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Submission to the IRB: Will Modified Training Improve the Probability of Successful Submission of IRB Protocols?

Yuhung H. Chou
University of North Texas Health Science Center at Fort Worth, yhc0007@my.unthsc.edu

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The ability to design, conduct, and oversee of a research project has becoming essential for the pharmacy residents to become pharmacists. Each year, pharmacy students undergo training on the specialized institutional review board (IRB) program at Baylor Scott and White Research (BSWRI) and how to submit their research application to the IRB. It is crucial for the pharmacy residents to undergo the IRB training since they typically struggle to submit their research applications due to lack of research background during undergraduate years. This year's training was modified to test whether the change will improve the submission process compared to the training in 2014 by implementing memory aids such as skeleton outlines and emphasis on important materials by the presenter. The effectiveness of the training was measured by the average number of times that the residents submitted to the IRB, as tallied by the iRIS database. The residents in 2016 performed the same compared to the residents in 2014. Further investigation needed to improve submission numbers.

SUBMISSION TO THE IRB: WILL MODIFIED TRAINING IMPROVE THE PROBABILITY OF SUCCESSFUL SUBMISSION OF IRB PROTOCOLS?

INTERNSHIP PRACTICUM REPORT

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Yuhung Holy Chou, B.S.

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CHAPTER I.

BACKGROUND AND LITERATURE

HISTORY OF THE IRB

In 1974, the United States required universities and research centers to establish the institutional review boards to monitor and approve human research. During World War II, Nazi scientists implemented human research without informed consent [1]. The experiments included involuntary research on psychiatric patients, anatomical studies of various human parts from victims who died from experimentation, pharmacological experiments on therapies for typhus, tetanus, and typhoid, and fatal experiments that exposed human subjects to freezing temperatures or low pressure [1]. After World War II in 1945, the Nuremberg trials were conducted to expose and discipline individuals who committed atrocities against captured prisoners [2]. During the trials, the judges from the Allied powers drafted the Nuremberg Code, a set of ethical codes, to reinforce federal research regulation [2]. The most important aspect of the Nuremberg Code was voluntary participation and informed consent for human subjects [2]. However, regardless of the Nuremberg Code, there were still scientists that conducted trials that ultimately harmed human subjects such as the use of thalidomide, the Willowbrook Hepatitis Studies, the San Antonio Contraception Study, and the Tuskegee Syphilis Study due to lack of oversight [2]. In 1950s, the Clinical Research Center (CRC) at National Institutes of Health (NIH) was created to manage

and regulate clinical research at CRC and oversee clinical research by establishing a review process by an ethics committee [2]. However, the regulation process was applied loosely at both public and private institutions in the United States. In 1964, James Shannon, a local investigator, called for policy that required any research study that was funded by Public Health Service to be reviewed by an ethics committee [2]. During the same year, the World Medical Association met and compiled the Declaration of Helsinki [2]. The highlight of the Declaration of Helsinki was to always put the interests of the human subject first. In 1966, Henry Beecher published “Ethics of Clinical Research” in the New England Journal of Medicine to bring awareness of the twenty two unethical clinical studies [2]. In 1974, the Congress passed the National Research Act which established the modern IRB system [2]. The National Commission for Protection of Human Subjects of Biomedical and Behavior Research was also established by the National Research Act, which eventually lead to the Belmont Report in 1978 [2].

The purpose of the IRB is to approve, monitor, and review research that has to do with human subjects to protect the rights and welfare of the subjects [3]. The Office of Research Subject Protection (ORSP) oversees the IRB and establishes deadlines for submission. At BSWRI, there are three IRBs: Red, White, and Blue [4]. IRB White and IRB Blue both review studies that involves greater than minimal risk, which means the probability of harm or injury occurring as a result of participation in a research study is higher than normal, daily life [4]. IRB Red is in charge of expedited studies, which are the studies that involves no more than minimal risk [4].

