institutions have been found to be out of compliance and lacking in knowledge on how to conduct human subject research. The purpose of this study was to find if a relationship existed between these variables and if so, what implications this may have for research misconduct and noncompliance for institutions of higher education.

Review of Literature

Federal regulations for human subjects research (HSR) were created as a result of unethical and harmful practices dating back to the 1930s as well as more recent issues in the 2000s in which researchers engaged in HSR studies without proper consent and approvals. Some examples of HSR violations are: conducting research without Institutional Review Board (IRB) review and approval, lack of informed consent, unapproved modifications to IRB approved research, the falsification of data, confidentiality breach and failure to follow IRB approved research design (United States Department of Health and Human Services, 2016). OHRP (2014) reported that in 2009 there were over 250 serious non-compliance issues within the realm of informed consent. Also, in 2013, there were approximately 200 serious non-compliance issues directed at protocol changes (United States Department of Health and Human Services, 2014).

In order to address issues such as these, and prevent continuous noncompliance, the OHRP makes available to the public through the *Division of Compliance Oversight* the determinations of non-compliance of institutions as well as their determination letters. This document provides the name of the institution, principal investigator and evaluation of allegation of noncompliance along with the determination and corrective action the university should take to help prevent another occurrence of non-compliance (United States Department of Health and Human Services, 2016). Examples of some corrective actions currently in place for some institutions are termination of research studies as well as halting the Principal Investigator's research activities, requiring additional training for researchers, contacting the research subjects who were inadvertently involved in the research misconduct and resubmitting protocols with new data collection procedures consistent with the action step they were informed of by OHRP (United States Department of Health and Human Services, 2016).

Various reasons have been considered as to why institutional researchers have conducted and continue to conduct HSR without proper approvals and compliance with the 45 CFR Part 46. Reasons for non-compliance have been suggested as either the faculty being unaware of proper research compliance procedures as well as the lack of importance of following through with these processes. According to Kramer, Miller, and Commuri, (2009), non-compliance may be credited to the lack of communication and a perceived closed climate between researchers and IRBs. Faculty may sometimes feel that they are unable to communicate with their IRBs and therefore are unable to get answers to questions in regards to HSR. This in turn, provides an opportunity for research misconduct and violations of 45 CFR Part 46. In order to understand more clearly the impact of HSR violations and the importance of preventing research misconduct in institutions of higher education, it is imperative to first review the history surrounding HSR abuses. HSR misconduct dates back to the early 1900s and continues with the more recent findings of non-compliance within institutions of higher education.

Belmont Report

Continuous research misconduct violations involving human subjects were the basis for the creation of an ethical foundation for researchers. In 1979, the *Belmont Report* recognized three ethical principles that would provide ethical guidance for research involving human subjects. *Respect for Persons*, *Beneficence*, and *Justice* were to be the foundation for ethical policy regarding all human subjects research (United States Department of Health and Human Services, 2010). The objective for these principles was to provide an analytical framework for the guidance and resolution of any ethical problems which may arise with human subjects research (United States Department of Health and Human Services, 2010). Also, in order to utilize these three ethical guidelines, one must distinguish the difference between biomedical and behavioral research and the "practice of accepted therapy" to guide in the review of HSR protections (United States Department of Health and Human Services, *Belmont Report*, 2010, p.3).

Respect for Persons.

Respect for Persons, described in the *Belmont Report*, is broken up into two moral requirements: (1) acknowledging the autonomy of the human subject, and (2) protecting those

who have diminished autonomy (United States Department of Health and Human Services, 2011). Respecting a person's autonomy is taking personal opinions and choices into consideration while refraining from hindering their actions unless they are harmful to others. For one to show a lack of respect for a human subject is to deny that individual the freedom of acting on their considered judgments, and withhold information that is necessary for the individual to make a considered judgment (United States Department of Health and Human Services, 2011). Also, it is pointed out that not all individuals have the capacity for self-determination as it is diminished either through illness, mental disability, or another circumstance, which would prohibit or severely restrict that freedom. If this is the case, these individuals would require extensive protection that may even lead to non-participation from activities that may be considered harmful to them. In the example of the studies that took place at the Willowbrook State School, it was clear that the mentally disabled students did not have protections under "diminished autonomy" as they were not given a choice to participate in the medical research studies because their parents and guardians gave consent for their participation. These parental consents allowed Willowbrook to conduct medical research and infect their children with viruses and then experiment with vaccinations for those infections (Starogiannis & Hill, 2008).

