Oglesby, Amanda E., The State of IRB Staff in America. Master of Science (Clinical Research Management), December, 2009, 116 pp., 4 tables, 17 figures, bibliography, 19 titles.

Purpose: To conduct a descriptive examination of Institutional Review Board (IRB) staff members across the United States

Objective: To determine a pattern or "type" of individual who is most drawn to working with IRBs and to develop a deeper understanding of the backgrounds and experiences of the IRB staff

Design: An IRB staff survey was distributed, via e-mail, to medical school IRBs which were grouped according to NIH funding in 2008.

Results: The IRB staff pursued an IRB career because of motivational reasons, and they were able to obtain the job due to their background and skills.

Conclusion: Results suggest there is a difference between amount of NIH funding and highest degree obtained, number of protocols reviewed, and number of full-time employees.

THE STATE OF IRB STAFF IN AMERICA

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the

Graduate School of Biomedical Sciences

University of North Texas
Health Science Center at Fort Worth

In Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE

By

Amanda E. Oglesby, B.A.

Fort Worth, Texas

December 2009

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CHAPTER I

INTRODUCTION

My internship site was the Office for the Protection of Human Subjects (OPHS) at the University of North Texas Health Science Center (UNTHSC) in Fort Worth, Texas. Among duties and responsibilities, the OPHS assists the Institutional Review Board (IRB) and investigators with the reviewing and editing of research protocols. The Institutional Review Board (IRB) is a committee designed to protect the rights and welfare of individuals involved in human subject research and is the unit responsible for approving all research protocols involving human subjects that are conducted by UNTHSC faculty, staff, or students. The studies reviewed by this institution include both biomedical and behavioral/social research.

During my experience at UNTHSC's OPHS, I had the opportunity to participate in all of the stages of protocol processing. This included categorizing protocols as exempt, expedited, or full-board in addition to reviewing research protocols (including documents of informed consent and waivers). In addition to reviewing protocols, I became familiar with the process required for the reporting of serious adverse events (SAEs) and wrote my own research protocol for this project.

Preparing for and attending the monthly IRB meetings were also part of my internship experience at the OPHS. I attended staff meetings prior to attending the IRB meetings which prepared me for the sequence of events and research material to be presented at the convened

meeting. I witnessed client (investigator/staff) interactions as well as communications between the IRB Chair and IRB Board members.

While working in and around all aspects of this human research protection program, a curious question emerged. Who are these IRB staff persons and how did they come to be in this dedicated and challenging career path? Current literature and research involving IRB staff provides information regarding years served, degrees obtained, and staffing but there is little to be found regarding "how" and "why" the IRB employees obtained their current positions. Federal regulations outline the composition of the IRB, but no such regulations exist for the IRB staff. Because of the important nature of the protection of human research participants, I thought it would be worthwhile to explore the various backgrounds, experiences, and training of these committed and hard-working employees.

The focus of my practicum work was a descriptive examination of IRB staff across the United States. This was accomplished by administering a survey designed to capture multiple aspects of IRB staff members' backgrounds and experiences. In addition, I inquired about multiple objective variables of IRB activities including: types of certification, number of people of staff, staff members' titles, degrees, and fields of degrees (majors). My many experiences at the OPHS have provided me with a strong foundation in human subject research education, and they have strengthened the skills needed to further my career in clinical research management.

CHAPTER II

INTERNSHIP SUBJECT

Background and Literature Review

Institutional Review Boards (IRBs), commonly referred to as "ethics committees," play a paramount role in the protection of human research subjects. As such, IRBs must maintain a high standard of operation. The IRB's operations can be defined as having three essential functions. [1] The first goal of the IRB is to ensure that human subjects involved in biomedical and behavioral research are protected to the highest extent while ensuring that the subjects' basic rights are attended to. Secondly, IRBs are critical in ensuring the conduct of ethically sound, well-informed research. Third, IRBs must work to heighten awareness and comprehension of the synergistic nature of research of all of the parties involved (subjects, investigators, regulators, etc.). The IRBs must effectively communicate with numerous parties including the research subjects, the investigators, the sponsors, and multiple other individuals and organizations. This is most often facilitated through the hard work and dedication of an IRB office staff.

According to Helen McGough, the Director of the Human Subjects Division at the University of Washington, "proper staffing is crucial to the effective operation of an IRB." [2] McGough argues that in order to adequately protect human research subjects, an institution with an IRB must be able to apportion ample resources to hiring proficient IRB staff. [2] Some IRBs have no staff at all while others have multiple staff members with varying positions. Most commonly,

IRB staff members are not members of the Board. An institution must have adequate resources for the IRB, but there is little guidance on how to staff an IRB office.[2]

IRB staff can span a spectrum of credentials. The clerical functions of an IRB staff member can include tasks such as taking minutes, keeping records, and making copies of documents.[3] Jeffrey Cohen, Ph.D., an independent consultant in Human Research Protections, suggests that professional IRB staff should have both academic training and administrative experience to be an effective liaison between the IRB and investigators.[3] In addition, he states that professional staff need to keep current with the literature regarding human subject protections and the federal regulations, and should attend conferences to stay current in the field. Cohen also suggests that IRB experience, reading literature, and exchanging information with others in the field is important in training novice staff. [3]

When IRBs and their office staff function correctly, important safeguards are in place and human subjects are likely to be treated with respect, beneficence, and justice. [4] Sometimes, simply finding the right person for the IRB team can be even more beneficial to the office than looking for the person with the most experience or credentials. [5] Tanna McReynold, CIP (Certified IRB Professional), mentions particular traits that are critical for a well-rounded IRB professional. These include loyalty to the institution, commitment, attention to detail, and working well with others. [5] She also states that a strong feedback system using positive feedback and reinforcement of the team are essential for the smooth operation of an IRB. [5] Hiring new staff may cost more money, but the results are worth it. [6] Well-trained and educated staff will be viewed as "colleagues" and as a result, regulatory compliance and efficiency will be improved. [6] One study was able to show that by hiring new, qualified staff, the institution was able to reduce the average number of days to bring a protocol from submission to review, and

reduced the average number of days from the IRB meeting to IRB correspondence. [7] Katreena Collette-Merrill, R.N. states that "the decrease in the days it takes the IRB to respond post-meeting was directly related to the hiring of an IRB coordinator. [7] The new staff will likely increase the speed by which protocols are processed and will improve the office's credibility. [6] In addition to clerical tasks, IRB staff members are also involved with pre-reviewing protocols, outreach and education, research design and input, regulatory guidance, and ethical suggestions.

One can easily see the importance of the role of the IRB staff. Surveying these individuals to gain insight to "how" and "why" these individual obtained their current positions will further an understanding of what constitutes the internal workings of these offices.

Preliminary Information/Previous Research

Background data for the IRB staff population are outlined by the 2008 IRB Workload and Salary Survey conducted by the Public Responsibility in Medicine and Research (PRIM&R) team. [8] It is important to note that persons responding to this survey were PRIM&R members and may not reflect the general IRB staff population across America because PRIM&R respondents are professionals who pay for membership.

The PRIM&R study investigated work demographics of IRB staff members, one of which was the total career time an employee spent working with IRBs. These statistics reflect the *total career time* each member has worked with IRBs (all positions associated with IRBs over a lifetime), as shown in Figure 1.

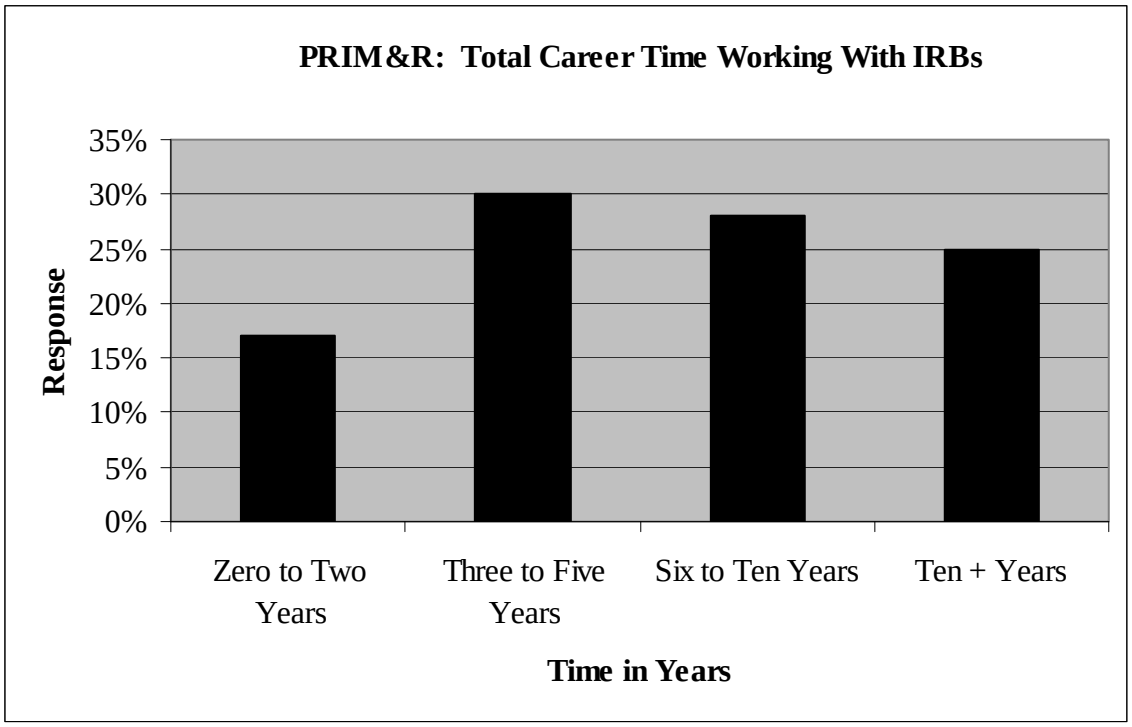

Figure 1: Total Career Time Working with IRBs as reported by PRIM&R in 2008, $N = 354$.

The total career time that IRB employees spent working with IRBs over a lifetime is presented. Many employees spent three to five years of their total career time working with IRBs.

Next, PRIM&R inquired about how long each staff member had been with his/her current employer (Figure 2).

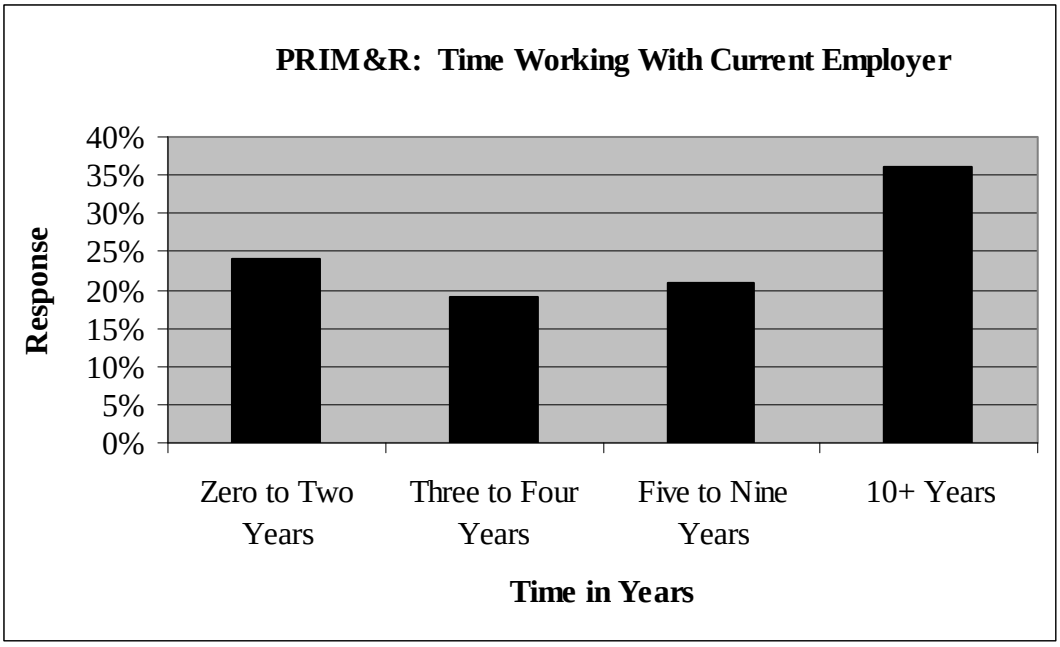

Figure 2: Time Working with Current Employer as reported by PRIM&R in 2008, *N* = 350. The time each IRB staff member spent, in years, working with his/her current employer is presented. Many employees worked for their current employer for over ten years.

Notably, 43% of employees have been at their current position less than 4 years. Also, within this category, it is difficult to determine if the employees have changed positions while working for the specified employer. PRIM&R did not report details regarding turnover. Perhaps employees changed positions due to high job-related stress or better-paying opportunities.

PRIM&R was also interested in determining the highest completed education level of the IRB employees. IRB staff with Bachelor's degrees and Master's degrees comprised the majority of those surveyed (Figure 3).

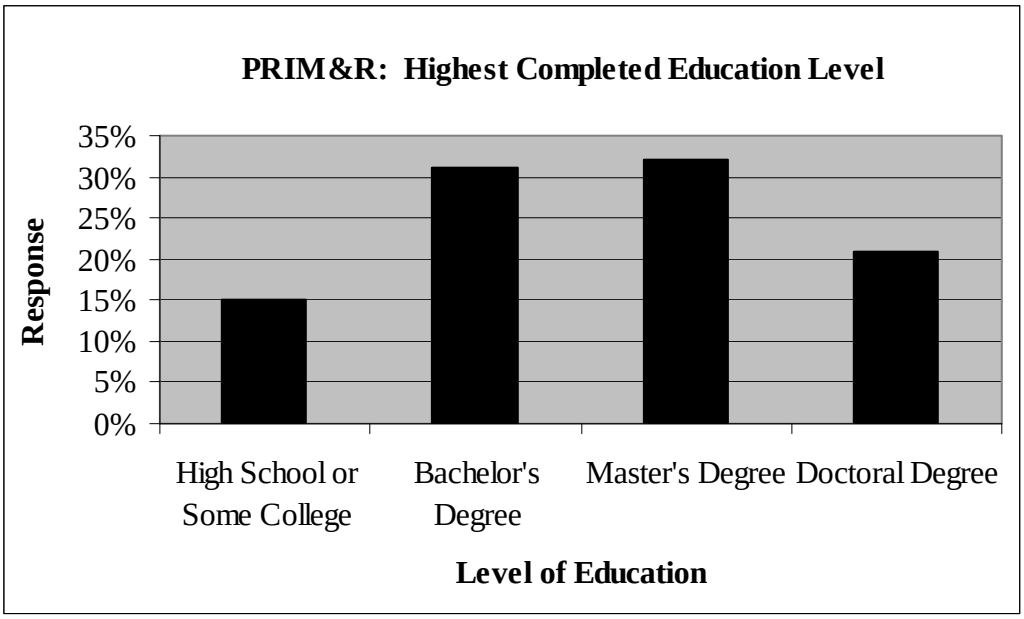

Figure 3. Highest Completed Education Level by IRB Staff, as reported by PRIM&R in 2008, *N* = 354. The majority of the employees had Master's and Bachelor's degrees.

Interestingly, little is known about the qualitative aspects of the various degrees. This practicum project examines these "majors" of degrees and assesses whether a correlation exists between "major" of degree and likelihood of working in an IRB office.

The number of full-time employees (FTEs) working 40+ hours a week was also determined by PRIM&R (Figure 4). The institutions with no FTEs probably have only part-time IRB staff.

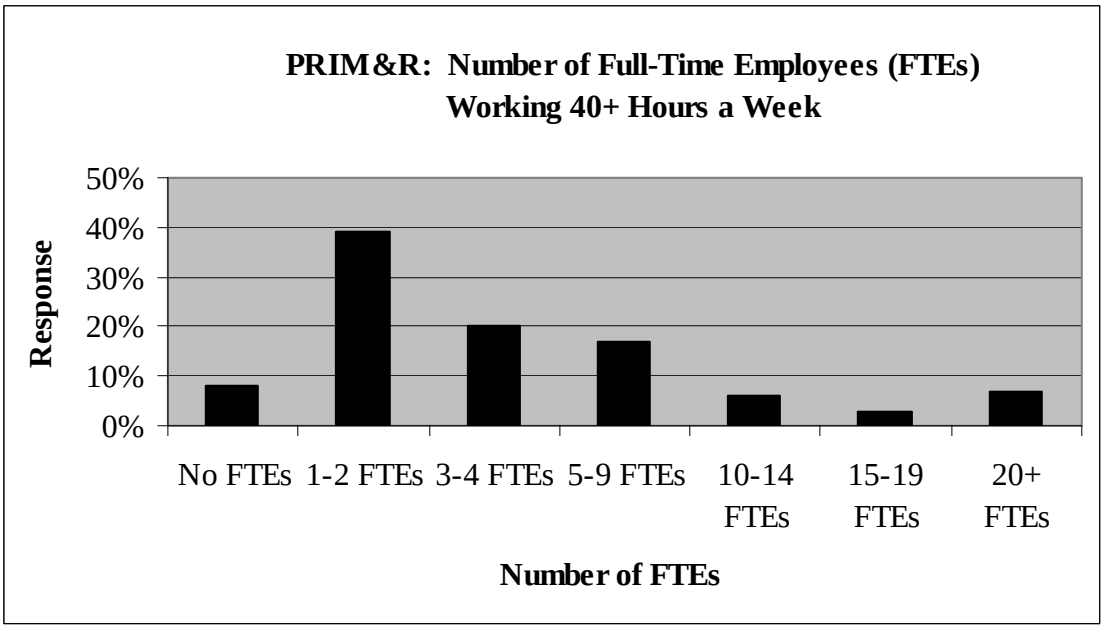

Figure 4. Number of Full-Time IRB Employees (FTEs) Working 40+ Hours a Week as reported by PRIM&R in 2008, *N* = 375. The largest single group of institutions reported having 1-2 FTEs.