IRB TRAINING

Because it is mandatory for the IRB to approval any study, the pharmacy residents must learn to fill out the documentations for their submission depending on what type of projects they will be conducting. The IRB training that BSWRI held each year facilitate the process of submitting study applications. In order for their applications to be approved, the residents must turn in all the required documents listed in table 1 and fill them out correctly. The two main focuses for the residents are the study application and the supplemental forms.

The study application will be submitted electronically. There are total of seventeen sections: general information, add departments, assign project personnel, type of application, type of project, funding information, scientific review, research team members, administrative/clinical oversight, use of FDA regulated products, drugs, devices, subject recruitment, data safety monitoring board, use of radiation, fluoroscopy, and supplemental review. Form 1 and Form 15 are the supplemental forms for new studies with Form 1 being used for interacting with human subjects and Form 15 for studying human samples.

A key component to a successful submission is knowing how submit to Baylor's electronic online application called "Integrated Research Information System," or iRIS [5]. Since the system is only used by Baylor, it can be difficult to navigate the submission site. During the IRB training, the presenter will demonstrate on how to build a study application in real-time on IRIS through the projector.

Although the pharmacy residents were taught on how to submit their applications, they still made mistakes that were emphasized during the presentation. The most common mistake was not having the appropriate documentation attached to the study application according to iRIS database. The two common missing forms were Form 35 and Form 18. Another major mistake

was not filling out Form 15 correctly with sufficient and consistent information since Form 15 was matched with the study application to ensure consistency. In order to expedite the submission process, memory retention of the IRB training is essential.

During a lecture, it is critical for the presenter to give handouts to reinforce lecture materials due to less note-taking and more time to process the information given [6]. However, the residents should take notes to enhance memory retention but also not having to spend time writing down materials without processing them. Thus, learning aids should be given to enhance learning for residents [7]. One particular method is to aid the residents with skeleton outlines, which will acquaint them with the topic's main point with vital subtopics under each main point [7]. The skeleton notes will allow more cognitive resources to process training materials during the presentation [7].

Other than learning aids, presenters also plays a role on facilitating the note-taking process for students [8]. Two effective methods are using organizational and emphasis cues to notify key points [8]. Organizational cues aid residents organize blocks of similar information, and emphasis cues use verbal cues to promote the importance of certain information [8]. Therefore, it is important for the presenter to organize a lesson outline and rehearse before the training.

SIGNIFICANCE

The pathway to become a successful pharmacist can be difficult, especially with increasing demand for preceptors with research experience [9]. The purpose of research for pharmacy residents is to equip them with the ability to conduct and manage a major clinical research project and make their resumes more competitive [9]. One of the most important processes is learning how to submit their applications to the internal review board (IRB) following the

process in Figure 1. During submission, it is critical for the resident to know and complete all the requirements to get approval in a timely manner. However, only 24% of research submissions were approved without modifications [10]. Other than completing the required documents, submitting protocols online using a new system can be confusing and stressful. In order to facilitate the submission process for the pharmacy residents, it is necessary to understand what to submit to the IRB and expedite the submission process.

SPECIFIC AIMS

The purpose of the project was to provide a more effective way to train pharmacy residents on what forms to complete and how to navigate through iRIS. If the modified method can deliver the learning material in a more eloquent way, it would expedite the submission process. The pharmacy residents could also direct more time and effort on completing their research studies on a timely manner. If possible, this study can also apply to future iRIS training for any new hospital staff for Baylor Health Center.

The null hypothesis was that this year's training is not going to be significantly different compared to the training in 2014. The alternative hypothesis was the training method would allow pharmacy residents to successfully submit their applications fewer times before the final approval compared to residents in 2014.

Interaction with subjects	Chart Review/Existing Specimens
1. Study Application 2. Form 1 3. Form 35 or PI electronic signature 4. Form 34 or administrator electronic signature 5. Form 18 or scientific reviewer electronic signature 6. Consent forms or Survey Cover Letter 7. Protocol 8. Investigator Drug Brochure (if applicable) 9. Other supplemental documents (questionnaires, advertisements, patient materials, instructional tools, etc.) 10. Finance Forms	1. Study Application 2. Form 15 3. Form 35 or PI electronic signature 4. Form 34 or administrator electronic signature 5. Form 18 or scientific reviewer electronic signature 6. Protocol 7. Other supplemental documents (if applicable) 8. Finance Forms

Table 1. Required documents for initial submission to the IRB.