Beneficence

Beneficence as an ethical principle for HSR provides that subjects are not placed in harm's way and the benefits for participating in the research are maximized while possible harms are minimized. In conducting research, it should be determined: (1) what is a benefit that outweighs the risks involved, and (2) what possible benefits should be foregone because of the risks involved (United States Department of Health and Human Services, 2011). Investigators are expected to review the longer-term benefits and risks that may result from the knowledge acquired through their research. An example of beneficence can be viewed through research involving children and treating childhood diseases. Research makes it possible for children to avoid possible harm from previously used routine practices that have turned out to be harmful. Difficulty surrounding the principle of *Beneficence* is that research presenting more than minimal risk to children without an immediate opportunity for a direct benefit is viewed as a conflict. There have been arguments by some that if more than minimal risk to children is possible, the research should not be approved. Others argue that preventing research that poses more than minimal risk to children only limits research that may possibly benefit children greatly in the future (United States Department of Health and Human Services, 2011). The requirement to attend to the principle of *Beneficence* has brought forth dilemmas for academic researchers because of the possible constraints they may encounter in their research as they will need to focus on having the benefits of the research outweigh the risks involved.

Justice

The requirement to attend to the principle of *Justice* brings forth the question of whom should receive the benefits of research as well has who will bear its burdens. As described in the *Belmont Report*, an injustice occurs when a benefit is denied to a person without good reason as well as when a burden is imposed unjustifiably. Individuals must consider what is equal as well

as what would be considered unequal. An example in which participants may require differential treatment may be in the resources they have at their disposable, such as possibly needing funds to pay for childcare in order to participate in a study (Brody, Migueles & Wendler, 2015). In order to provide equal benefits to persons, distribution formulations are available through this ethical principle. There are five formulations which are: "1) to each person an equal share, 2) to each person according to individual need, 3) to each person according to individual effort, 4) to each person according to societal contribution, and 5) to each person according to merit" (United States Department of Health and Human Services, *Belmont Report*, 2010, p. 6).

Examples of injustice in research are the exploitation of prisoners in Nazi concentration camps, the infected Black men in the Tuskegee Syphilis Study, and the Willowbrook School students. In each of these instances, informed consent of the participants was not provided to researchers. This prompted the notion that study participants were being systematically chosen based on their availability, manipulability, and compromised position rather than how they related to the problem studied. Also, it is demanded through the principle of *Justice* that the benefits of research supported by public funds are to be available to all individuals in need of them, not only those who can afford them (United States Department of Health and Human Services, *Belmont Report*, 2010).

Informed Consent.

As described in the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* in 1979, otherwise known as the *Belmont Report*, the informed consent process provides a potential research subject with sufficient information regarding the study in a language that is understandable to the participant, so he/she will be able to make a voluntary decision about whether or not to participate as a human subject (United States Department of Health and Human Services, 2011). According to Nijhawan, Janodia, Muddukrishna, Bhat, Bairy, Udupa and Musmade (2013), informed consent has also been described as an obligation of the investigator to the subject to inform them about personal benefits and risks the individual will face in the study.

In the informed consent process, it is very probable that challenges may arise through various complexities. Some of the possible challenges that researchers may face are language barriers, religious influence, false expectations, patient perceptions, child participation, the participation of vulnerable people and groups, as well as cultural beliefs (Nijhawan et al., 2013). Language barriers may become prominent in the consent process as there in no proven method to measure a participant's level of understanding. A lack of understanding may occur in this situation and therefore cause the participant to withdraw from the study at a later point. Considering religion in the consent process is necessary in order to understand if a possible conflict will occur due to a participant's religious beliefs. False expectations may become an issue in the consent process if the participant has a certain expectation of the research outcome that is either negative or positive. During the consent process, patient perceptions may intervene as well as patients may perceive the study as harmful or decline participation because they fear the outcome of the study. The participation of children under the age of 18 may also pose a barrier in the consent

process for the reason that parents may give consent for their child to participate, but the child may refuse to assent. Children over the age of seven are required to provide assent in order to permit participation in a research study involving human subjects. It is also important to look at vulnerable populations and groups in the consent process because they may have communication barriers and misunderstanding of their role in the research due to their disabilities or special care needs. Lastly, differences in cultural values may present a barrier in certain regions. For example, clinical investigations in India are based on regional values as well as practices and the concept of disease through the perception of social values within the family's villages and power hierarchies (Nijhawan et al., 2013).