Lastly, PRIM&R inquired about types of certifications of IRB staff members (Figure 5). Certifications available to IRB staff members include the following: Certified IRB Professional (CIP), Certified IRB Manager (CIM), Certified Clinical Research Professional (CCRP), Certified Clinical Research Coordinator (CCRC), and Certified Clinical Research Associate (CCRA).

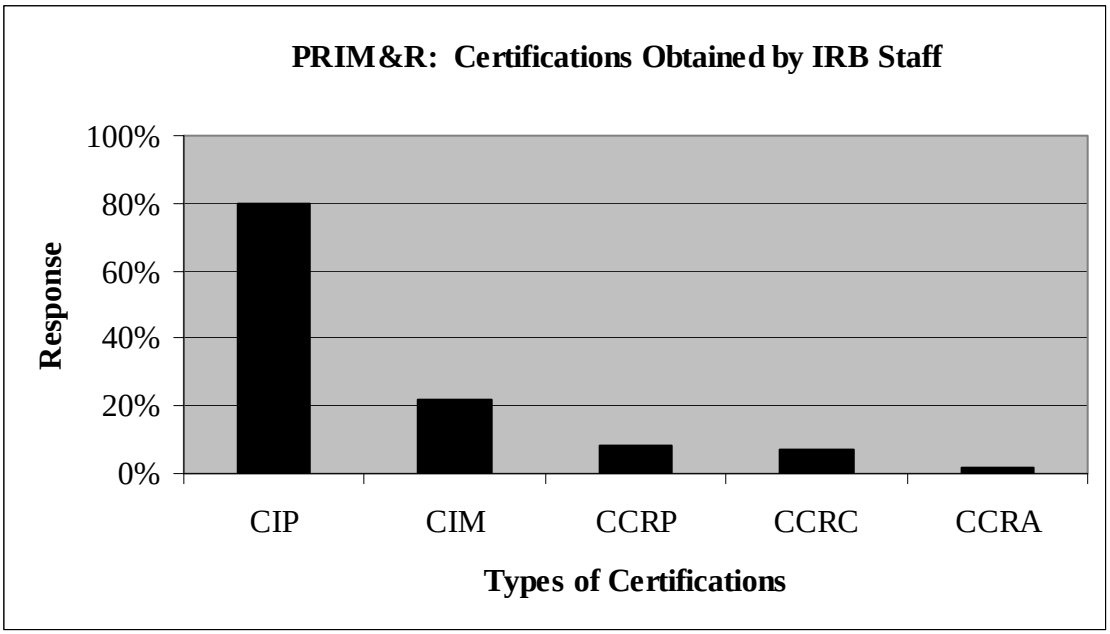

Figure 5. Certifications Obtained by IRB Staff as reported by PRIM&R in 2008, *N* = 354. Key: Certified IRB Professional (CIP), Certified IRB Manager (CIM), Certified Clinical Research Professional (CCRP), Certified Clinical Research Coordinator (CCRC), and Certified Clinical Research Associate (CCRA). Most IRB staff (80%) reported being Certified IRB Professionals.

The PRIM&R study reported 80% CIP certification, likely due to the large number of established, professional, paid members belonging to the PRIM&R organization. Thus, IRB employees not belonging to PRIM&R (usually lower paid, clerical staff without certifications) are not represented in the PRIM&R study.

High job satisfaction was reported with many aspects of work experience including the challenge of the job, opportunity to have meaningful work, benefits, job security, work schedule, organization's reputation as a good employer, and the organization's success.

In addition, PRIM&R reports that the higher the level of effort, as indicated by an "Engagement Index," the longer the employee retention. The "Engagement Index" includes

variables such as: agreeing with the organization's goals, willingness to work extra hours to help the organization succeed, going the "extra mile" to meet business needs, and job satisfaction. [8]

To summarize, the PRIM&R study reported:

1. Most IRB staff members (74.1%) had a Bachelor's or Master's Degree
2. Most employees (58%) had spent six or less years as an IRB staff person
3. Most employees (63%) had been at the same IRB job with their current employer for less than five years

Regarding certifications, the PRIM&R study did not have a "no certification" option on their survey; therefore, further studies are needed to compare the certification versus non-certification or IRB staff.

Specific Aims/Objective:

Minimal data regarding the previous training, experience, and backgrounds of IRB staff members exists. Even less is known about "how" and "why" staff members become involved in human research protection programs. This practicum project began as a descriptive examination of IRB staff in the United States. This was accomplished by administering a survey designed to capture multiple aspects of IRB staff members' backgrounds and experiences. The primary areas of interest include:

1. **How** the member's first IRB position was acquired
2. **Why** the member's first IRB job was acquired
3. Why the member is *still* at an IRB job
4. Type of prior experience
5. Expertise brought to the office
6. How to stay current in the field

7. How to acquire the knowledge needed to become an informed IRB staff member
8. Best part of the job
9. Feelings about investigators
10. What's most important to effective function of an IRB office?
11. What is the key to success?

This project also inquired about multiple objective variables of IRB activities including: types of certification, average protocol load, average protocol approval time, number of people on staff, how many IRBs each staff has worked with, and staff members' titles, academic degrees, and fields of degrees (disciplinary major).

It was anticipated that a pattern or "type" of individual who is most drawn to working with IRBs might be determined and a deeper understanding of the backgrounds of the IRB staff could be developed.

Significance:

The goal of the Institutional Review Board (IRB) is to maintain the safety and protect the rights of human subject research participants.[2] IRBs are, therefore, under tremendous pressure to ensure the welfare and safety of these individuals. Because of this huge responsibility, the members who comprise the IRB are selected based on qualifications and experience as outlined by the federal regulations. The composition of the IRB support staff, however, is not federally regulated. As such, the staff may actually lack essential resources and training minimums that are required for IRB members.[2]

Prior to IRB members having an opportunity to review the research protocols, the IRB staff is often assigned the task of pre-reviewing the protocols. [2] The staff, therefore, plays a critical role in the process of protecting the rights and safety of research subjects. Without adequate training

and experience, IRB staff may inadvertently handicap the investigator or endanger a subject.[6] This suggests a critical need for the proper training and experience of IRB staff. IRB employees entering the world of human subject protection should have education in ethical principles as well as knowledge of federal, state, and local regulations. Another example of the importance of the IRB staff lies in the fact that such individuals responsible for the protection of human subject research participants are at an increased liability risk.[9] One study showed that when clerical staff were asked to interpret federal guidelines, mistakes were made.[6]

This practicum project is significant to the IRB community in general. If one can determine "how" and "why" people go into this field, a better understanding of who these people are and how one might improve recruiting competent employees for human subject research offices could be developed.

Materials and Methods of Project Design:

A. Group Identification

Medical school IRBs were specifically investigated because of the availability the 2008 BRIMR report, which clearly reports funding and allows one to easily group and investigate institutions based on their funding. For this study, U.S. medical schools with IRBs were grouped according to National Institutes of Health (NIH) funding for 2008, as reported by the Blue Ridge Institute for Medical Research (BRIMR).[10] They were so grouped to assess the idea that the more funding an institution receives, the better trained and more experienced their IRB staff and the more active their IRB operations (or vice versa – it may be hard to determine which came first).

The three groups of medical schools studied in this project are:

Tier One – $100-500 million in annual NIH awards – 38 IRB Office Directors Contacted

Tier Two – $30-100 million in annual NIH awards – 30 IRB Office Directors Contacted

Tier Three – Less than $30 million in annual NIH awards – 34 IRB Office Directors Contacted

Medical school IRBs were the only IRBs contacted because there was not an easily accessible way to obtain information regarding other IRBs (such as commercial IRBs). Also, there was simply not enough time to find and interview other IRBs. A future study could perhaps investigate other "subgroups" of IRBs.

B. Subject Selection

IRB office directors at these medical schools throughout the United States were contacted via e-mail. These directors and/or chairs of the IRB offices were first contacted and asked to forward the survey to all of their IRB employees. The directors were contacted via e-mail twice regarding this survey, approximately one month apart. Eligible subjects included the current IRB staff (male and female, 18 years old and older) of up to 100 medical schools across the United States.

C. Questionnaire/Survey Development

A variety of questions regarding the IRB staffs' employment, training, experiences, and backgrounds was included. The questions were derived by examining multiple questionnaire formats, including the PRIM&R questionnaire.[8] The "IRB Staff Status Questionnaire" can be found in Appendix A.

D. Survey Field Test at UNTHSC

The Human Research Protection Coordinators at the Office for the Protection of Human Subjects at UNTHSC reviewed the questionnaire prior to distribution. Feedback regarding multiple aspects of the questionnaire was obtained and the wording of the questions was adjusted accordingly. UNTHSC staff were not included in this study because they had helped in developing the questionnaire.

E. IRB Review

Prior to conducting the research, a research protocol, along with all required documents needed for informed consent, was submitted to the UNTHSC IRB for review and approval.

F. Questionnaire Sent to Subjects

The Directors/Chairs of the IRB offices of medical schools throughout the United States were contacted via e-mail and asked to forward the survey to all of their IRB staff members. The staff then received the letter, along with the survey and consent form, asking them to participate in the survey. Approximately one month later, the directors were contacted again, asking them to forward the survey to employees again. The objective was to increase response rate wherever possible. Design and distribution of the survey was developed through "surveymonkey.com."

G. Data Analysis

Quantitative data was analyzed using descriptive statistics. The data and percentiles are visualized by the use of histograms and pie charts. For some items, chi –square tests of independence were used to test for statistical significance. It should be noted that the number of respondents used in these analyses sometimes vary from the total number of respondents due to missing data (not all subjects answered all questions).

Results and Discussion:

The survey was conducted through "surveymonkey.com," was created on June 18, 2009, and was officially closed on August 31, 2009. During this active period of 10 weeks, the survey was sent to the following: 38 Directors from Tier One Medical Schools (high funding), 30 Directors from Tier Two Medical Schools (medium funding), and 34 Directors from Tier Three Medical Schools (low funding). The Directors were then asked to forward the survey to all of their IRB staff. Because the survey was forwarded, it is impossible to know how many IRB employees

were initially contacted. However, a total of 130 subjects started the survey and 117 subjects (90%) completed the survey. There were twenty-four questions in all, and both subjective and objective information was obtained. Appendix A contains the "IRB Staff Status Questionnaire."

Institutional Demographics

Subjects from medical schools with high amounts ($100 – 500 million) of NIH funding were the primary respondents in this survey (Figure 6).

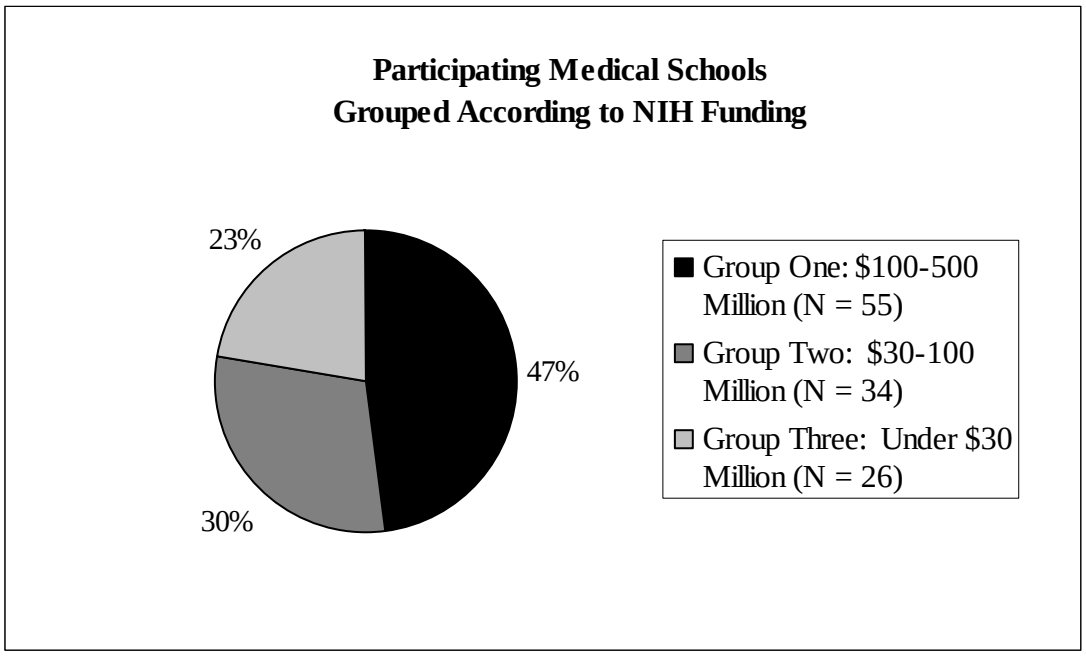

Figure 6. Participating Medical Schools Grouped According to NIH Funding, $N = 115$. The distribution of subjects according to medical school funding is presented. Respondents were primarily from Group One institutions (those with $100-500 Million in NIH funding). This is an approximate reflection of the national distribution (33% of schools in each group).

Subjects were also asked about what type of research their institution reviews. Institutions predominantly reviewed both biomedical and behavioral/social research. Only 3.4% of the

institutions surveyed review solely biomedical research. None reviewed solely behavioral/social research. This is most likely due to the fact that only medical school IRBs were contacted.

Staffing Demographics

Multiple positions exist within the office working with the IRB. Frequently, there is an IRB Director who functions as the chief administrative support for the IRB.[2] This position typically requires a Bachelor's degree (major not specified), at a minimum, with a master's degree preferred. Two years experience in program administration is also suggested.[2] Along with the IRB Director, the IRB office may be staffed with one or more program coordinators. These employees are responsible for screening new and renewal applications as well as assisting investigators with the completion of their applications. [2] An IRB Administrator will often serve as a member on the IRB. He will advise IRB members and investigators on state laws and federal regulations as well as provide ethical guidance.[2] Generally, a Master's degree (major not specified) and two or more years of IRB-related work experience are required for this position.[2] It should be noted that, depending on the office, an IRB Director and IRB Administrator are titles that describe the same position. Individuals often gain experience for these positions through having previously acted as an IRB Board member; in addition, "on-the-job" training plays a big role in gaining the knowledge required for these positions.

Other positions include compliance coordinators who screen protocols and advise investigators in order to bring their protocols into compliance with federal regulations and Program Managers who coordinate protocols so that researchers have applications suitable for presentation to the IRB. [2] In addition, there are Review Coordinators and Specialists who help investigators with questions regarding their IRB submissions.

The first question in this study asked the subjects to describe their job (Figure 7).

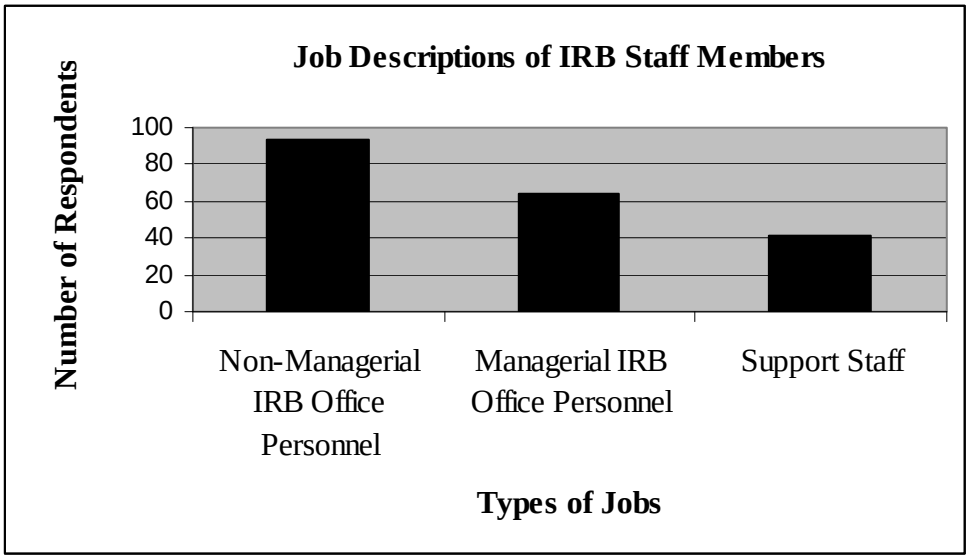

Figure 7. Job descriptions of IRB staff members, $N = 128$.

Respondents were asked to choose all positions that applied to them. Non-Managerial IRB Office Personnel include Compliance Coordinators, Expedited/Exempt/Full-Board Team Members, IRB Review Analysts, IRB Review Coordinators. Managerial IRB Office Personnel include Directors/Assistant Directors of Human Subject Protection Programs, IRB Administrators, IRB Directors/Assistant Directors, and IRB Program Managers. Support Staff include Education Specialists, Electronic Submission Specialists, and IRB Administrative Assistants.

Overlap occurs within these positions because most of these jobs deal with assisting the investigators with the preparation and screening of their protocols in order to bring them into compliance with the federal regulations. Notably, there were few electronic submission coordinators, perhaps because this is an emerging field which is likely to increase as IRBs begin transforming their practices to a “paperless” system.

In addition to job self-description, subjects were asked about professional certification, since certifications for IRB staff are quickly becoming a way to obtain employment or receive a promotion. In particular, the Certified IRB Professional (CIP) certification is increasing in numbers among IRB staff.[11] Because this certification was created recently (in 1999), this could account for some of its popularity. The IRB community views this certification as way to demonstrate experience as well as professionalism.[11] Other types of certification that IRB personnel can obtain are: Certified IRB Manager (CIM), Certified Clinical Research Professional (CCRP), Certification as a Clinical Research Coordinator (CCRC), and Certification as a Clinical Research Associate (CCRA). (See Figure 8.) These certifications are obtained by completing and passing a written exam after accruing related work experience prior to taking the exam. Several organizations provide training for these exams. Each certification reflects a sub-specialty in the field of clinical research, which includes IRB professionals.