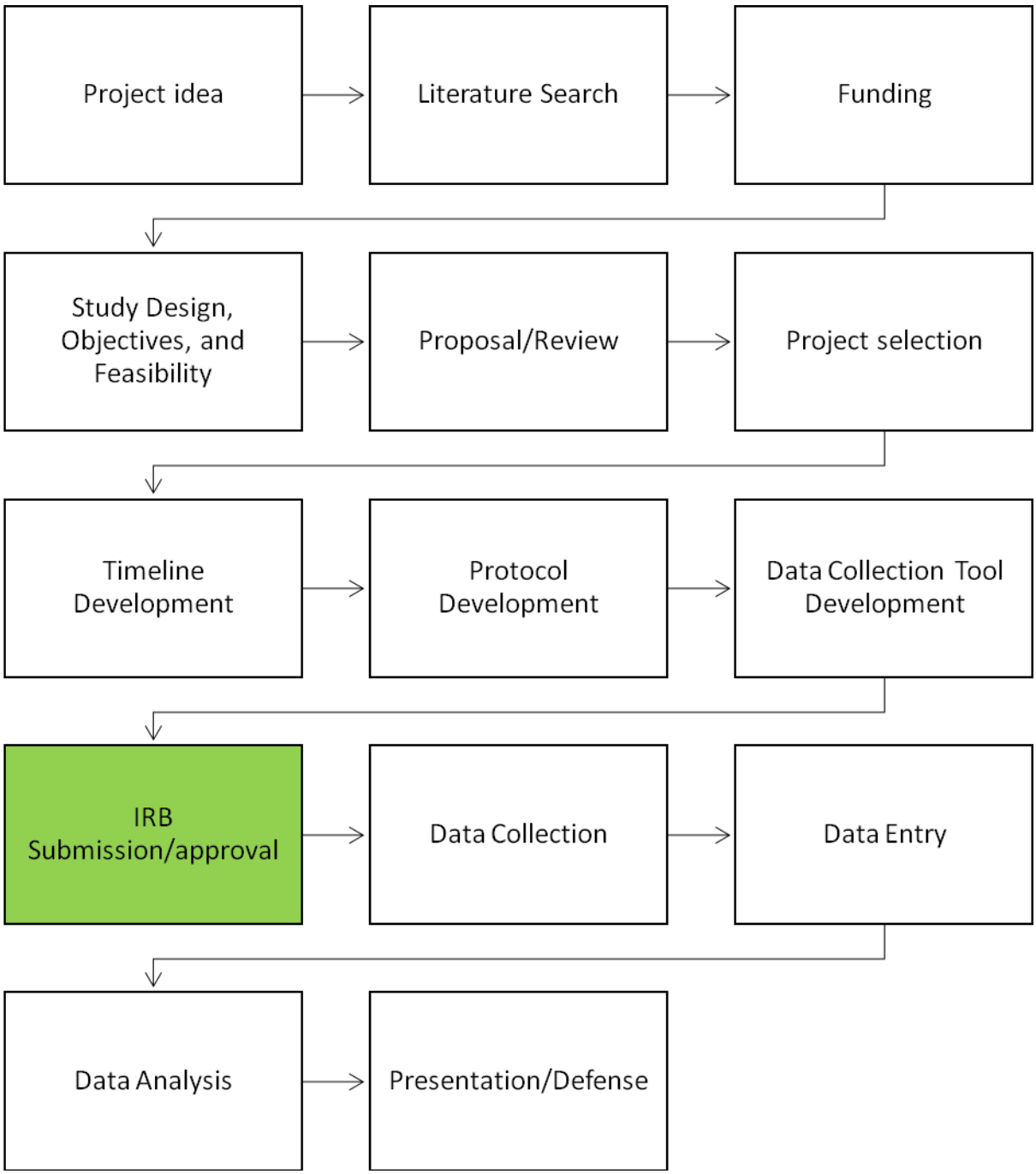

Figure 1. The generalized process of each research project.