Methodology

Population and Sample

The population for this study consisted of all full-time and part-time faculty whose members were listed on the corresponding university website in each academic department within each of the five south Texas institutions of higher education. Each institution is a four-year university and identified by the state of Texas as a public institution. All five of the institutions currently participate in human subjects research studies and also have an Institutional Review Board in place to review protocols for institutional approval. The participating faculty belonged to different colleges within their universities and is currently active as faculty members within their college. The sample was self-selected. Emails with the link to the survey were sent out to all full-time and part-time faculty members within every academic college meeting the sample criteria and 12.5% of 1,500 faculty members responded to the survey.

Instrumentation

Data were collected through the dissemination of a web-based survey created by the researcher. Permission was received to use and modify *IRB Final scales*. The initial questions on demographics were utilized. This survey focused on the amount of knowledge of human research subject's compliance in regard to professional experience as a faculty member. The survey measured the knowledge of faculty in HSR. The survey is divided into four subsections; Codes and Regulations, Respect for Persons, Beneficence, and Justice. The four subsections were totaled together as an overall score called Total Governing Principles. All of the subtotals and total were considered interval data.

Data Analysis

A standard Multiple Linear Regression (MLR) was performed for determination of a relationship between the Total Governing Principles of Codes and Regulations and the experience of faculty in higher education research as well as a one-way multivariate analysis of variance (MANOVA).

In order to focus the study, four areas of faculty knowledge and the U.S. Human Subjects Research History and Ethical Principles were selected as a means to identify potential significance in experience of faculty in higher education and knowledge of HSR protections. The four areas of faculty knowledge analyzed were completed human subject research

protocols, amount of publications, areas of study, and years spent as a faculty member in higher education. The four areas of the human subjects research history and ethical principles analyzed were the Total Governing Principles of Codes and Regulations, Respect for Persons, Beneficence, and Justice.

Results

The sample of the population was comprised of 187 surveys administered via SurveyMonkey, to faculty members at five higher education institutions in south Texas. A descriptive analysis of this study's participants is provided through a demographics breakdown along with information regarding experience in higher education and experience in research. Table 1 provides demographic information about faculty.

Table 1. Faculty Demographic information

Race	n	Percent
African American/Black	6	3
Asian	3	2
Caucasian/White (non-Hispanic)	133	72
Hispanic	34	18
Native American/Alaskan Native	0	0
Other	10	5
Gender	n	Percent
Male	77	42
Female	107	58
Age (years)	n	Percent
20-29	5	3
30-39	44	24
40-49	44	24
50-59	44	24
60+	46	25

Of the respondents, 133 (72%) participants were Caucasian/White (non-Hispanic) which was the highest percentage in race. The second largest represented group was Hispanic, with 34 (18%) participants. African American/Black, Asian, and Native American/Alaskan Native were least represented at 3%, 2% and 0% respectively. Gender of faculty participants were

shown as fairly equal with 77 (42%) male participants and 107 (58%) female participants responding to the survey. In terms of age, the age ranges of 30-39 (24%), 40-49 (24%), 50-59 (24%) and over 60 (25%) years of age was equally distributed. Only 5 (3%) of survey participants fell in the 20s age range.