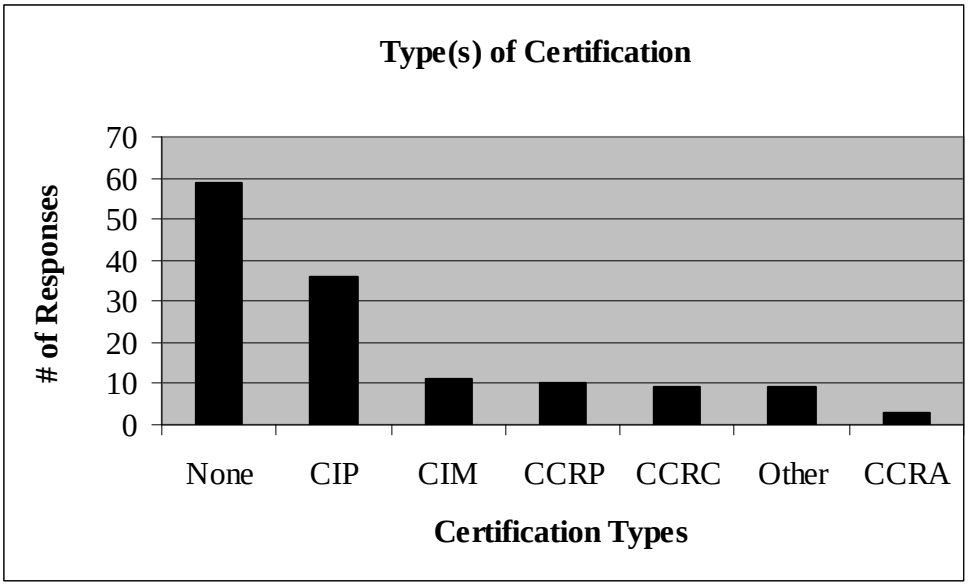

Figure 8. Types of Certifications Held by IRB Staff Members, *N* = 121. Key: CIP = Certified IRB Professional, CIM = Certified IRB Manager, CCRP = Certified Clinical Research

Professional, CCRC = Certified Clinical Research Coordinator, and CCRA = Certified Clinical Research Associate. Certified IRB Professional (CIP) was the most common certification.

Interestingly, over 50% of the employees surveyed have no certification at all. This could reflect a high number of clerical positions or professionals who have yet to take the exam. What this means to the quality of the reviews by the various institutions has yet to be determined.

Educational Background

The education of IRB staff members can have a large impact on the daily operations of an IRB office. This survey produced distinct findings regarding IRB staff members' education and academic majors. Most of the IRB employees in this study (52%) held at least a Bachelor's Degree.

Notably, 16.4% of the subjects had only high school diploma or "some college" experience. Again, this could be problematic when aiming to have high quality, informed employees working with complex human subject protocols.

A deeper investigation into the fields of study of these subjects produces unique patterns among majors. For example, employees with Bachelor's Degrees were most likely to have degrees in Math and Science (Figure 9).

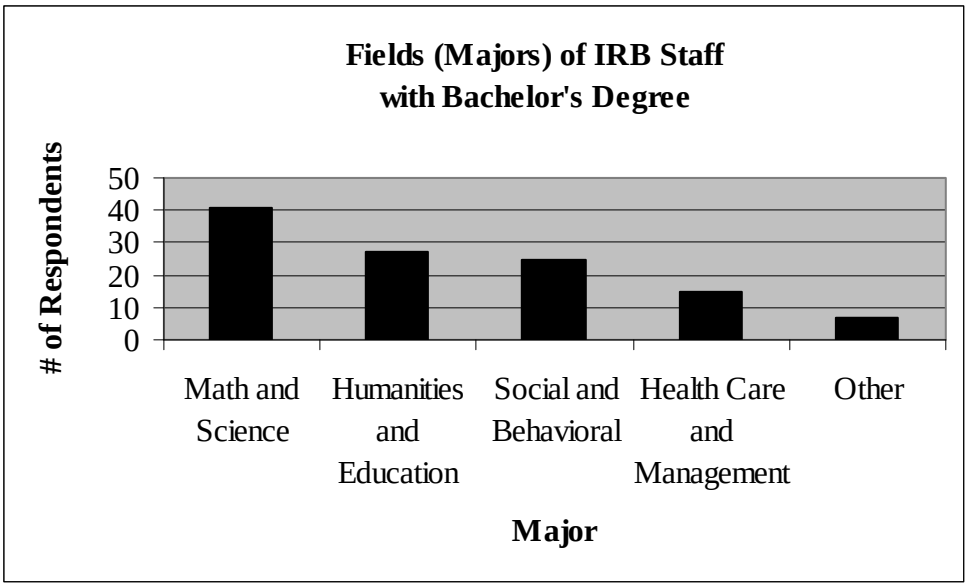

Figure 9. Fields (Majors) of IRB Staff with Bachelor's Degrees, *N* = 106. Math and Science majors include Nursing, Public Health, and Science (Biology, Chemistry, and Physics) degrees. Humanities and Education majors include Art, Education, English, Humanities, and Journalism degrees. Social and Behavioral majors include Anthropology, Criminal Justice/Law, Psychology and Social Science, and Public Administration degrees. Health Care and Management include majors in Business, Human Services in addition to Health Care and Management degrees.

When examining Master's Degrees, however, the primary major shifted from degrees in Math and Science (22.2%) to Social and Behavioral Sciences degrees (29.6%). Figure 10 shows the majors of IRB staff members with Master's degrees.

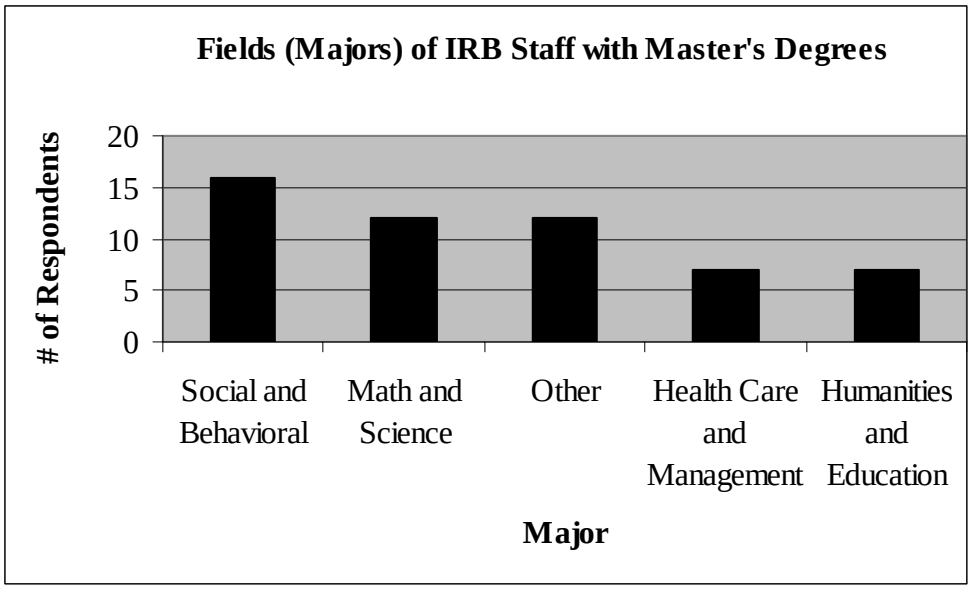

Figure 10. Fields (Majors) of IRB Staff with Master's Degrees, *N* = 46. Social and Behavioral majors include Psychology, Sociology, and Public Administration Degrees. Math and Science majors include Nursing, Public Health, and Science (Biology, Chemistry, Physics, etc.) degrees. "Others" include degrees in Theology, Dental Hygiene, and Elementary School Guidance Counselors, among others. Health Care and Management include Business as well as Health Care and Management Degrees.

Doctoral Degrees displayed an equal representation of Math and Science majors (Biology, Chemistry, Medical Doctor, etc.), as well as Doctorates in Social/Behavioral Science (Psychology, Jurisprudence/Criminal Justice, etc.), *N* = 12.

Work Experience

In addition to education, many other factors factor into the "quality" of an IRB staff member. Time spent working as an IRB Staff Person (Figure 11), the number of IRBs worked with throughout one's entire career (Figure 12), and the length of time an employee stays at the same

IRB job with the current employer (Figure 13) may make a difference in the efficiency of the IRB office.

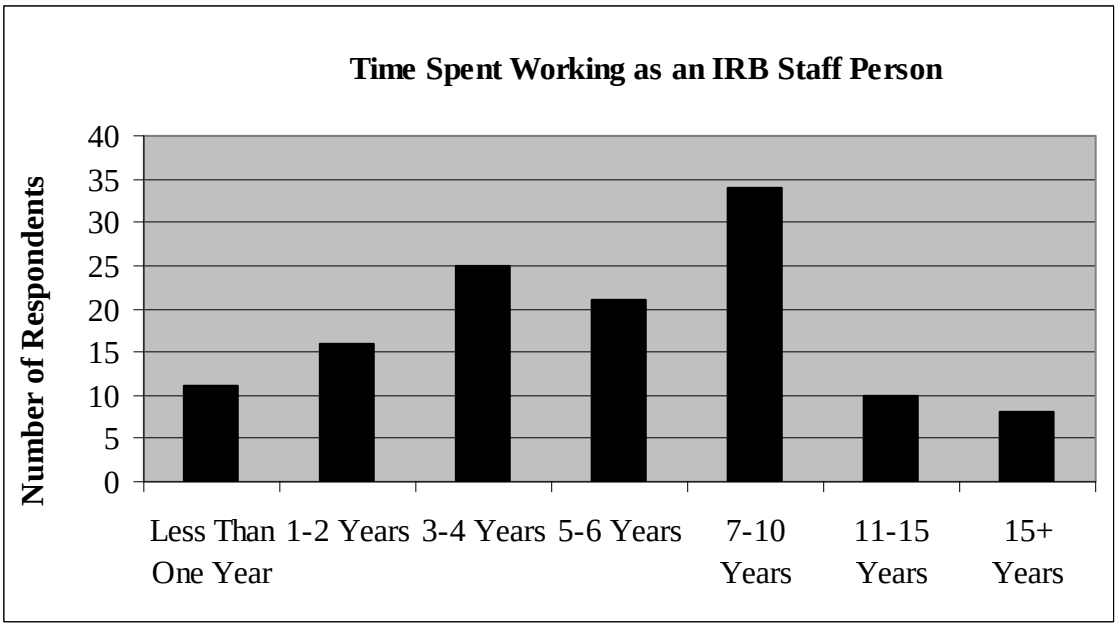

Figure 11. Time Spent Working as an IRB Staff Person, *N* = 125. Most employees (27.20%) spent 7-10 years working as an IRB staff person. For purposes of this survey, an "IRB Staff Person" includes IRB Chairs, *N* = 2. Median Value = 5-6 Years.

The number of IRBs in which the employees had worked throughout their entire careers as a staff person is shown in Figure 12. The respondents who selected "zero" were individuals such as Program Managers and Research Compliance Officers who deal with the structuring of office personnel and protocols, rather than those working directly with specific IRBs.

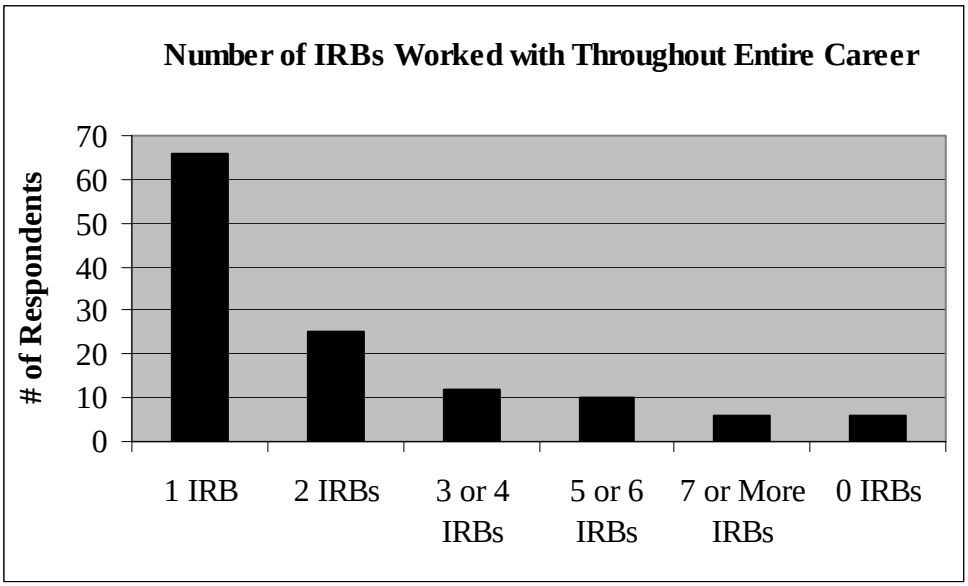

Figure 12. Number of IRBs Worked with Throughout Entire Career, *N* = 125. Most IRB employees (52.80%) reported working with only one IRB. Employees who selected "Zero IRBs" were individuals such as Program Managers and Research Compliance Officers who deal with the structuring of personnel and protocols, rather than specific IRBs.

The amount of time (in years) an IRB employee has spent at the same IRB position is represented in Figure 13.

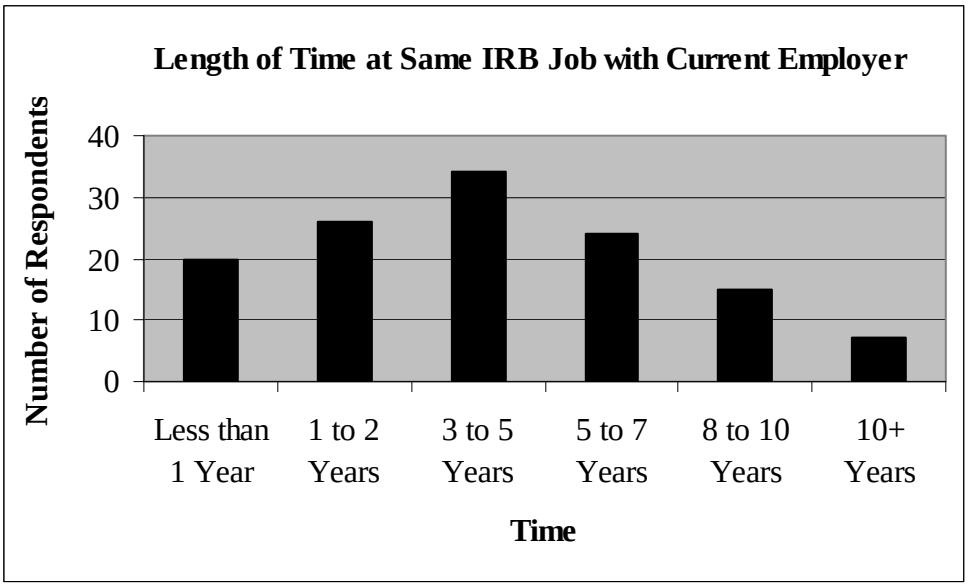

Figure 13. Length of Time at Same IRB Job with Current Employer, *N* = 126. Most IRB employees (26.98%) reported being at the same job for 3 or more years. On the other hand, nearly 63% of these employees have been with their current employer for less than five years. [Median = 3-5 Years.]

The first IRBs were formed in the 1970s to provide human subject research participants with protection.[6] At first, they were primarily staffed with clerical employees. While this seemed acceptable at the time, it was soon discovered that these untrained, inexperienced staff members were unable to handle the heavy workloads.[6] While the workloads increased, so did the level of regulatory scrutiny of IRBs.[6] Consequentially, these factors played a huge role in the hiring of additional staff members.

It has been stated that, over the years, IRB office/systems have increased the number of staff employed, but these individuals are often low paid and inexperienced which can lead to problems with efficiency and regulatory compliance.[6] Another problem is created when

experienced (but underpaid or even inexperienced) staff members leave their institutions and are replaced with another inexperienced or untrained employee.[6]

Adequate staffing is a necessity and a federal requirement.[2] Without it, the efficiency with which an IRB operates is compromised. Understaffed IRB offices create an environment where an increasing load of paperwork places an extra burden on the IRB office staff.[12] When the staff focuses their efforts and time on heavy paperwork loads, the office often loses sight of its primary goal: the safety and welfare of human subjects.

The number of new, full-board studies reviewed by an institution per year can determine many factors in the IRB workplace such as turn-around time of protocols (volume), job satisfaction of employees (demand/pressure), and satisfaction of investigators (timely review). Approximately 25% of the respondents of this study reviewed an average of 201-400 protocols per year. UNTHSC reviews approximately 130 protocols per year (in fiscal year 2008-2009).

Depending on how many employees each institution has, a staff-to-protocol ratio can be critical to the office's response time. The average full-board review approval time at these institutions was 30-60 days (Figure 14).