CHAPTER II.

MATERIALS AND METHODS

SUBJECTS

Pharmacy residents who attended the IRB training in 2014 and 2016 were screened for their submission histories on iRIS. Four residents from 2014 and two residents from 2016 were eligible for the study. There are total of one male and three females from 2014, and one male and two females from 2016.

PROCEDURE

The study evaluated the effectiveness of the IRB training by comparing the average number of submissions made from pharmacy residents from 2014 and 2016 before the final approval by the BSWRI IRB. The pharmacy residents were selected under inclusion and exclusion criteria to minimize bias based on their submission histories obtained from iRIS.

1. Inclusion criteria:
    a. The pharmacy resident must be new to iRIS.
    b. The pharmacy resident must submit an expedited study.

2. Exclusion criteria:

    a. The pharmacy resident had prior submission history on iRIS.

    b. The pharmacy resident attended the iRIS training in the past with Baylor.

The residents in 2014 were given Form 1, Form 15, iRIS Clinical User Guide, non-clinical informed consent template, survey cover letter template, presentations on common errors that students made, and a real-time presentation on how to build a research application on iRIS through a projector. All the submission histories were examined from residents from 2014 to see if any resident met the criteria. Two of five residents were selected and their names were replaced by 01-001, 01-002, 01-003, and 01-004 after transferring their submission histories on an excel sheet. The gender of the residents was symbolized by M or F, male or female. The 01 was used to identify the residents from 2014. The residents were also informed and given email addresses of IRB specialists if they had questions before their submissions. Few residents contacted Heather and had average of one phone call or one email reply per resident who reached out for assistance. Heather was also the one who looked at each individual study and determined the status of the individual study since she processed expedited studies back in 2014.

The residents this year were provided with the same materials and presentation from 2014 but with additional note outlines for Form 1, Form 15, and research application presentation. The residents from 2016 also had an email follow up two months after the training to offer assistance. Any resident who asked for help only received one phone call or one personal meet up to ensure fair use of time and resources and eliminate any potential bias. The residents were selected based on the criteria and their submission histories were acquired. The names of the residents were replaced by 02-001, and 02-002. The gender of the residents was symbolized by M or F, male or female. The 02 was used to identify the residents from 2016. After the study application was

uploaded, Heather was the one who processed the studies submitted by the residents. The data for residents from 2016 were obtained from September 2016 to October 2016.

During the data collection, de-identification was used by removing names and replacing with numbers to ensure confidentiality and privacy. The data were pasted and saved on to an excel sheet on a password-protected computer in BSWRI.

ANALYSIS

The average numbers of time from the two sub-groups were compared by Welch's t-test. The calculation was carried out on a formatted excel sheet with Welch's t-test. The justification of using Welch's t-test are listed below:

1. The two samples had unequal sizes.
2. The data had two types of variables for each subgroup: one nominal variable (year of the class) and one measurement variable (the number of times that the residents submitted before the final approval).
3. Normality and homogeneity of variances are not assumed in this case.

If the p-value is less than 0.05, there would be a statistical significance between the IRB training in 2016 and 2014.

CHAPTER III.

RESULTS AND DISCUSSIONS

RESULTS

The data from 2014 residents were obtained from iRIS after the UNTHSC IRB approval (Table 2). There were total of four residents from 2014. The average number of submissions by the 2014 residents was 2.5 times. The data from 2016 residents were obtained between the month of October and November 2016 (Table 2). There were total of two residents from 2016. The average number of submissions by the 2016 residents was 2.5 times. The average number of submissions did not differ between 2014 and 2016 ($t=5$, $p=1$), shown on table 4.