In order to better understand faculty experience and knowledge of human subjects research protections, demographic questions included the average number of research articles published by a faculty member in a year, years in higher education, the faculty area of discipline, and average number of protocols submitted to the IRB. Results show that 108 (59%) faculty members indicated that they publish on an average 1 to 3 articles in a year while only 3 (2%) of faculty indicated that they publish approximately 7-9 articles. Reviewing further, 56 (30%) participants stated that, on average, they do not submit any articles for publication. The response for years of experience in higher education is greater in the 0-9 years level, revealing that 43% of respondent's have minimal years of work experience in higher education. Respondents with over 40 years of experience in higher education make up only 2% of the participants. Faculty respondents showed higher representation in the Arts (31%), STEM (30%), and Education (20%) fields of study. Other disciplines such as Law (3%) and Business (4%) were least represented. Lastly, when faculty was asked how many IRB protocols they submit on average within a year, 87 (48%) participants stated they submit between 1-3 protocols. Of the 182 respondents to this question, 76 (42%) revealed that on an average year they do not submit any protocols to the IRB. According to survey responses, the most protocols submitted to the IRB were in the range of 7-9 protocols by only 3 (2%) faculty participants. These results are seen in Table 2

Table 2. Faculty Research and Experience in Higher Education

Articles Published Per Year	n	Percent
0	56	30
1-3	108	59
4-6	15	8
7-9	3	2
Years worked in Higher Education	n	Percent
0-9	80	43
10-19	55	30
20-29	25	13
30-39	18	10
40-49	8	4
Discipline	n	Percent
Arts	57	31
Business	8	4
Counseling and Psychology	20	11
Education	37	20
Law	6	3
Science Technology Engineering and Math (STEM)	54	30
IRB Protocols submitted	n	Percent
0	76	42
1-3	87	48
4-6	16	9
7-9	3	2

Faculty respondents scored the highest amount of correct responses (136) to the question: "What is an appropriate method for maintaining confidentiality of private information obtained from human subjects?" The lowest number of correct responses (28) was for the question: "When are researchers specifically required by NIH policy to describe data and safety

monitoring?" Under the *Respect for Persons* category, faculty respondents appeared to have had the most correct answers with the highest correct score within the subsection (130) for the question "Why might an individual have diminished autonomy?" and the lowest score (87) for the question "In order to participate in research, children must?". For the subsection of *Codes and Regulations*, faculty respondents received a low amount of correct responses (62) for the question "Identify the event(s) that led to the HHS Policy for Protection of Human Research Subjects", and a higher score (109) for the question "The Belmont Report is significant because?"

Based on the data collected, it seems that faculty provided the highest amount of correct responses for questions in the subsections of *Beneficence* and *Justice* within the survey. Correct responses in these sections were as high as 136. It should be noted that in each question of the survey, there were over 30 missing responses where faculty participants chose not to answer. The question: "Which of the following is true regarding applications for NIH-funded research overseas?" had the most missing responses (50).

A multiple linear regression (MLR) was then conducted to determine the best linear combination of completed human subjects research protocols, amount of publications, areas of study, and years spent as a faculty member in higher education for predicting knowledge of the Total Governing Principles of Codes and Regulations. This combination of variables was not significant in predicting faculty knowledge of the Total Governing Principles of Codes of Regulations. The overall ANOVA was $F(4,136) = .98$, $p = .42$, with none of the four variables significantly contributing to the prediction. The R squared value was .03, which is a low effect size. There was no significant relationship between the criterion variable of Total Governing Principles of Codes and Regulations and the predictor variables of completed human subject research protocols, amount of publications, areas of study, and years spent as a faculty member.

An MLR was then conducted to determine the best linear combination of completed human subjects research protocols, amount of publications, areas of study, and years spent as a faculty member in higher education for predicting knowledge of Respect for Persons. This combination of variables was not significant in predicting faculty knowledge of Respect for Persons. The overall ANOVA was $F(4,133) = .72$, $p = .43$, with none of the four variables significantly contributing to the prediction. The R squared value was .03, which is a low effect size. There are no significant differences between the criterion variable of Respect for Persons and the predictor variables of completed human subject research protocols, amount of publications, areas of study, and years spent as a faculty member in higher education.

An MLR was then conducted to determine the best linear combination of completed human subjects research protocols, amount of publications, areas of study, and years spent as a faculty member in higher education for predicting knowledge of Beneficence. This combination of variables was not significant in predicting faculty knowledge of Beneficence. The overall ANOVA was $F(4,132) = .60$, $p = .70$, with none of the four variables significantly contributing to the prediction. The R squared value was .02, which is a low effect size. There is no significant relationship between the criterion variable of Beneficence and the predictor

variables of completed human subject research protocols, amount of publications, areas of study, and years spent as a faculty member in higher education.