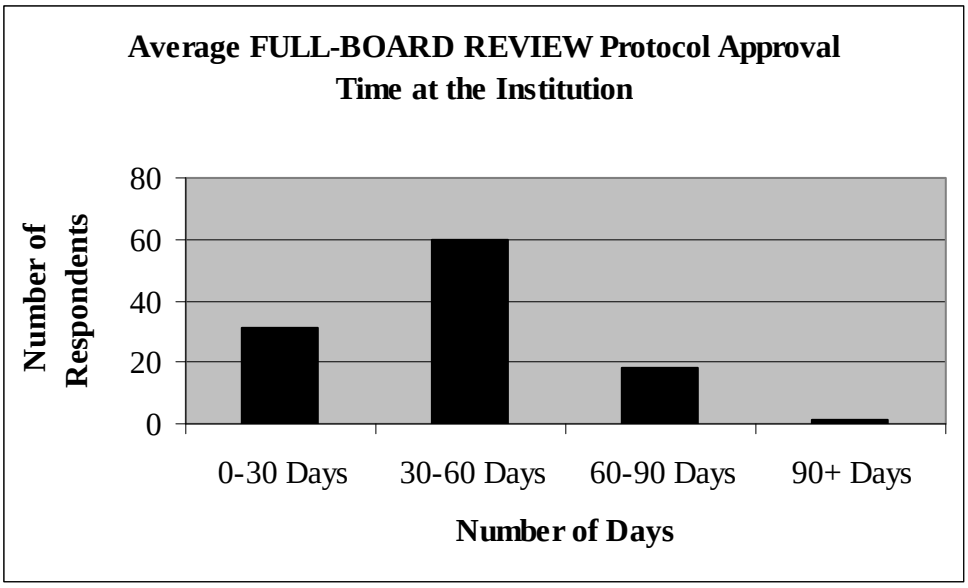

Figure 14. The Average Full-Board Review Protocol Approval Time at the institution, *N* = 110. Over 50% of respondents reported taking 30 or more days for approval. Median Value = 30-60 Days.

Staff Background

The majority of IRB staff members bring an assortment of non- IRB related experience to their current job. Many of these employees have worked as grant or contract personnel while others have been involved in business or research administration. Additionally, some staff have medical experience, having worked as a nurse, clinical research coordinator, or a pharmaceutical sales representative.

Clerical experience (32.79%) was reported as the most common non-IRB related experience brought to the IRB office. This is interesting to note in an environment where the requirement of the knowledge of the federal regulations must be accurately applied to research protocols involving human subjects. It is reassuring, however, to see that nearly as much clinical research

coordinator (CRC) experience (31.15%) has been received, as being a CRC involves knowing much of such regulations.

The training an IRB staff receives often comes from a variety of sources. Attending conferences and taking human subject protection courses and continuing education courses often account for much of an IRB employee's training. Most important, "on the job" experience frequently provides the majority of a staff member's knowledge base. In fact, team-based learning has been applied to medical ethics education and has shown to increase a student's engagement and satisfaction with the material.[13]

Research education cannot be viewed as a one-time learning process.[14] Attending conferences, reading current IRB literature, and following the ever-changing federal regulations will help an IRB staff member stay well-informed. IRB employees need recurrent awareness of updates in able to be competent staff.[14]

Most of the respondents (99.2%) cited "on the job" experience as being a source used in training for their IRB job, $N = 123$. The vast majority of respondents stated that they have obtained up to or more than 75% of their skill set "on the job," $N = 122$.

Staff Competence (Qualitative)

There is some controversy regarding the characteristics of a competent IRB staff. Some of the traits most often cited as being required by IRB staff members are: good oral and written communication skills, the ability to interact with people from diverse backgrounds, the management of high work volumes, and the ability to learn regulatory, ethical, and scientific information.[2]

The subjects of this study were asked about the primary skills, qualities, education, and experience that helped them with their current IRB position. "On the Job" experience showed to

be the most helpful, with "Attention to Details" being the next most helpful. Both written communication skills and the ability to multitask were seen as important to contributing to the success of the employee's position. "On the job" experience was reported as being the most helpful (70%), $N = 123$.

An employee's satisfaction with his job is a direct link to his retention at that position. Many positive aspects of working with an IRB were expressed in this survey; however, none of them stands out more clearly than that of having "meaningful work." Other respondents enjoyed the challenge of the job, while having a flexible schedule was also seen as a benefit. Meaningful work was reported by over 30% of the respondents, more than any other aspect, $N = 117$.

By far, this study shows that most IRB employees are still at their job because they state that they enjoy this line of work. Stability of the position also plays an important role in this decision. Interestingly, salary and benefits do not rank high on this list. Enjoying the line of work and job stability were the top two responses.

The findings from this survey show that the majority of the subjects (63.8%) found client (investigator-staff) interactions to be smooth and effective. Investigator/Staff interactions are often a "hot topic" of discussion. Jeffrey Cohen, Ph.D., CIP states that both skill and tact are required when working efficiently with an investigator.[3] Communicating with researchers requires the ability to communicate effectively, without damaging the investigator's trust. When this trust is broken, the critical investigator/staff relationship (and the protection of human subjects in research) is in jeopardy. This can lead to faculty attacks on academic IRBs, attacks which are not uncommon.[6] Researchers often get frustrated while interacting with IRB office staff, often because the investigators are being asked to make changes to their protocols in order

to be in compliance with federal regulations. Also, investigators often want a fast turn-around time (not always possible, especially if one is taking the time to properly evaluate a protocol).

Viewing the IRB process as a help, not an obstacle, to research has been the focus of many discussions regarding IRB-Investigator interactions.[12] "Investigators and research staff often take a sour view of the IRB process, thinking of it as a burdensome hurdle on the path to starting a clinical trial." [12] Studies have shown that researchers are concerned about the quality of their IRB reviews.[15] This way of thinking must change in order to maximize the effective communication needed for the proper protection of human research subjects. This might be accomplished by providing educational compliance workshops to the investigators. Dawn Dowling, BS, CIP, states that ideally, IRB staff will be trained in order to work effectively with investigators and any problems that may arise regarding their application.[12] This training will facilitate the interactions between the investigator and staff and will hopefully ease any of the investigators fears regarding the approval of his research. Indeed, many institutions are beginning to offer "education and outreach" services to train new investigators. Because of this, the human subjects involved in the research will likely be better protected. "Both principal investigators and IRBs have research participants' best interests at heart, but they're just looking at it from different angles" says Ann Johnson, IRB Administrator at the University of Utah in Salt Lake City.[16]

The majority of the subjects (63.8%) reported smooth and effective communications with the investigators, $N = 116$. Some respondents expressed concern regarding the frustrations associated with poor submissions. Sometimes, as one respondent noted, this was a result of investigators not having English as their primary language.

On another aspect of staff development, the search for the fundamental reasons as to "how" and "why" IRB staff became involved in their positions was one of discovery. The respondents described their answers to these subjective questions, and the "like" responses were grouped together.

When discussing "why" one chooses a position working with an IRB, certain groupings of reasons developed. A summary of these findings can be found in Figure 15. (Specific responses can be found in Appendix B.) Groupings for this test were as follows: motivational, career-minded, practical, and "did not pursue"/other.

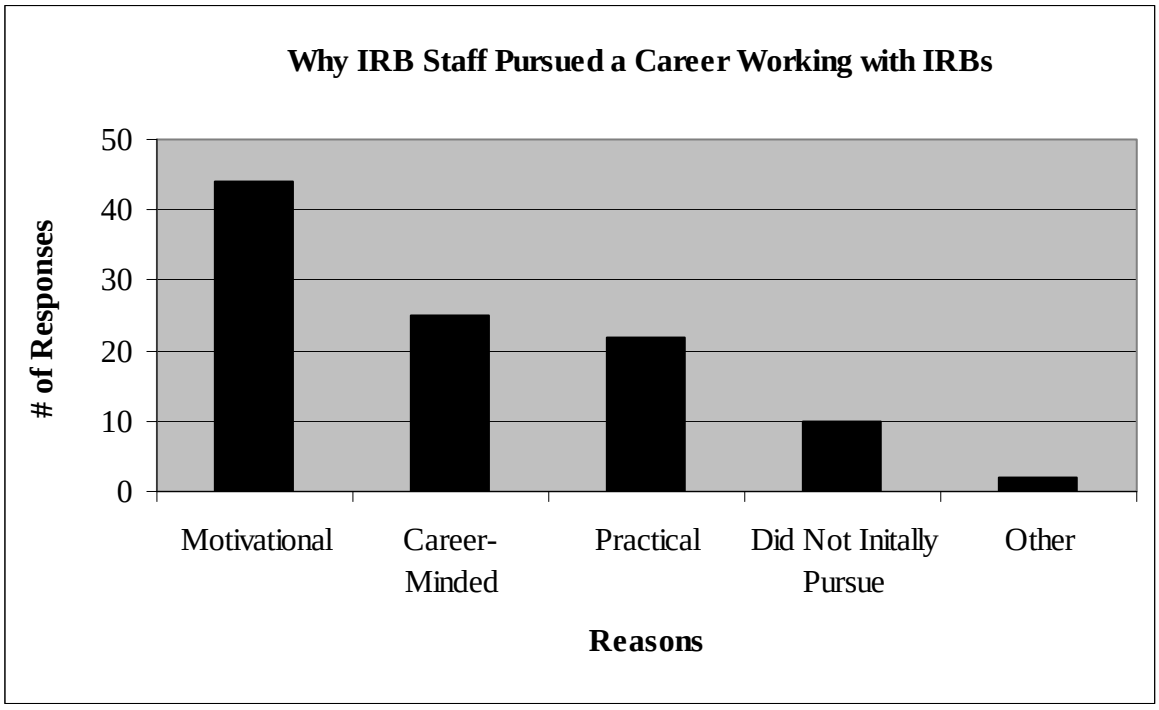

Figure 15. Why IRB Staff Pursued a Career Working with IRBs, N = 103. Reasons as to why IRB staff pursued a career working with IRBs are grouped according to responses written in by subjects. Individual responses are categorized as follows and can be found in Appendix B: Motivational (Importance/Impact of Job, Find Job Interesting, Wanted Change, Find Job Rewarding, and Interested in Research), Career-Minded (Advancement, Good Opportunity, Had

Good Background, and Like Regulations), and Practical (Wanted Job, Temporary Employee, Request/Referral from Friend).

The fact that a job working with an IRB appeared "interesting" was the primary contributing factor determining "why" one pursued such a career (18.45%). Others found advancement to be the reason (10.68%). It is interesting to note that many of the subjects simply "wanted a job" (11.65%). Others simply "did not initially pursue" (9.71%) a job working with the IRB. These subjects include individuals who were given positions as others retired as well as those who were looking for "any interesting position."

On the other side, is the question regarding "how" an individual becomes involved with IRBs. These responses, too, were varied and grouped according to likeness and can be found in Figure 16. "Background and skills" are the primary reason the subjects were able to obtain their jobs. (See Appendix C for a complete listing of subjects' responses.)

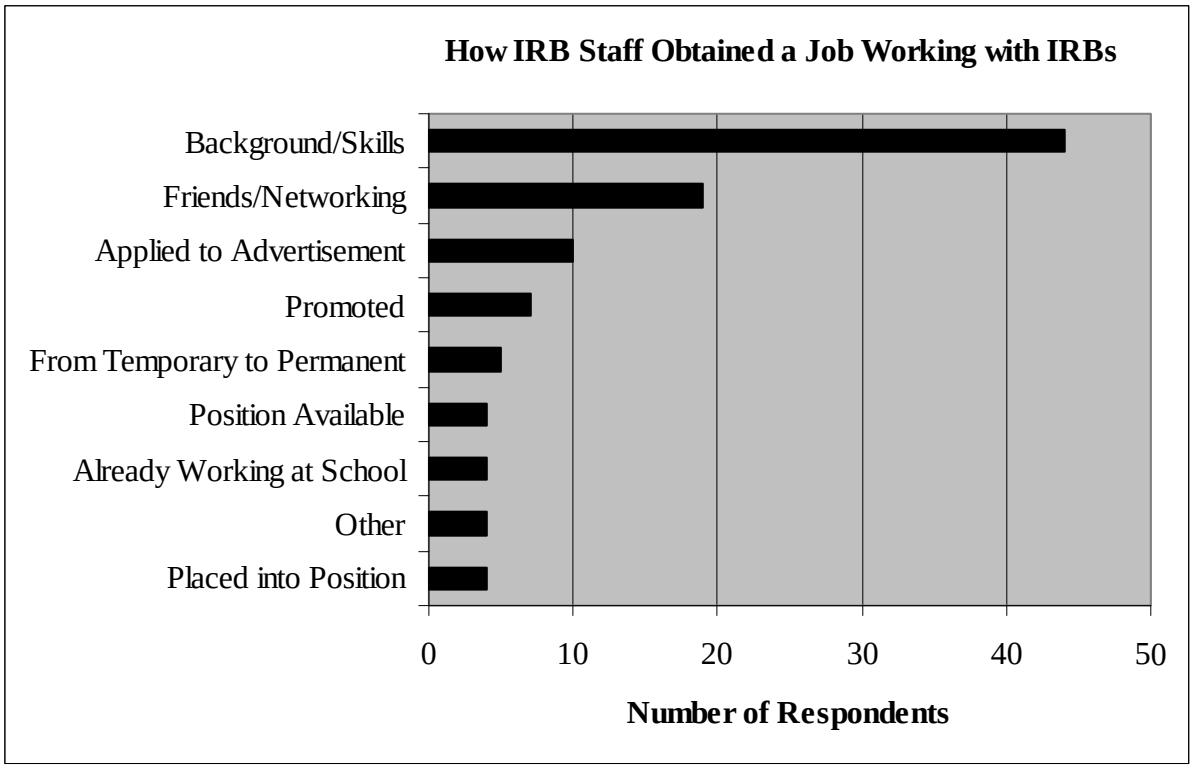

Figure 16. How IRB Staff Obtained a Job Working with IRBs, $N = 101$. Reasons as to how IRB staff obtained a job working with IRBs are grouped according to responses written in by subjects. Individual responses and groupings can be found in Appendix C. Most employees attribute gaining an IRB position to their background and skills (43.56%).

Finally, this project also asked subjective information about a third topic: how has working with an IRB changed them as individuals? Again, the replies to this question were grouped according to similar traits and recorded (Figure 17). Appendix D has a complete listing of the subjects' responses.

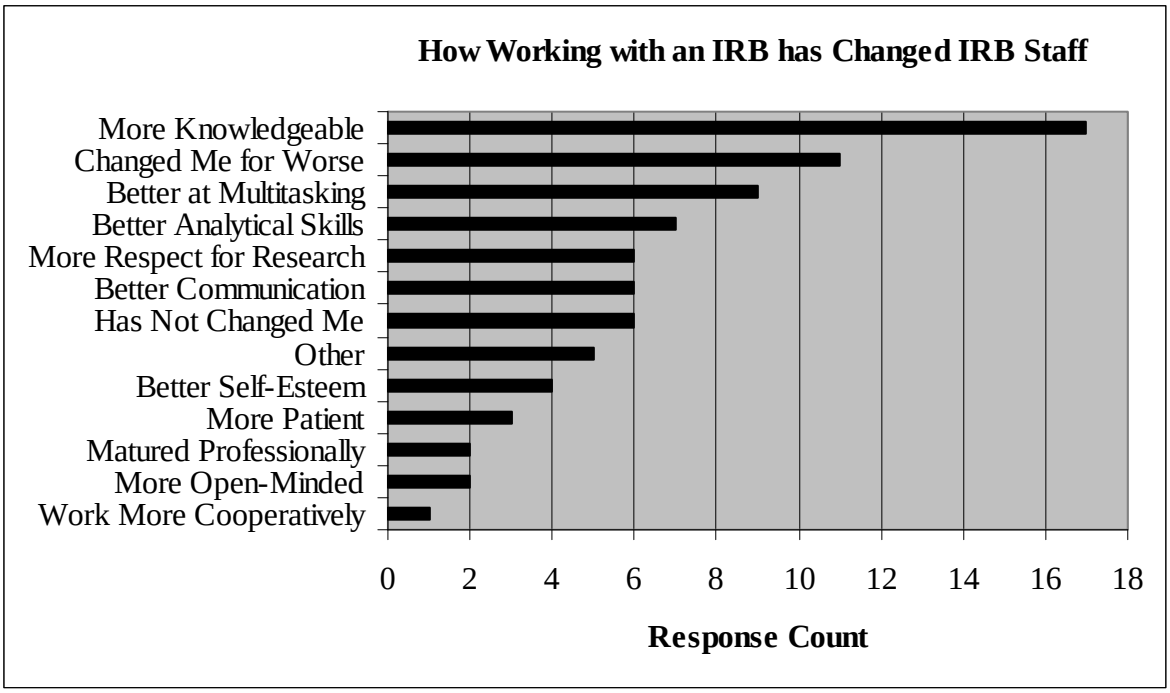

Figure 17. How Working With an IRB has Changed IRB Staff, *N* = 79. Changes that IRB staff have experienced as a result of working with IRBs were grouped according to responses written in by subjects. Individual responses can be found in Appendix D. Over 20% of respondents feel they have become more knowledgeable as a result of working with an IRB while over 13% say it's changed them for the worst.

Many employees view themselves as more knowledgeable as a result of their experience working with IRBs (21.52%). Of the subjects who responded with positive changes, 48% of them were non-managerial, 29% were managerial, and 22% were support staff. It is a bit disconcerting, however, to find that nearly 14% of the subjects feel that working for an IRB has changed them for the worse. Such negative reactions included: not sleeping well at night, becoming more cynical, becoming more hesitant to participate in research studies, and eating more chocolate and drinking more alcohol. Of the 11 subjects who responded with "Changed

Me for the Worse," 6 subjects were Managerial Office Personnel and 5 subjects were Non-Managerial Office Personnel. They were from Highly-Funded Medical Schools (46%), Middle-Funded Medical Schools (27%), and Low-Funded Medical Schools (27%). A future direction of this study might be to examine individual personality differences among these subjects.

Analysis of Medical School Funding

First, a chi-square test suggests there is a relationship between amount of medical school funding and highest degree obtained by IRB staff: X^2 (4, N = 114) = 12.5, p < .05 (Table 1). Tier Three medicals schools have more IRB staff with high school diplomas as the highest level of education obtained than expected. Surprisingly, more funding does not necessarily mean having more employees with advanced degrees (raw score = 25, z = .18) nor did low funding correlate to fewer advanced degrees (raw score = 13, z = .47), suggesting that post-graduate degrees does not offer "value-added" for work within an IRB office.

Table 1: Highest Level of Education Obtained

	Tier One (High Funding)	**Tier Two (Middle Funding)**	**Tier Three (Low Funding)**
High School	6	4	9 [a]
Bachelor's Degree	24	17	4
Master's/PhD	25	12	13

[a] The significant difference lies in the number of high school degrees (as being the highest level of education) obtained by Tier Three medical schools, z = 2.27.

Second, the chi-square test of independence determined that there is, not unexpectedly, a significant difference between the number of full-time IRB employees and the amount of medical school funding; X^2 (2, N = 114) = 44.4, p < .05 (Table 2).

Table 2: The number of Full-Time IRB Employees in an IRB Office

	Tier One (High Funding)	**Tier Two (Middle Funding)**	**Tier Three (Low Funding)**
1-10 Employees	8 [a]	15	24 [b]
11+ Employees	47 [c]	18	2 [d]

[a] Tier One medical schools had fewer "low number" of employees (1-10 employees) than expected, z = -3.12.

[b] Tier Three medical schools had more "low number" of employees (1-10 employees) than expected, z = 3.27.

[c] Tier One medical schools had more "high number" of employees (11+employees) than expected, z = 2.59.

[d] Tier Three medical schools had fewer "high number" of employees (11+) than expected, z = -3.4.

Third, as one might expect, there is a significant difference between the number of full-board protocols reviewed and the amount of medical school funding. [X^2 (2, N = 103) = 24.0, p <.05, as suggested by a chi-square test of independence (Table 3).

Table 3: Number of Full-Board Protocols Reviewed

	Tier One (High Funding)	**Tier Two (Middle Funding)**	**Tier Three (Low Funding)**
0-400 Protocols	15 [a]	18	23 [b]
400+ Protocols	32 [c]	13	2 [d]

[a] Tier One medical schools had fewer "low number" of protocols (0-400 protocols) than expected, z = -2.09.

[b] Tier Three schools had more "low number" of protocols (0-400 protocols) than expected, z = 2.54.

[c] Tier One medical schools had more "high number" of protocols (400+ protocols) reviewed than expected, z = 2.3.

[d] Tier Three schools had fewer "high number" of protocols (400+ protocols) than expected, z = - 2.79.

No statistical significance was found between the amount of medical school funding and the following: certification, academic category of major, time spent working as an IRB person, number of IRBs worked with, time spent at same IRB position, approval time, *WHY* an IRB career was pursued, *HOW* IRB staff became involved with IRBs, and how IRB job changed employee.

Summary and Conclusions

Significant difference was found between amount of NIH funding and the following: the highest degree obtained by IRB staff members, the number full-time employees at an IRB office,

and the number of protocols reviewed. Table 4 presents the composite IRB staffer according to funding.

Table 4: Composite IRB Staffer According to Funding

	Tier One Medical Schools (High Funding)	**Tier Two Medical Schools (Middle Funding)**	**Tier Three Medical Schools (Low Funding)**
Highest Degree Obtained	Bachelor's Degree	Bachelor's Degree	Master's Degree
# of Full-Time IRB Employees	21+ Employees	11-20 Employees	3-5 Employees
# Full Board Studies Reviewed Per Year	1001-3000 Studies	Tie: 101-200 and 201-400 Studies	201-400 Studies

Respondents primarily held non-managerial positions, did not have professional certification, and used "on the job" experience in training for their IRB position. Specifically:

- Subjects with a Bachelor's Degree majored mostly in sciences such as biology, physics, and chemistry and math while those with Master's Degrees majored primarily in behavioral or social science. Doctoral recipients were mostly law or science majors.
- Approximately fifty-three percent of the individuals reported working with only one IRB throughout their entire career.

- The average full-board review protocol approval time was 30-60 days.
- Previous non-IRB related experience was mostly corporate experience (clerical and business).
- Respondents indicated that they were *still* at an IRB job primarily because they enjoyed the line of work (39.0%) and had stability at their current job (33.9%).
- The question asking "Why a career working with an IRB was pursued" resulted in two polar results: 18.4% indicated that they found the career to be interesting while another 11.7% indicated that they simply wanted a job. When determining "quality" of IRB professionals, the fact that one group had a genuine interest in the career while the other group only wanted a job seems to present a challenge. Do the employees who ended up at their current position by happenstance perform any better than those who found it to be interesting? These are interesting questions that should be further investigated.
- Many subjects (43.56%) stated that the reason regarding "How they were able to obtain a position working with an IRB "was because of background, skills, and experience. This is particularly reassuring, considering the demanding skills required to become and effective IRB staff member.
- Lastly, when asked how working with an IRB has changed the staff, 21.5% of respondents indicated that they became more knowledgeable. When one combines this percentage with that of those who responded indicating that their abilities to multitask, communicate, and analyze became better, this comprises an astonishing 49.4%. Because these traits are viewed as "positive" in terms of working with IRBs, this is encouraging news. Surprisingly, though, 13.9 % of people stated that working with the IRB had changed them for the worse. The fact that these employees continue to remain

Conclusion: Results suggest there is a difference between amount of NIH funding and the highest degree obtained by IRB staff members. There also appears to be a significant difference between amount of funding and the number of protocols reviewed as well as the number full-time employees at an IRB office.

Future studies might investigate personality differences among IRB staff members. In addition, hospital IRBs and commercial IRBs can be examined. The reasons as to "why" and "how" these IRB staff members are in their current position may vary greatly compared to medical school IRBs. This could be due to a variety of factors including motivation, pay, job satisfaction, working with more physicians (at hospitals), and working with more businessmen (with commercial IRBs). Future studies of this type will, undoubtedly, provide new insight as to "who" these IRB staff members really are.

CHAPTER III

INTERNSHIP EXPERIENCE

Internship Site Activities

My internship site was located at the University of North Texas Health Science Center (UNTHSC) in Fort Worth, Texas. I worked at the Office for the Protection of Human Subjects (OPHS), which, in turn, works directly with the Institutional Review Board (IRB), the group responsible for maintaining the safety and protecting the rights of human subject research participants. Being an intern at the OPHS has provided me with valuable experience related to the functioning of the IRB. At UNTHSC, the OPHS/IRB reviews both biomedical and behavioral research protocols and evaluates the potential risk to subjects; therefore, I was exposed to a variety of research protocols including cell biology, genetics, psychiatry, public health, community medicine, pathology, and osteopathic manipulative medicine. At UNTHSC, the OPHS consults with investigators regarding federal, state, and local regulations and assists them with numerous aspects of their research including the development of protocols and consent forms. I learned about these regulations governing ethical research as described in the Belmont Report[17], Nuremberg code,[18] federal regulations (45 CFR part 46 as well as 21 CFR parts 50 and 56 for the Food and Drug Administration), and the Declaration of Helsinki.[19]

The staff at the UNTHSC's OPHS consists of six individuals: the director of the OPHS and Chair of the IRB (PhD), one senior human research protection coordinator, three human research protection coordinators (specializing in various types of research), and an administrative services officer. Three of these individuals are CIP (certified IRB professional) certified, and three of them have Master's Degrees. During my internship, most of my training was "on the job" training.

At UNTHSC, investigators submit their protocols, and then the human subject protection coordinators review their application to check for content and completeness. Once the application has been categorized properly (exempt, expedited, or full-board), the file goes to the IRB Chair or IRB for further evaluation. During my experience as an intern, the OPHS staff and human research protection coordinators asked for assistance with many of these duties. Such activities included the editing and pre-reviewing of serious adverse event reports (for both on-site and off-site studies), the filing and organization of such reports, and the documentation and processing of office files. In addition, I became familiar with the various protocol review categories and conducted some exempt category reviews. Part of my experience as an intern with the OPHS included attending the monthly IRB meetings. Prior to the monthly IRB meetings, I attended the OPHS staff meetings and was involved with reviewing all related documents regarding the processing of an IRB meeting. Such documents included the pre-review notes and the Chair's Report. The Chair's Report is a summary including new projects and full-board amendments that have received final IRB approval, amendments/modifications to previously approved projects, and the reporting of serious adverse events and protocol violations and deviations. In addition, the expedited continuing review of protocols, the expedited review of

new protocols, and the expedited review of amendments to approved projects, and the review of new IRB projects (exempt category), and new protocols deferred for IRB review are reported.

Attending the IRB meetings enabled me to gain valuable insight to the organization, structure, and workings of these meetings. I observed the review and discussion of continuing reviews and final reports, the full-board review of protocol amendments as well as the full-board review of new protocols. Both significant and technical findings were discussed as well as any conflicts of interest. Most importantly, the risk level of protocols was assessed. As a result, I obtained a deeper understanding regarding the procedures and policies involved in making ethical decisions regarding research approval.

Because the IRB reviews human subject research protocols, I became familiar with the various components of research protocols and developed a deeper understanding of what constitutes a well-written protocol synopsis, consent form, and phone script. I also learned about the use of multiple forms including the full-board IRB protocol application (new projects) review form, the exempt review application, the expedited review application, and the progress report form.

In addition to working alongside the OPHS staff, I was also responsible for completing two IRB-related projects. The first project was the production of annual reports for the past three fiscal years, grouped according to school. Schools included the Texas College of Osteopathic Medicine (TCOM), the Graduate School of Biomedical Sciences (GSBS), the School of Public Health (SPH), the School of Health Professions (SHP), and the Health Institute of Texas (HIT). Each school was then subdivided into its departments. In order to create these reports, I read through the IRB meeting minutes for each of the last three fiscal years and recorded all IRB-related activity. The number of new, expedited, and exempt category protocols was recorded as

well as the number of continuing reviews for all of the research categories. Serious adverse events, protocol violations and deviations, deferrals, and final reports were also noted. Additionally, I calculated the total protocol actions for each department and then determined the total number of all Board actions (protocol actions and serious adverse events) for each department. Once I obtained these numbers, I created an OPHS Annual Report spreadsheet which contains all of the above-mentioned categories. Each Excel workbook has thirteen worksheets: twelve for each of the months in the fiscal year (from September to August) as well as a "Summary" worksheet in which total counts for all of the months have been calculated. Workbooks for the fiscal years of 2006-07, 2007-08, and 2008-09 were created.

I also developed an OPHS Annual Report Template for future use by the OPHS for easy tracking of IRB-related activity. As well as becoming proficient in creating Excel spreadsheets, I also obtained knowledge regarding the creation of graphs in Excel. For the "Annual Report Summary," I developed numerous charts and graphs depicting the changes over the last three fiscal years. Included, too, were graphs displaying the activity of the various schools at UNTHSC.

My second project at the OPHS was the development of a measure or "metric" of how the office had performed over the last fiscal year (2008-09) regarding "turn around" time (time from investigator's submission to the OPHS' response). To begin this project, I looked through individual files and recorded the category of research and date submitted. For exempt and expedited category projects, I noted the date of the OPHS' response to the investigator, the investigator's response date, and the final approval date. I also recorded the department, investigator's name, and whether or not it was a student project. Then I calculated the response times for the OPHS and investigator. For full board projects, I recorded the IRB's meeting date

and the date of Board Action. Finally, I calculated the total time from the first IRB meeting to final Board approval. I then developed summary tables for the exempt, expedited, and full-board category projects which indicated the average response time for the OPHS and the investigator as well as the total time from initial submission to approval. While working on this project, I gained experience and familiarity with the OPHS database by using it to cross reference findings from the individual protocol files.

Working in the OPHS has also supplied me with a broad set of skills that will further my clinical research management career with an emphasis on human subject research education. In addition, my critical thinking, writing, and problem-solving skills have been enhanced as a result of this internship experience. This is a great job because it allows employees to use their skill set to help individuals participating in research.

Journal Summary

The daily diary chronicles my day-to-day activities while working in the OPHS as an intern. Everything from making copies, to filing, to editing incoming protocols and attending the IRB meetings was recorded. The daily diary accounts for my time while working at the OPHS, and it reflects my increasing responsibilities as an intern. The journal can be found in Appendix E.

APPENDIX A

IRB STAFF STATUS QUESTIONNAIRE

IRB Staff Status Questionnaire

1. What title describes your job? (choose all that apply)

IRB Administrative Assistant
IRB Administrator
IRB Director
IRB Program Manager
IRB Review Analyst
IRB Review Coordinator/Specialist
Compliance Coordinator
Education Specialist
Expedited/Exempt Team Member
Full Board Team Member
Support Staff
Other (please specify)

2. What is your highest level of education?

High School/Some College
Bachelor's Degree
Master's Degree
Doctoral Degree

3. If you have a Bachelor's Degree, in what field (major) is your degree?

Art/Humanities
Business
Criminal Justice/Law
Education
Engineering
English/Journalism/Communication
Health Care
Health Care Management
Human Services
IT/Computer Science
Nursing
Psychology/Social Science
Public Administration
Public Health
Science (Biology, Chemistry, Physics, etc.)
Not Applicable
Other (please specify)

4. If you have a Master's Degree, in what field (major) is your degree?

Art/Humanities
Business
Criminal Justice/Law
Education
Engineering
English/Journalism/Communication
Health Care
Health Care Management
Human Services
IT/Computer Science
Nursing
Psychology/Social Science
Public Administration
Public Health
Science (Biology, Chemistry, Physics, etc.)
Not Applicable
Other (please specify)

5. If you have a Doctoral Degree, in what field (major) is your degree?

Art/Humanities
Business
Criminal Justice/Law
Education
Engineering
English/Journalism/Communication
Health Care
Health Care Management
Human Services
IT/Computer Science
Nursing
Psychology/Social Science
Public Administration
Public Health
Science (Biology, Chemistry, Physics, etc.)
Not Applicable
Other (please specify)

6. Throughout your entire career, HOW MUCH TIME have you spent working with IRBs as a STAFF person?

Less than one year, 1-2 years, 3-4 years, 5-6 years, 7-10 years, 11-15 years, 15+ years

7. As a STAFF person, HOW MANY IRBs have you worked with throughout your entire career?

0
1
2
3-4
5-6
7+

8. How long have you been in this same IRB job with your current employer?

less than 1 year
1-2 years
3-5 years
5-7 years
8-10 years
10+ years

9. What type of previous non-IRB experience or expertise did you bring to your job in the IRB office? (choose all that apply)

Animal Care
Business Administration/Accounting
Clerical
Clinical Research Coordinator
Grant/Contract Personnel
Laboratory (Assistant, Technician, etc.)
Marketing
Nurse/Medical
Pharmaceutical Sales
Other (please specify)

10. Which of the following have you used IN TRAINING for your IRB job? (choose all that apply)

"On the Job" experiences
Attending Conferences
Taking Courses and/or Continuing Education Classes
Reading Literature
Other (please specify)

11. Approximately what percentage of your skill set was obtained "On the Job?"

Little/None
Up to 25%
Up to 50%
Up to 75%
More than 75%

12. What has HELPED you the most with your current IRB job? (pick top 3)

Education
"On the Job" Training/Experience
Attention to Details
Ability to Multitask
Ability to handle heavy work loads
Loyalty/Commitment
Verbal Communication Skills
Written Communication Skills
Other (please specify)

13. What type(s) of certification do you have? (check all that apply)

Certified IRB Professional (CIP)
IRB Manager (CIM)
Certified Clinical Research Professional (CCRP)
Certification as a Clinical Research Coordinator (CCRC)
Certification as a Clinical Research ASsociate (CCRA)
None
Other (please specify)

14. Remembering back to your first IRB job ever...please describe WHY you pursued a career working with IRBs.

15. Remembering back to your first IRB job ever...please describe HOW you were able to obtain a job working with IRBs.

16. Which describes client (investigator-staff) interactions at your office? (choose all that apply)

Smooth and effective communications
Often experience delays
Constant challenge to keep everyone "in the loop"
Frustrations on both sides
Other (please specify)

17. What aspect of your current position provides you with the MOST satisfaction? (choose best answer)

Salary
Benefits
Meaningful Work
Hours/Work Schedule Flexible
Job Security
Challenge of the Work
Other (please specify)

18. Because there are many possible jobs for someone with your skill set, and you could choose any one of them, which of the following describes why you are still at this IRB job? (choose all that apply)

Enjoy the line of work
Stability at current job
Salary/Benefits
Other (please specify)

19. How many full-time IRB employees are in the IRB office where you work?

0
1-2
3-5
6-10
11-20
21+

20. What type of research does your institution review?

Biomedical
Behavioral/Social
Both biomedical and behavioral/social

21. What is the average FULL-BOARD REVIEW protocol approval time (from time investigator submits protocol until they receive official approval) at your institution?

0-30 days
30-60 days
60-90 days
90+ days

22. Approximately how many NEW, FULL-BOARD studies are reviewed by your institution per year?

0-50
51-100
101-200
201-400
401-600
601-1000
1001-3000
3000+

23. How has having a job working with an IRB changed you?

24. The following three groups of medical schools are categorized based on NIH funding. Please select the group which best describes your institution.