An MLR was then conducted to determine the best linear combination of completed human subjects research protocols, amount of publications, areas of study, and years spent as a faculty member in higher education for predicting knowledge of Justice. This combination of variables was not significant in predicting faculty knowledge of Justice. The overall ANOVA was $F(4,125) = .30$, $p = .90$, with none of the four variables significantly contributing to the prediction. The R squared value was .01, which is a low effect size. There is no significant relationship between the criterion variable of Justice and the predictor variables of completed human subject research protocols, amount of publications, areas of study, and years spent as a faculty member in higher education.

A multivariate analysis of variance was conducted to assess if there were differences among the three groups of completed human subjects research protocols on knowledge of Codes and Regulations, Respect for Persons, Beneficence, Justice, and Total Governing Principles of human subjects research. A statistically significant difference was found, Wilks' $\Lambda = .882$, $F(8, 250) = 2.03$, $p = .04$, multivariate $\eta^2 = .06$. Examination of the dependent variables found that only Justice showed a statistically significant contribution, $p = .01$ and partial $\eta^2 = .08$, a medium effect size. None of the other variables was significant.

Table 3. Correlation Coefficients for Relations Among Five Measures of Completed HSR Protocols

Measure	1	2	3	4	5
1. Codes and Regulations	__				
2. Respect for Persons	.50	__			
3. Beneficence	.84	.70	__		
4. Justice	.40	.20	.10	__	
5. Total Governing Principles of HSR	.00	.00	.00	.00	__

A multivariate analysis of variance was conducted to assess if there were differences among the three groups of total publications on knowledge of Codes and Regulations, Respect for Persons, Beneficence, Justice, and Total Governing Principles of human subjects research. There was no statistical significance found, Wilks' $\Lambda = .934$, $F(8, 248) = 1.07$, $p = .38$, multivariate $\eta^2 = .03$.

Summary, Conclusions and Recommendations

The purpose of this quantitative study was to analyze the significance between the knowledge of south Texas higher education faculty and the Total Governing Principles of U.S. Codes and Regulations in the areas of knowledge of Codes and Regulations, Respect for Persons, Beneficence, and Justice.

Upon examining the faculty's responses to the Total Governing Principles of the Codes and Regulations multiple-choice question portion, it was revealed that faculty scored the highest amount of correct responses on the question, "What is an appropriate method for maintaining confidentiality of private information obtained from human subjects?" and scored the lowest on "When are researchers specifically required by NIH policy to describe data and safety monitoring?" It is important also to take into account that there were between 30-50 missing responses from faculty participants throughout this portion of the survey.

No significant difference was found among the criterion variables of *Total Governing Principles of Codes and Regulations*, *Beneficence*, *Respect for Persons*, and *Justice* and the predictor variables of completed human subject research protocols, amount of publications, areas of study, and years spent as a faculty member in higher education. A significant difference was found in the area of knowledge of Justice. It would appear that the amount of human subjects research protocols submitted by faculty contributes to the knowledge of faculty in the area of Justice of human subjects' protections.

According to the data, there is evidence that faculty are not being kept up-to-date on U.S. Federal Regulations regarding human subjects' protections in research. Based on the survey questions, the incorrect responses reveal that many faculty members are uninformed in the areas of *Codes of Regulations* and *Beneficence*. These areas focus on the 45 CFR Part 46 (Codes and Regulations) and the benefit-to-risk ratio for a human subject (Beneficence). Faculty respondents also left many questions unanswered in each of the four sections of the Total Governing Principles of Codes and Regulations. It can be implied that faculty left these unanswered because they either did not know the correct answers or they were confused by the questions. For this reason, it is necessary for institutions to train all faculty on protections for human subjects. The U.S. Health and Human Services provides training opportunities for all researchers seeking to utilize human subjects as participants for research.

In order to address the need for faculty knowledge in HSR, institutions should provide ongoing training for all faculty within all colleges. Trainings should focus on each area of the U.S. Codes and Regulations and should be offered in various formats for accessibility to accommodate all faculty. Rigorous schedules, as well as location, may not always allow for faculty to attend on-campus training for HSR protections. Therefore, training on HSR should be available face-to-face as well as online. Also, developing a training format which relates to the types of research faculty are conducting would assist in the understanding of how HSR protections are relevant across all areas of study.

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