Group A (Tier One, High NIH Funding):

Albert Einstein
Baylor
Boston
Case Western Reserve
Columbia
Cornell
Duke
Emory
Harvard
Indiana
John Hopkins
Mayo Clinic
Mount Sinai
New York Univ SOM
Northwestern
Oregon
Stanford
Univ of Alabama
Univ of California Los Angeles
Univ of California San Diego
Univ of California San Francisco
Univ of Chicago Pritzker
Univ of Colorado
Univ of Iowa
Univ of Maryland
Univ of Michigan Medical School
Univ of Minnesota Minneapolis
Univ of North Carolina
Univ of Pennsylvania
Univ of Pittsburgh
Univ of Rochester
Univ of Southern California
Univ of Texas SW
Univ of Virginia
Univ of Washington
Univ of Wisconsin
Univ of Massachusetts
Vanderbilt
Washington
Yale

Group B (Tier Two, Middle NIH Funding):

Brown, Dartmouth
Georgetown
Jefferson Medical College of TJU
Med Univ of South Carolina
Medical College of Georgia, Medical College of Wisconsin
Ohio State
Suny Stony Brook
Temple
Tufts
Univ of Arizona
Univ of Arkansas
Univ of California Davis
Univ of California Irvine Cal
Univ of Cincinnati
Univ of Connecticut
Health Center
Univ of Florida
Univ of Illinois
Univ of Kentucky
Univ of Louisville
Univ of Med and Dent of N J/R W J Med School
Univ of Miami
Univ of Nebraska
Univ of New Mexico
Univ of Oklahoma
Univ of Tennessee
Univ of Texas Health Science Center Houston
Univ of Texas Health Science Center San Antonio
Univ of Texas at Galveston
Univ of Utah
Univ of Vermont
Virginia Commonwealth
Wake Forest
Wayne State

Group C (Tier Three, Low NIH Funding):

Albany Medical
Creighton
Drexel
East Carolina
East Tennessee ST Univ Quillen
Eastern Virginia
Finch, Florida International
Florida State
George Washington
Howard
Loma Linda
Louisiana State New Orleans
Louisiana Shreveport
Loyola Univ, Marshall
Medical College of Ohio at Toledo
Meharry Medical College
Mercer
Michigan State
Morehouse
New York Medical College
Northeastern Ohio
Rush
Southern Illinois
St. Louis
Suny Buffalo
Suny Brooklyn
Suny Syracuse
Texas A & M
Texas Tech
Tulane
Univ of Central Florida
Univ of Hawaii
Univ of Minnesota Duluth
Univ of Mississippi
Univ of Missouri Columbia
Univ of Missouri Kansas City
Univ of Nevada
Univ of North Dakota
Univ of South Alabama
Univ of South Carolina
Univ of South Dakota
Univ of South Florida
West Virginia
Wright

APPENDIX B

RESPONSE TEXT:

DESCRIBE WHY YOU PURSUED

A CAREER WORKING WITH IRBS

Describe WHY you pursued a career working with IRBs

(Total *N*=103)

MOTIVATIONAL

Interesting/Challenging:

1. I have an interest in biomedical research.
2. General interest
3. An interest in biomedical ethics
4. Personal interest in clinical research
5. Interesting; challenging
6. Interest in medicine and research
7. The job as described was incredibly interesting.
8. Interest in regulations and compliance
9. Interested in the ethical nature of the work, and regulatory arena
10. I actually worked with IRBs when submitting studies to the IRB. As a Regulatory Affairs Associate, it seemed interesting to protect the subjects welfare and rights as human subjects on investigational studies.
11. I pursued a career working with the IRB because I have always been interested in HST. I plan to obtain my degree in Biochemisty, so being on the administrative side of the IRB will make doing my student research bit less challenging.
12. Was interested in the administrative side of health research
13. Knew I was qualified, thought it would be a new challenge
14. I thought it would be interesting to learn all of the types of research that happen. Here we review everything from the use of the Jarvick heart, to simple surveys.

15. I had previously worked as a study coordinator and became most interested in the compliance side of research.

16. I was intrigued by the amount of detail involved and more generally what it is that we actually do, help to protect the subjects.

17. I became interested in IRB management while serving as an IRB member.

18. This is a well respected area dealing with compliance in safety and welfare of human research toward meeting standards & elements of accreditation of which I have a background and experience. Interested in the details…

19. Sounded interesting and like an essential service needed in the institution (long term job security)

Importance/Impact/Contribution:

1. Wanted to contribute in some small way

2. Healthcare issues; patient issues; to provide guidance and instruction

3. After working on the researcher side, I wanted to work with an ethics board to make sure participants are protected from harm.

4. The people/office was just a great environment, the ability to be able to educate others and be able to help regulate research (not be pushing research like pharmaceuticals, but being the stop-gap for bad research)

5. I wanted to effect change relating to research and ethics on a broader scale on campus.

6. The ability to impact clinical research at the implementation level; use my professional experience to make a small difference in the quality of patient care.

7. I wanted to stay in the field of research administration, but to travel less frequently. I also wanted to contribute to the protection of human subjects in research.

8. Supported the IRB mission: protecting the rights of research participants

9. I liked knowing I made a difference in people's lives.

10. I wanted to make a difference in people's lives. Although behind the scenes, working for an IRB has offered me the opportunity to do just that.

11. It is a vital field. It is the most important aspect of ensuring safe and productive environment for human research.

Wanted Change:

1. Transition from hardware support to software development

2. I was looking for an alternative to my dead end job coordinating research studies-- I had hit a ceiling.

3. It seemed to be a natural transition from conducting clinical trials.

4. I was ready for a desk job and happy to turn-in my pager after more than 40 years as a clinical and research nurse.

5. I wanted a change in career.

6. I was changing from teaching children to teaching adults and the IRB had an opening for a training specialist.

Research Interest:

1. I wanted to work for USF, have an interest in research (motivations behind, tasks associated with, steps to publications, do's and don'ts).

2. Ability to combine research and legal interests while working for a renowned institution.

3. Interested in research administration

4. I like reading research.

5. I was interested in research.

Rewarding:

1. As a Clinical Research Coordinator, I had always enjoyed the process of submitting items to the IRB and drafting responses to the comments. I appreciated the process and the IRB's work to protect the safety and welfare of subjects. I always felt as though the IRB made great improvements to the research.
2. I believed that it would be a rewarding career path.
3. Seemed as if it would be rewarding

CAREER-MINDED

Advancement:

1. Advancement from prior job as research manager.
2. Advancement
3. Needed a better paying job but did not want to leave campus
4. Needed a job that was not funded by grants
5. It was an opportunity for promotion in the research office.
6. Ready to move up from Grant Production work. I worked with the PIs on IRB submissions.
7. It was a natural progression from Research Coordinator.
8. Career opportunity. Higher level at the university
9. Was interested in research but didn't want to be granted funded.
10. Advancement in research administration
11. I didn't. I was just looking to move up in the institution and working with the IRB was one of the duties.

Had a Good Background:

1. Institution needed experienced manager for compliance office

2. I was initially hired to do the invoicing for our IRB so my accounting back ground came into play.

3. It was a logical next step after my 5 years as a clinical research coordinator and combined my legal interests with clinical research.

4. The Compliance Manager position combined both my interests and experiences (research and law).

5. To work in regulatory compliance seemed to integrate all of the education and work experience I had accrued to that point.

6. Natural progression from working as a study coordinator and regulatory affairs coordinator for clinical trials.

7. I worked developing a research site. Wanted to combine work experience at the site with IRB training to find a way to interpret the regulations to help sites comply.

8. Based on my previous position, I was familiar with the IRB process in submitting applications.

9. A good melding of my health care and law backgrounds.

Like Working with Regulations/Regulatory Details:

1. I enjoy the administrative side of working with the regulations.

2. Liked the regulatory area, good with details

3. The regs are only about 17 pages. I figured I would be able to help digest them into practical guidance and assist in informing the national conversation which was growing rapidly in the late 90s.

4. I enjoyed the attention to detail.

Good Opportunity:

1. It was a good opportunity at the time.

PRACTICAL

Wanted a Job:

1. I was in high-school looking for a part-time position.

2. Happenstance. I wanted to work at the University and I meet the job skills needed for the IRB job.

3. I needed a job and they had an opening.

4. I did not know what an IRB was. I was offered the job and I needed a job, so I took it.

5. Needed a job at the time, it became available.

6. Looking for a new career outside of industry that involved research and medical writing

7. Needed a job

8. It was a job. (Market was bad.)

9. Wanted to move out of the small environment that existed in the psychopharmacology unit.

10. I didn't pursue an IRB job, I was looking for any job that would be interesting.

11. I applied for a number of jobs and the first one that offered a position to me was as a Consent Form Specialist. I applied for this position because I knew I have above average writing skills and could excel at editing documents. I also have a good attention to detail and would be able to spot errors or omissions well. I also thought it would be exciting to not conduct research or contribute to one project, but rather, to see the research cycle from IRB submission through study closure.

12. Moved to a small town and was laid off from remote job (as a CRA)

Referral/Request/Friend:

1. It was recommended to me by the Vice Chancellor

2. It was a fluke. A friend who worked in HR suggested I interview for the position because of my background in literature. She knew I was well-spoken and a good writer and thought it would be a good match.

3. Requested to join department by former Vice President

4. I didn't necessary pursued the job in IRB but I knew someone who worked at an IRB told me about a position.

5. I had a friend who worked there and notified me of a job opening; she told me my skill set would match the job.

6. It was fate. I had no idea what an IRB was, but I happened to meet the person hiring…three weeks later, I had a job.

Temporary to Permanent Position:

1. I started as a temp

2. My mother works for an IRB and was hiring a temporary employee. I applied for the position, and soon became a permanent employee.

3. I started as a temporary employee and did not really know what I was getting into, too.

4. Came as a temp and like work and still here.

DID NOT INITIALLY PURSUE

1. Pursuit of this job was not career specific, just economically motivated.

2. It was totally by accident...I did not pursue a position with an IRB.

3. I actually didn't try to pursue a career working with IRBs.

4. I didn't really pursue so much as fall into

5. I didn't pursue the job; I just ended up at the IRB since my boss was getting out of clinical research and was also the overseer of the IRB. I just sort of migrated over.

6. I had not intended it as a career, but the job description appeared to require the problem-solving, writing, and research skills I had acquired from my graduate education as well as my love of science.

7. I didn't really pursue it. As people retired it was given to me in the grants office.

8. Did not pursue career in IRB, was hired as a temp and then just stayed because job was interesting

9. The only thing I actually enjoying doing in life is watching TV, which, shockingly enough, isn't particularly lucrative. In other news, degrees in English and Art History really don't pay the rent. Boy, if I had a nickel for every time I saw a job posting for "Art Historian Wanted"... Having no applicable skill set for any job in particular, I pursued a career in the first job that came along. And WHAT a career!

10. I didn't- it pursued me

OTHER

1. This is my first one.

2. I had a great mentor where I was taught to able to focus and develop a plan of action. Thru this mentor, I figured the best way to determine what I needed to know, was to first establish what I didn’t know. That way I could identify where I was deficient and see which areas I needed to concentrate most of my efforts on. Because I work at a relatively specialized IRB,

there were several regulations and procedures that I had no experience with at all. So it was critical for me to clearly distinguish my weak spots and pursue a career in the IRB.

APPENDIX C

RESPONSE TEXT:

DESCRIBE HOW YOU WERE ABLE TO OBTAIN

A JOB WORKING WITH IRBS

Describe HOW you were able to obtain a job working with IRBs

(Total *N*=101)

BACKGROUND AND SKILLS

1. I had extensive experience as a CRC at a large world known teaching hospital.

2. My background as a research coordinator opened doors for me.

3. Already directing other research compliance functions

4. I think I obtained the job because I possessed the skills they needed at the time.

5. IT position opened due to lack of oversight and database mgmt per an FDA Audit

6. I applied for the advertised position and since it deals with "accreditation" and program management, I was right for the position with my background experiences & education.

7. Years of clerical experience

8. OHRP shut-down at academic center convinced them they needed to hire administrative lawyers as regulatory specialists

9. Legal background & familiarity with regulations & how to find & interpret

10. I have previous experience in an academic department as a clerical, which involved federal grant preparation.

11. I fit the qualifications.

12. I was able to obtain a job working with the IRB because I demonstrated my commendable work ethic and ability to multitask.

13. My credentials, I hope.

14. Applied-had relevant work experience

15. Completion of University Extension certificate program in Clinical Trials

16. I was young enough and my ability to learn was quick enough that I seemed to be a good fit in the company.

17. The IRB Office was undergoing a significant transition at the time I applied. The person who hired me wanted personnel who were good at working with people, had strong writing and analytical skills, and were interested in facilitating ethical research.

18. I think my experience working with central IRBs and local IRBs when submitting studies gave me some knowledge on how an IRB functions.

19. I was able to obtain this job because of my willingness to learn, my educational background in medical terminology and anatomy and interest in HSR.

20. Good at multitasking.

21. Knowledge and understanding; able to multi-task under strict deadlines

22. I believe my experience in research and with researchers at the institution.

23. Not sure how to answer this, but I think the combination of my healthcare experience with my psych. research helped.

24. I had worked as a clinical research coordinator at the same university that I now work as an IRB staff person. I knew how the IRB worked and I knew the individuals who worked here. I had research experience and with my law degree I was well qualified.

25. Via experience in research and education

26. After gaining several years of experience as a study coordinator, I applied for an IRB Research Monitor position.

27. I believe it was my verbal skills, and proven ability to handle a HUGE workload

28. Clinical work

29. Based on previous administrative experience and bachelor's degree.

30. My professional and personal skills allowed me to easily adapt to directing a human subjects protection program.

31. Extensive regulatory, clinical trials, research knowledge and experience.

32. The IRB sought to convert to an electronic system from a paper-based process, and my skills included significant familiarity with web-based systems.

33. I had the computer skills they were seeking.

34. Was asked to stay on as a permanent employee. Job was very interesting

35. Research background which brought familiarity with IRB process and procedures

36. I had experience as a research coordinator and an inclination towards regulatory materials. Previous jobs demanded almost as much regulatory knowledge but in different areas. I knew and demonstrated that I function well in a regulatory environment.

37. Experience with research sites, medical training and willingness to learn.

38. I have a strong work ethic and ability to learn quickly and adapt to new surroundings.

39. I searched local educational institutions' online job forums and saw the job advertised. I was working towards my Master's degree at the time and felt that with my background with writing and analyzing health policy papers, I would be able to handle editing consent forms and attending IRB meetings to raise consent issues. My educational background is in the conduct of research.

40. Previous experience in Human Research protection in Europe

41. When I first started, IRBs were more interested in individuals with clerical and not regulatory experience. This was before Hopkins was shut down by OHRP!

42. Background in health care and research

43. My experience with proposal/grant submission in the sponsored research office and my ability to organize and multitask

44. Experience in program compliance and in research.

FRIENDS AND NETWORKING

1. Recommendation

2. Apparently it just happened...I applied for a position and then selected. Too I think because of who I knew in this department played a part in hiring me.

3. Colleague was going on maternity leave and asked me to cover.

4. I had worked in health research and was familiar with the IRB staff

5. I interviewed with the IO, who knew the Chair of the department I was currently working for. I suspect it was simply a case of being known for good organizational and writing skills within the school that led to my hiring.

6. IRB Staff was familiar with my work as a Research Coordinator.

7. I was requested from the temporary job pool at my institution

8. I was able to obtain a job working with the IRB through networking.

9. Worked closely with the IRB as a study coordinator/regulatory affairs coordinator. Developed a good working relationship. Actively recruited by the IRB Director.

10. I had lost my job and was unsure of my career path. A person whom I had worked with recommended a career in the IRB field and put me in touch with the IRB Director.

11. Referral from a friend

12. My boss who served on the IRB encouraged me to apply for an opening in the IRB office.

13. Networking with someone in the organization.

14. Referral.

15. My friend told me about it and I applied for the position.

16. IRB staff came to me.

17. I had connections.

18. I'm a coat-tail rider and a compulsive follower and when a friend of mine told me to apply, I did. Having done the exact same thing for my previous two jobs, I heeded her commands and ended up applying to an institution that I had never even heard of and had absolutely no interest in.

19. I was recruited by the IRB Director after serving as a Board member.

APPLIED TO ADVERTISEMENT

1. Applied for an open position at a university

2. Applied to an ad in a legal newspaper

3. I applied for the job and then followed up by finding anyone I could on campus to put in a good word for me.

4. Applied for it

5. With a MS degree and background in research monitoring, I applied for an IRB staff (associate manager) position. About 6 months later, I was called in for an interview and the position was offered to me.

6. I applied for the job. The IRB was desperate for someone who could actually do the job. I am spectacular at multitasking and getting things done masterfully, so I was a good pick.

7. It was part of the job that I was hired for.

8. I sent my totally awesome resume in and got an interview, then completely wowed the staff with my sparkling personality.

9. I sent my CV and the IRB called me for an interview.

10. Applied impromptu, institution needed a part-time replacement and I was willing to take a position with lower skills requirements than my experience in order to get in to door. (Then went full-time and advanced in the office, because it started out as a 1 person office and grew fast.)

PROMOTED

1. I began as an Intake Coordinator, basically triaging studies as they were submitted by investigators, and applied myself to learn the process and regulations in order to pursue a coordinator (higher level administrative assistant) role.

2. Given promo opportunity to take on more work

3. Promoted within research office - from general clerical support to administrative support to the IRB.

4. VA research office needed part time assistance so got on-job training with them which allowed me to hired full time at the University Medical School when position became available

5. I applied for and got an administrative support position and was promoted within 6 months to IRB analyst.

6. At first I was only invoicing for the IRB but since been trained with working with some parts of the IRB

7. Started working in the Vice President For Research office with all compliance committees and moved over to strictly IRBs

FROM TEMPORARY TO PERMANENT

1. I started as a temp.

2. I started as a temporary employee and gained some experience there before being hired on permanently.

3. I started as a temporary employee and did not really know what I was getting into too.

4. Came as a temp

5. Fell into it as a temp, stayed when offered a permanent position

POSITION AVAILABLE

1. Transitioned from a research coordinator position to a vacant position in the IRB office.

2. Opening on campus and I was familiar with IRB submissions.

3. Open position available

4. A position opened up in the Human Research Protections Office.

ALREADY WORKING AT SCHOOL (*N*=4)

1. Internal candidate, experience as researcher, advanced degree

2. I was already working at the medical school

3. Opportunity became available in an expanding Human Research Protection Program at my own institution

4. Volunteer on boards and sub-committees - then requested to join department

OTHER

1. Was not difficult at that time

2. The job was much simpler 18 years ago.

3. I was currently working within the Academic Medical Center and participated in a project with some IRB staff people. I viewed one of the IRB staff people as a mentor and was very interested when an opportunity was presented.

4. The experience, wisdom, expertise, and intelligence of my colleagues, are without a doubt the most important resources I had – and continue to have today. Collectively, they have been teaching me everything I needed to know since the day I walked in the door – all full of motivation and drive but without a stitch of IRB experience. Their support, encouragement, and unwavering belief in me, even in the absence of my own sometimes, enabled me to harness my anxieties (at least somewhat) and gave me the confidence to see it through.

PLACED INTO POSITION

1. I was placed into the position.

2. I was in the right place at the right time.

3. I basically fell into it.

4. I wanted an IRB at my local hospital and kept asking the CEO until one day he appointed me the Chair and Administrator (in addition to my duties as staff psychologist)

APPENDIX D

RESPONSE TEXT:

HOW HAS HAVING A JOB WORKING

WITH AN IRB CHANGED YOU?

How has having a job working with an IRB changed you?

(Total: $N = 79$)

MORE KNOWLEDGEABLE

1. I was a CRC for most of my life...I really did not understand the IRB...actually hated it...I now understand why they do what they do.
2. I have a better understanding of how and why research is done.
3. More knowledgeable about HRPP
4. I have learned a lot more about human research and the effects of it
5. More aware of drug development
6. I didn't realize how much info/data IRB received from drug companies etc.
7. More aware of diseases out there and how research is trying to help them
8. I have become more knowledgeable in this field.
9. I have become more aware of the medical industry in general and I have learned to transfer the ethical standards with which my work relies on and apply them to my everyday life.
10. Better understanding of how regulatory framework affects researchers and protects subjects
11. Provided a better understanding and functions of the IRB
12. More knowledge on research regarding humans.
13. Given me more knowledge in regards to reading informed consents when I have gone to Emergency room or doctors office
14. I am now more interested in this line of work, and have learned things regarding research that I wouldn't have learned otherwise.
15. And that's how I learned about the Belmont Report.
16. More knowledgeable

17. I am more career minded. Also I am more aware of the impact that federal guidelines/regulations have on the lives and well-being of individuals.

CHANGED ME FOR WORSE

1. There have been many changes in our office and this has made me apprehensive as to what will be changed on any given day.

2. It's made me more cynical. I am a proponent of research but I don't know if I would ever participate in a study after working for an IRB.

3. More aware of pharma industry. More reluctant to initiate a new treatment for a medical condition myself or someone in my family suffers from, when existing treatments are satisfactory.

4. This is a high stress job, I have started drinking more than I probably should since working here, but sometimes I just need a fast way to unwind at the end of the day.

5. Surprised by the casual attitude many coordinators/investigators have regarding regulations pertaining to research.

6. It has made me a little less likely to take what a physician has to say at face value. I am now more comfortable and therefore more likely to ask more questions about health care matters pertaining to me or my family.

7. It has made me hesitant to participate in research studies.

8. I eat more chocolate than I used to.

9. I approach my own medical needs with a broader knowledge base and a critical eye.

10. I don't sleep well at night anymore.

11. Made my skin thicker

BETTER AT MULTITASKING / WORKING UNDER PRESSURE/ MORE DETAIL-ORIENTED

1. More detail oriented

2. Made it so I was more capable of multi-tasking and handling high stress situations.

3. It's a good job for someone who is a little obsessive-compulsive. Not that I feel I'm more obsessed, but I do feel that I have developed excellent organizational and multi-tasking skills. I've also enhanced my written and verbal communication skills as well as my ability in handling difficult people and/or situations.

4. I have learned to pay more attention to detail.

5. Made me more attentive to detail

6. Even though I always thought myself to be a very organized and detail oriented person, I find that I have become even more organized.

7. Closer attention to detail

8. I tend to be too detail oriented and I do carry work home because I do not have enough time to review studies at the job.

9. Helped me to multi task and work under pressure.

BETTER ANALYTICAL SKILLS

1. Has helped develop critical thinking

2. It has taught me to adjust to a moderately-paced office on a daily basis and to problem-solve in an efficient manner.

3. I over-analyze everything.

4. Working with an IRB has challenged me to look at things from a more analytical and from a global viewpoint.

5. My ability to think through a law/regulation and apply it to various situations has developed.

6. I acquired the most valued skills working closely with the IRB: Teamwork, Analytically, Interpersonally, Oral Communication, and Flexibility and it gave the chance to pursue my educational career.

7. Enhanced analytical abilities; more adaptation skills; greater attention to details; refinement of consulting and verbal skills

MORE RESPECT/APPRECIATION FOR RESEARCH

1. It has made me appreciate research being done more.

2. I have a greater appreciation for those who participate in research.

3. It has given me a better understanding of what a researcher has to go through, and all of the federal regulations that are involved.

4. It has enhanced my awareness of how ethical/unethical people can be and how unethical and uncaring some sponsors can be.

5. I have a deeper respect for the regulations and understand the rationale for what I used to think of as "annoying rules."

6. Has given me a better understanding and appreciation of how much work and how many people are involved in ensuring that research is done properly.

BETTER COMMUNICATION SKILLS

1. I am an even better communicator, neat-freak, perfectionist, and organizer.

2. I have become more precise in my written communication, and more observant of others oral communication. Tending to details more efficiently.

3. I'm not sure, because I have a lot of experience that led me to this position, so it could be maturity, but I feel I am better able to interact with difficult personalities and also people who need lots of help and direction. I like being someone people want to talk to when they have a question. Also, I think my formal writing has improved.

4. I have developed as a professional with strong oral and written communication skills.

5. Better communication skills

6. Better able to express my viewpoints and consider opposing views and extra careful about written communications

HAS NOT CHANGED ME

1. It hasn't.

2. I don't believe it has changed me.

3. It has neither heightened nor lessened my interest in HSR, so I don't think it has changed me much.

4. I don't understand the question; I do not believe my job has "changed" me.

5. Changed me how?

6. n/a

OTHER

1. I take nothing for granted. Have no fear of asking tough questions.

2. It’s made me realize that the staff care much more than reviewers about ensuring protections.

3. I really focus on the regulatory aspect of the job in regards to the subjects welfare and rights as a human subject.

4. It has given me a stronger sense of our national priorities.

5. Made me more aware of the difficulties faced by low-literacy and non-English speaking people in the health care setting

BETTER SELF-ESTEEM / REWARDING

1. It's rewarding work, when the office functions as it should.

2. It reinforces my skill set and gives me the opportunity to achieve/accomplish. The ability to accomplish always helps maintain a healthy self esteem.

3. It has given me more self confidence because I feel that I am learning new things everyday and as that happens, I become more competent at what I do. Also, I think that this work is challenging because no two situations or studies are identical.

4. I now sleep, eat and feel better without the stress of clinical call, week-ends, nights and holiday work. The young staff here are so friendly and take good care of me as the 'granny' in the place. It's a happy place and I love it (even when I have to do audits and contend with unappreciative PIs).

MORE PATIENT

1. Made me more patient with people!

2. I like to think I have become more patient, less apt to jump to conclusions, more comfortable with ambiguity, and increased my awe of the skills and commitment of researchers to moving science and patient care forward.

3. Become more patient with people and acquired better skill set for resolving business process issues more efficiently

MATURED PROFESSIONALLY

1. I have grown professionally and personally.

2. It has matured me to be working with medical professionals and I've become very efficient in the review of all types of applications.

MORE OPEN-MINDED

1. Given me to be more open minded

2. Broaden my horizons tremendously

WORK MORE COOPERATIVELY

1. Learned to work more cooperatively with others

APPENDIX E

DAILY JOURNAL

Office for the Protection of Human Subjects
Clinical Research Management Internship

May 14, 2009:
• Successfully completed the following CITI training modules as required for IRB (Institutional Review Board) Members:

Required Modules	**Date Completed**
Belmont Report and CITI Course Introduction	05/14/09
History and Ethical Principles - SBR	05/14/09
History and Ethical Principles	05/14/09
Defining Research with Human Subjects - SBR	05/14/09

May 18, 2009:
•Met with Dr. Brian Gladue to discuss possible projects for research proposal. Possibilities include producing/writing instructional manuals for OPHS and IRB use, developing a new system for organizing/monitoring/prioritizing serious adverse events, conducting research involving IRB staff training and experience.
•Met with Deb Ceron to discuss feasibility of creating a product designed to improve the processing of serious adverse events.
•Met with Itzel Pena to discuss recruitment of human subjects for research purposes.

May 19, 2009:
• Successfully completed the following CITI training modules as required for IRB Members:

The Regulations and The Social and Behavioral Sciences - SBR	05/19/09
Basic Institutional Review Board (IRB) Regulations and Review Process	05/19/09
Assessing Risk in Social and Behavioral Sciences - SBR	05/19/09
Informed Consent - SBR	05/19/09
Informed Consent	05/19/09
Privacy and Confidentiality - SBR	05/19/09
Social and Behavioral Research for Biomedical Researchers	05/19/09
Records-Based Research	05/19/09
Genetic Research in Human Populations	05/19/09
Research With Protected Populations - Vulnerable Subjects: An Overview	05/19/09

•Conducted research on-line regarding possible topics for research projects. I specifically looked at problems that IRBs face as well as problems with IRBs. Drs. Ceci and Bruck, through their writings in “Perspectives on Psychological Science,” provided discussion regarding the need for evaluation and competence of IRB members.

May 20, 2009:
•Attended first committee meeting with Dr. Gladue, Dr. Patricia Gwirtz, and Dr. Tina Machu to discuss internship and research proposal.
•Presented long-term goals and specific aims of proposed project. My General Long-Term Goal was to determine the relationship between the training and experience of the IRB office staff and the likelihood of "successful" human research projects. Specific Aim #1 would test the hypothesis that the better trained/experienced the IRB staff, the fewer the number of serious adverse events. Specific Aim #2 would test the hypothesis that the better trained/experienced the IRB staff, the more efficient and effective the protocol approval process.
•Reached decision regarding project after discussion with committee members. I will conduct a thorough investigation of IRB staff across the nation and will determine the experience, training, motivation, etc. of such employees. I will develop extensive surveys and distribute via e-mail (and follow-up with phone calls) to retrieve data. Results will be analyzed and discussed.

May 21, 2009:
• Successfully completed the following CITI training modules as required for IRB Members:

Research with Prisoners - SBR	05/21/09
Vulnerable Subjects - Research with Prisoners	05/21/09
Research with Children - SBR	05/21/09
Vulnerable Subjects - Research Involving Minors	05/21/09
Research in Public Elementary and Secondary Schools - SBR	05/21/09
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	05/21/09
International Research - SBR	05/21/09
International Research	05/21/09
Internet Research - SBR	05/21/09
Group Harms: Research With Culturally or Medically Vulnerable Groups	05/21/09
FDA-Regulated Research	05/21/09
HIPAA and Human Subjects Research	05/21/09
Workers as Research Subjects-A Vulnerable Population	05/21/09
Hot Topics	05/21/09
Conflicts of Interest in Research Involving Human Subjects	05/21/09
The IRB Member Module - "What Every New IRB Member Needs to Know"	05/21/09
University of North Texas Health Science Center	05/21/09

•All modules for the "IRB Member" CITI training have been successfully completed.

May 27, 2009
• Conducted literature search (through journals) for information regarding IRB staff. The following journals were reviewed: "IRB Advisor," "The Hastings Center Report," "IRB Ethics and Human Research," "Research Practitioner," and "Family Health International."

May 28, 2009
• Attended "Health Disparities" Conference to satisfy requirements for BMSC 5900.001.

May 29, 2009

- Attended "Health Disparities" Conference to satisfy requirements for BMSC 5900.001.

June 1, 2009

- Completed "Information Resources Security Training" and set up work station (computer, printer, accounts, etc.)
- Prepared IRB Staff Survey Questions including training, experience, and objective variables
- Conducted literature search for IRB staff questions
- Met with Dr. Gladue to discuss internship, project ideas, and office procedures

June 2, 2009

- Submitted a "Request a Database Search" form to the UNTHSC reference library
- Received and read (in preparation for today's IRB meeting) the following: pre-review notes, chair's report, meeting minutes, and agenda
- Assisted Mary Wilson with purchasing and preparation of food items for the IRB meeting
- Attended UNTHSC's IRB meeting

June 3, 2009

- Read multiple serious adverse event (SAE) reports
- Continued working on IRB Staff Survey Questions
- Developed hypotheses related to IRB Staff training/experience as a function of protocol approval time, amount of federal funding, and number of reports of conflict between IRB and investigators
- Assisted Deb Ceron with the stamping and copying of documents to be delivered to investigators

June 4, 2009

- Consulted with reference librarian in order to install "Write-N-Cite" and updated Refworks account
- Met with Dr.Gladue to discuss research proposal; narrowed down scope of questions for survey
- Read three issues of the "Research Practitioner" and one issue of "The Monitor," as provided by Deb Ceron

- Obtained sample CRM research proposal and guidance from Itzel Pena
- Reviewed previous e-mail research survey conducted by Elizabeth Buchanan, Ph.D.

June 5, 2009

- Developed multiple sections of research proposal including the following: problem/hypothesis, summary, significance, literature review, preliminary data, and general internship experience.

June 8, 2009

- Edited and finalized research proposal and submitted it to Dr. Gladue for review
- Developed "Informed Consent" document
- Obtained example of research protocol and began preparing document
- Viewed numerous "Refworks" modules in order to format my bibliography

June 9, 2009

- Edited my research proposal per Dr. Gladue's suggestions and comments; in addition, I corrected the informed consent documents
- Developed e-mail version of research questionnaire
- Began finding contact e-mails for the Directors of the medical schools that I will be using in my research

June 10, 2009

- Continued conducting internet research in order to find contact e-mails for the Directors of the medical schools that I will be using in my research
- Edited my cover letter to subjects, reflecting means by which subjects are contacted (Directors first, then staff members and possibly phone calls)
- Edited my research design in my protocol and proposal to reflect this change of contact of subjects

June 11, 2009

- Obtained remainder of contact information for the three groups of medical schools with varying degrees of NIH funding that will be used in my research; goal was to identify the Director of Human Subject Protection Office, IRB Director, and if that information wasn't available, a general office e-mail address
- Conducted additional research and found more references to use for the "Discussion" section of my practicum project

- Edited questionnaire to reflect change in "tone" of questions; For fear of putting the subjects at risk, all questions that could be perceived as "negative" (such as "What's the worst part of your job?") were removed

June 12, 2009

- Formatted the medical school contact info into three categories of funding; used numerical sequence to keep track of groupings
- Wrote part of the "Discussion" section for my practicum report using the new-found references
- Met with Dr. Gladue to discuss the edited draft of my research proposal; discussed ways to revise the questionnaire
- Studied a sample survey to get ideas for my questionnaire

June15, 2009

- Reviewed on-line surveys to determine if I will use a web-based questionnaire
- Continued to edit questions for survey, made corrections to protocol
- Assisted Ms. Mary Wilson with the movement of files from the conference room
- Developed a telephone and "In-person" script for protocol

June 16, 2009

- Submitted research proposal to Dr. Gwirtz and Dr. Machu for evaluation
- Formulated e-mail groups and alphabetical listing of medical schools for addition to survey
- Reviewed previous research surveys to help determine format for informed consent (e-mail, telephone, and in-person) and questionnaire
- Edited letter to Directors to include web site link; will likely use "Survey Monkey" for questionnaire (web-based) format

June 17, 2009

- Read six "surveymonkey.com" training modules for designing study questionnaire
- Conferred with Heather Cline regarding survey software available to UNTHSC students; contacted librarian with questions, who will call back tomorrow
- Received input regarding my project survey from the OPHS staff; made appropriate corrections and additions

- Continued research and writing for practicum

June 18, 2009

- Opened "surveymonkey.com" account; designed practice survey; tested survey's ability to be forwarded (through use of same link) and discussed issues with technical support
- Began obtaining staff members' e-mail addresses for mailings (should the Directors' response not be good)
- Created official questionnaire through "surveymonkey.com"
- Edited draft of "Auditing Procedures" for research coordinator

June 19, 2009

- Submitted my protocol (exempt category) for IRB approval; obtained signatures from appropriate faculty
- Edited questionnaire on "surveymonkey.com"
- Created address book (for Directors) for survey distribution
- Visited with technical support personnel in UNTHSC's library
- Obtained remainder of staff e-mail contacts from medical schools

June 22, 2009

- Met with Dr. Gwirtz to discuss proposal and editing comments
- Ammended proposal to include Dr. Gwirtz's suggestions
- Received response from Dr. Dyson regarding my protocol; made appropriate corrections to protocol
- Activated link to survey in preparation for the "mail-out"

June 23, 2009

- Met with Deb Ceron and discussed serious adverse event reports; pre-reviewed and edited multiple SAEs
- Pre-reviewed incoming IRB protocol; met with Itzel Pena to discuss findings
- Studied federal regulations and guidelines

June 24, 2009

- Met with Dr. Tina Machu and discussed edits to proposal
- Attended the Clinical Trial Coordinators Meeting
- Revised "Letter to the Director" per Dr.Gladue's suggestion; obtained approval for amendment from Dr. Dyson
- Distributed survey to Directors across the United States
- Reviewed and edited serious adverse event reports
- Met with Itzel Pena to discuss Exempt category procedures

June 25, 2009

- Located additional e-mail addresses for Human Subject Research Office Directors and distributed more surveys
- Attended Pre-IRB Staff Meeting
- Prepared questionnaire and cover letter for individuals requesting hard copy of survey

June 26, 2009

- Modified "Letter to Director: Follow-Up (Attempt #2)" for approval by Dr. Dyson
- Finished distributing survey to Directors
- Prepared consent forms to include in mail-out packet for subjects' requesting hard copy of questionnaire
- Attended Excel course offered by UNTHSC library personnel

July 20, 2009

- Reviewed my IRB staff study results through surveymonkey.com
- Finalized "New Letter to Directors" in preparation for follow-up of IRB directors; prepared and addressed e-mails for directors and will distribute upon approval from Dr. Dyson
- Explored various graphing techniques for display of results
- Met with Dr. Gladue to discuss my OPHS projects

July 21, 2009

- Began Project #1 (the development of annual reports) for the last three fiscal years
- Met with IT technician to establish database establishment
- Discussed details of Project #1 with Dr. Gladue

July 22, 2009

- Recorded data from the Minutes and Chair Reports for 2006-2007; this included documenting full-board, expedited, and exempt protocols as well as serious adverse events, continuing reviews, amendments, and protocol violations.
- Met with Dr. Gladue to discuss the categorization of the departments

July 23, 2009

- Continued recording data from the Minutes and Chair Reports for 2007
- Attended the OPHS Staff Meeting to discuss items on the agenda for the next IRB meeting

July 24, 2009

- Continued recording data from the Minutes and Chair Reports for 2007-2008
- Obtained approval from Dr. Gwirtz for my "Declaration of Intent to Graduate"

July 27, 2009

- Continued working on the preparation of OPHS annual reports for the past three fiscal years.
- Recorded data from IRB Minutes and Chair Reports for 2007-2008 including the following information: the number of full-board, expedited, and exempt protocols as well as the frequency of serious adverse events, continuing reviews, amendments, and protocol violations.

July 28, 2009

- Recorded data from IRB Minutes and Chair Reports for 2008-2009
- Began developing EXCEL spreadsheet for annual report

July 29, 2009

- Continued working on EXCEL spreadsheet for annual report
- Categorized IRB Minutes and Chair Reports for 2006-2009 and determined format of the presentation of the data

July 30, 2009

- Recorded data for OPHS annual report according to months/fiscal year and prepared initial analysis
- Formatted spreadsheet to include UNTHSC schools and departments; in addition, I subdivided protocol actions and board actions into appropriate categories

July 31, 2009

- Researched various database formats, including other IRB databases
- Examined the OPHS database for current features and capabilities
- Began the process of looking through protocol folders in preparation for Project #2

August 3, 2009

- Recorded data (approval dates, submitted dates, re-submitted dates, etc.) from protocol folders and the OPHS database for all CLOSED projects for the fiscal year 2008-2009

August 4, 2009

- Continued to record data (approval dates, submission dates, re-submission dates, etc.) from protocol folders and the OPHS database for all CLOSED projects for fiscal year 2008-2009
- Assisted Ms. Wilson with preparation of refreshments for IRB meeting
- Attended the August 2009 UNTHSC IRB meeting

August 5, 2009

- Began the process of recording data (approval dates, submission dates, re-submission dates, etc.) from protocol folders and the OPHS database for all EXPEDITED and FULL-BOARD projects for fiscal year 2008-2009
- Submitted Group Three (medical school IRBs) "Follow-Up" e-mails regarding my survey
- Recorded two months' worth of data from binders for the annual report

August 6, 2009

- Assembled the "IRB Minutes" binders to reflect the correct date/month corresponding to the Chair's Reports
- Met with Dr. Gladue to discuss the annual report project and design of spreadsheet
- Submitted Groups One and Two (medical school IRBs) "Follow-Up" e-mails regarding my survey

August 7, 2009

- Edited the EXCEL spreadsheet for the annual report to reflect correct departments
- Began entering data from the fiscal year 2006-7 into the spreadsheet for OPHS annual report

August 10, 2009

- Finished entering data from the fiscal year 2006-7 into the spreadsheet for OPHS annual report
- Entered data from fiscal year 2007-8 into the spreadsheet for OPHS annual report

August 11, 2009

- Completed data entry from fiscal year 2007-8 into the spreadsheet for OPHS annual report
- Entered data from fiscal year 2008-9 into the spreadsheet for OPHS annual report

August 12, 2009

- Prepared tables (from Excel) comparing data from FY 2006-2009
- Created departmentalized tables (complete with all Board actions) for FY 2006-2008

August 13, 2009

- Created template for FY 2008-2009 for spreadsheet, table summary, and itemized tables
- Arranged data (by department) into Excel which now displays departmental totals for all board actions

August 14, 2009

- Created graphs in Excel (for use in OPHS annual report) for fiscal years 2006-7, 2007-8, 2008-9
- Developed an annual report template in Excel; this template includes a comprehensive summary page, a complete listing of the months as well as an itemized list of departments. In addition, this product contains the formulas used for the calculations of OPHS data. This template will serve as the means by which the OPHS at UNTHSC prepares and enters data for annual reports.

August 17, 2009

- Collected data from closed research projects (exempt and expedited) for the past fiscal year regarding the following: date of submission, date of approval, date of OPHS' first action, date of PI's response

- Began collecting data from open research projects (exempt, expedited, and full-board) for the past fiscal year

August 18, 2009

- Continued collecting data from open research projects (exempt, expedited, and full-board) for the past fiscal year

August 19, 2009

- Collected additional data from protocols for report

- Assisted Deb Ceron by making copies of serious adverse event reports

- Assisted Itzel Pena by sorting through protocols packets for IRB members; divided the packets into individual components (protocol synopsis, informed consent, advertisements, etc.)

August 20, 2009

- Developed Excel spreadsheet for 2008-2009 OPHS Metrics. Created categories including: date submitted, date of OPHS response, date of PI response, approval date, and time from submission to approval.

- Began entering data for exempt category projects

August 21, 2009

- Continued entering data for the "2008-2009 OPHS Metrics" Excel spreadsheet

- Calculated time from PI's submission to approval

- Calculated time from PI's submission to OPHS response

August 24, 2009

- Located some of the files (Full-Board, Expedited, and Exempt) that were missing from the "Metrics Report" and entered data into Excel spreadsheet

- Analyzed data from "The State of IRB Staff in America" study; grouped similar responses in the open-ended questions and sorted according to category

August 25, 2009

- Continued entering data into the Excel spreadsheet for the "Metrics Report"
- Met with Dr. Gladue to discuss my progress on the completion of the annual report and the "Metrics Report"
- Entered the PI's name, department, and student investigator information into the Exempt and Expedited category spreadsheets for the Metrics project

August 26, 2009

- Created new Excel spreadsheet for Full-Board protocols
- Found and entered dates and data for Full-Board protocols including the following: submission date, Board Meeting date, approval date, deferral date, PI response date, final approval date; in addition, I listed the investigator's name, the PI's department as well as student investigator information

August 27, 2009

- Attended OPHS staff meeting in preparation for September's IRB meeting
- Continued collecting data for "Metrics Report"
- Obtained and began entering data from the August 2009 Chairs Report

August 28, 2009

- Finished entering data into the annual report spreadsheet
- Developed graphs comparing data from the past three fiscal years for the annual report
- Created summary page (complete with formulas for calculations) for Fiscal Year 2008-2009

August 31, 2009

- Created and integrated additional fields to the 2008-2009 OPHS Metrics spreadsheet
- Calculated OPHS and PI response times for Exempt, Expedited, and Full-Board category research
- Developed tables displaying OPHS and PI statistics

September 1, 2009

- Grouped "like" responses from "IRB Staff Status Questionnaire" in order to analyze and graph for report
- Assisted Mary Wilson with the purchasing and preparation of refreshments for the IRB meeting
- Attended UNTHS's September Institutional Review Board meeting

September 2, 2009

- Created graphs for "IRB Staff Status Questionnaire" data
- Developed additional graphs for PRIM&R data that will be used in practicum report

September 3, 2009

- Began writing practicum report for thesis entitled "The State of IRB Staff in America"
- Reviewed guidelines for thesis and obtained a sample thesis to assist with format of practicum report
- Met with Dr.Gladue to discuss OPHS Annual Report, the "Metrics" Project, and my research/results for my practicum report

September 4, 2009

- Read sample thesis provided by Dr. Gwirtz to develop an understanding of proper formatting for my practicum project
- Improved graphs for practicum project in order to clarify results
- Started writing introduction and background for practicum project

September 7, 2009

- Labor Day Holiday

September 8, 2009

- Continued writing "Background and Literature Review" for practicum project
- Wrote an abstract; created title page, acknowledgement page, and table of contents
- Began writing "Materials and Methods" section of project

September 9, 2009

- Continued writing in the "Materials and Methods" section of project
- Consulted UNTHSC manual for regarding the preparation (format, spacing, etc.) for practicum project
- Imported graphs into the paper and began discussion

September 10, 2009

- Finished "Materials and Methods" section of project
- Edited "Background and Literature Review"
- Began writing the "Results and Discussion" section of project

September 11, 2009

- Created Appendices for practicum project by downloading and importing files into my paper (from surveymonkey.com)
- Edited the imported files to meet style and guideline recommendations for the filing of a thesis
- Continued labeling and importing graphs into body of thesis

September 14, 2009

- Continued writing "Results and Discussion" portion of thesis
- Obtained references for project through "Refworks.com"
- Changed spacing and coloring of graphs for thesis project

September 15, 2009

- Began composing PowerPoint presentation for thesis project
- Imported graphs; changed coloring and spacing as appropriate
- Developed a "notes" document to assist with presentation of material

September 16, 2009

- As required by all UNTHSC students, I set up a LIVE e-mail account, forwarded Groupwise e-mails, set up a "POP" subscription, and completed migration form.
- Consulted with Information Technology Department regarding LIVE student account and installed Internet Explorer 7.0
- Set up an Organization Management account, as requested for GSBS students

- Continued working on notes for PowerPoint presentation

September 17, 2009

- Obtained additional references for thesis project and presentation
- Changed all graphs in PowerPoint to reflect percentages, rather than response count
- Utilized Write-N-Cite tool to incorporate references into PowerPoint slides

September 18, 2009

- Rearranged composition/presentation of graphs for thesis project
- Gathered information regarding IRB audits including: audit forms for IRB approved projects, self-assessment audit tools, behavioral audit forms, and information on how to conduct site visits
- Obtained book entitled "Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance" and read chapters regarding federal regulations and IRBs

September 21, 2009

- Continued analysis of "IRB Staff Status Questionnaire" data
- Produced graphs showing the findings of PRIM&R's background data

September 22, 2009

- Began writing figure captions for thesis data
- Searched for missing files in order to complete Metrics Project

September 23, 2009

- Compared all of the protocols from Fiscal Year 2008-2009 (as reported in the Minutes and Chair's Reports) to those protocols presented in the Metrics project
- Analyzed data until I was able to justify/clarify every entry

September 24, 2009

- Entered new/correct data into the Annual Report and Metrics Project
- Corrected all the graphs and tables in the Annual Report and Metrics Report to reflect changes

September 25, 2009

- Recalculated totals for Metrics project
- Met with Dr. Gwirtz to discuss thesis project
- Finished making adjustments/corrections to the Annual Report and Metrics Project

- Began editing of new protocol

September 28, 2009

- Reviewed and edited incoming protocols (one full-board and one expedited); entered data into database; checked for Conflict of Interest Forms and CITI training verification; verified all forms submitted; checked for completeness of application

September 29, 2009

- Continued reviewing and editing incoming protocols (finished first expedited protocol and began a second, new expedited protocol); checked for Conflict of Interest Forms and CITI training verification; verified all forms submitted; checked for completeness of application

- Met with Dr. Gladue to discuss thesis project and my work on incoming protocols

September 30, 2009

- Developed "Checklist for Incoming IRB Protocols" for OPHS

- Continued editing "The State of IRB Staff in America" using Dr. Gwirtz's and Dr. Gladue's recommendations

October 1, 2009

- Regrouped data and rearranged graphs in thesis to reflect suggestions

- Attended OPHS staff meeting in preparation for October IRB meeting

October 2, 2009

- Continued development of additional graphs for thesis project

- Rearranged subjects' comments to reflect the grouping presented in thesis

October 5, 2009

- Continued editing thesis (worked from home)

October 6, 2009

- Edited/grouped the written-in responses from subjects responding to the "IRB Staff Status Questionnaire"

- Assisted Mary Wilson with the purchasing and preparation of refreshments for the IRB Meeting

- Attended the October 2009 UNTHSC IRB meeting

October 7, 2009

- Analyzed results from "IRB Staff Status Questionnaire," specifically groupings of medical schools
- Plotted data for questions in survey into an "IRB Staffer Composite" which is included in results section of thesis

October 8, 2009

- Modified the OPHS checklist for IRB protocols
- Calculated the breakdowns of data for the three tiers of medical school for thesis
- Reviewed incoming Exempt category protocol

October 9, 2009

- Completed UNTHSC's on-line "Code of Ethics" training for 2009
- Entered September 2009 Chair's Report data into OPHS Annual Report Excel Spreadsheet
- Met with Dr. Karan Singh to obtain advise regarding statistical analysis of research project
- Continued working on statistical analysis of research project

October 12, 2009

- Met with Dr. Tina Machu regarding thesis project; obtained advise regarding statistical analysis of data
- Edited Power Point slides to reflect changes made in thesis

October 13, 2009

- Entered October 2009 IRB Minutes data into OPHS Annual Report Excel Spreadsheet
- Learned how to conduct post-hoc analyses on chi-square results

October 14, 2009

- Conducted post-hoc analyses on data from "IRB Staff Status Questionnaire"
- Learned how to report chi-square test of independence results
- Reviewed incoming Exempt category protocol

October 15, 2009

- Calculated Z scores for data; entered into thesis
- Edited body of thesis to reflect results from analyses

October 16, 2009

- Expanded the ”Results and Conclusions” section
- Consulted Clinical Research Management Handbook and formatted thesis according to instructions

October 19, 2009

- Met with Dr. Gladue to discuss OPHS Staff Public Presentation Training and Workshops; began collecting ideas for slide presentations
- Conducted research involving clinical research management and public policy in the state of Texas; attempted to define a solution to applying research and scholarship in the interest of the people in the state of Texas

October 20, 2009

- Reviewed lecture presentations for the Department of Epidemiology, School of Public Health, CAMSTRR (Complementary and Alternative Medicine Short-Term Research Rotation), and STAR (Steps Toward Academic Research) Fellows
- Researched regulatory compliance issues in regards to conflicts of interest and adverse event reporting

October 21, 2009

- Researched information regarding clinical trials in Texas; prepared proposal for UTA’s Distinguished Scholars competition which describes how current knowledge can be applied to improve the lives of Texans
- Met with Dr. Gladue to discuss database project; began looking into options for producing reports from database info in Excel format

October 22, 2009

- Took multiple training modules in Access including the following: Queries, Forms, Tables, Databases, etc.
- Developed outline for UTA Distinguished Scholars competition
- Met with Dr. Gladue and OPHS staff for presentation training

October 23, 2009

- Reviewed three Exempt category protocols
- Prepared summaries of Exempt studies for Chair's Report
- Began entering departmental information for database project

October 26, 2009

- Entered departmental and investigator information into the OPHS database
- Exported Excel data into Access database
- Began working on Serious Adverse Event (SAE) project with Deb Ceron

October 27, 2009

- Worked on SAE project (obtained on-site and off-site reports, created new files, etc.)
- Edited Standard Operating Procedures (SOPs) for OPHS

October 28, 2009

- Continued working on SAE project (transferring SAEs to new files, editing previous filing system, creating labels, etc.)
- Continued editing SOPs for OPHS
- Attended OPHS staff meeting

October 29, 2009

- Provided Heather Cline with editorial suggestions for the SOPs
- Edited Pre-Review Notes for IRB Meeting
- Continued working on SAE project

October 30, 2009

- Took advanced "Access" training modules for queries and reports
- Transferred data from Excel to Access; practiced generating reports
- Continued reading through the SOPs for editorial comments

November 2, 2009

- Entered Chair's Report data for October 2009 into the 2009-10 OPHS Annual Report Excel spreadsheet
- Reviewed an Expedited protocol

- Continued to edit the SOPs

November 3, 2009

- Prepared statement for Chair's Report for Expedited protocol
- Assisted Mary Wilson with the purchasing and preparation of refreshments for the IRB meeting
- Attended UNTHSC's November IRB meeting

November 4, 2009

- Began making corrections, per Dr. Gladue's input, to "The State of IRB Staff in America" project

November 5, 2009

- Continued to make recommended changes to thesis report
- Attended the OPHS Presentation Training

November 6, 2009

- Worked on thesis; developed new tables and deleted appropriate figures

November 9, 2009

- Worked on notes to accompany my PowerPoint presentation for thesis defense
- Created/edited slides for the basic OPHS PowerPoint presentation

November 10, 2009

- Edited PowerPoint slides for thesis defense
- Continued working on slides for the OPHS slide presentation

November 11, 2009

- Attended two Clinical Research Management thesis defenses
- Developed additional slides from the PowerPoint for my project

November 12, 2009

- Finished editing the OPHS slide presentation; submitted it to colleagues for critique
- Fine-tuned PowerPoint slides in preparation for practice presentation with Dr. Gwirtz
- Attended CRM thesis defense

November 13, 2009

- Added clipart images/edited my thesis PowerPoint presentation as well as my OPHS slide presentation
- Met with Dr. Gwirtz and discussed my thesis defense and practiced presenting my PowerPoint presentation

November 16, 2009

- Edited my PowerPoint slides for my thesis defense
- Worked on slides/presentation for OPHS Presentation Training

November 17, 2009

- Reviewed and edited two OPHS Human Subject Protection Coordinators' "Basic OPHS Presentation" slides
- Practiced/worked on my version of the OPHS Basic Presentation slide set
- Continued working on the creation of the new SAE filing system

November 18, 2009

- Attended Clinical Trials Coordinators Meeting with Deb Ceron
- Attended CRM thesis defense
- Worked on SAE filing system

November 19, 2009

- Attended OPHS staff meeting
- Attended OPHS "Presentation Training"
- Worked on SAE filing system

November 20, 2009

- Presented thesis presentation to OPHS office for evaluation
- Attended CRM defense
- Worked on SAE filing system

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