DISCUSSION

The result showed that there was no change in effectiveness of the modified training in 2016 compared to classic training in 2014. One of the major factors might be the presenter. The person who gave the training was not able to present for the 2016 residents due to unforeseen circumstances. Another IRB specialist had to present without any preparation. One of the changes for this year's training was to emphasize important points during the presentation in order to help the residents remember the common errors that were made in 2014. However, the IRB specialist that gave the presentation in 2016 did not know what points to emphasize. The

incident might not help residents understand how to avoid common errors, which caused the equal number of submissions this year.

Another factor might be the skeleton notes not being effective. Each section on the skeleton notes was spaced out based on what Heather would need to take notes. The space provided may not be enough for the residents to take notes effectively.

A third factor that might have contribute to the lack of effectiveness was that there were not many residents submitting this year. There were two residents who intended to submit during October but later decided to delay their submission until January 2017. The result may have led to insufficient data points to determine whether the training was effective or not effective.

Although the result was not statistically significant, the residents from 2016 had fewer major corrections sent back to them compared to the residents from 2014. The stipulations are shown on table 3. The reviewer from 2014 and 2016 stated that the skeleton outline did improve the quality of the submission by eliminating major corrections such as not missing documents or study application not consistent with Form 1/15. The two residents that submitted this year were not missing any forms and everything was filled out correctly. The studies were sent back for minor changes. It was an interesting observation since the average number of submissions did not change.

Lastly, the data from the residents from 2015 were not compared against the 2016 data due to two reasons. The IRB department was reported to be under staffed in 2015, so there were not enough resources to provide full support for the residents when they called in to ask questions. The second reason was due to lack of residents that attended in 2015. Because there were more residents in 2014, the chance of having more submissions was higher compared to the residents in 2015.

LIMITATIONS

There were some limitations to the study. Since only pharmacy residents were studied, the study cannot be applied to other populations such as new scientists or doctor. Another major limitation was not being able to collect demographic information. During the training, only names of the residents were obtained. Thus, only genders can be inferred. Other vital information such as ethnicity or age could not be collected. Lack of demographic information contributes to the lack of generalization of the study.

FUTURE DIRECTIONS

There was not a change in the number of submissions requiring correction between 2014 and 2016. However, there were fewer errors and the stipulations were less involved in 2016. The major change to make for future studies is to develop an objective measure of the significance of the errors made. Another improvement is to have training material standardized. Since the IRB specialist from 2016 was not able to deliver the training material due to lack of preparation, it is essential to make sure that does not happen next time by printing out a summary sheet of what the main presenter was going to talk about. This may improve the quality of the submission from the residents along with the skeleton notes outline.

Another improvement that can be made is to provide another way to learn about the IRB materials. Since everyone learns differently, some students may not learn best from lectures. The IRB department can record online videos for some pharmacy residents to watch online since some people learn better on their own. Other than videos, the IRB department can also different memory aids other than the skeleton notes provided. The change may increase memory retention of the training materials.

SUMMARY AND CONCLUSIONS

The study was done on two groups of residents (2014 and 2016), and the result showed no change after the modification of the IRB training. Although the average number of submissions turned out to be no change, the quality of the submissions seemed to improve with fewer corrections required. There were still possibilities for the training to improve the number of submissions by eliminating confounding variables. The study can be refined by using other memory aids or better presentation on how to avoid common mistakes.

Welch's T-Test		
	Numbers of Submission made	
	2014	**2016**
	3	2
	2	3
	2	
	3	
Total population	$n_1 = 4$	$n_2 = 2$
Average	2.5	2.5
	p-value-->	1

Table 2. Number of submissions over the two years of the project.

2014 Residents	
01-001M	1. Missing Form 34/18 2. Missing Form 15 3. Form 15 does not match study application
01-002F	1. Missing Form 34/18 2. Protocol needed clarification 3. Form 15 not filled out correctly 4. Need clean data sheet
01-003F	1. Form 18 not filled out correctly 2. Study application not filled out correctly 3. Data collection sheet 4. Form 15 need clarification
01-004F	1. Form 34/18 not filled out correctly 2. Form 15 need revision 3. Need clarification on study application
2016 Residents	
02-001F	1. Co-investigator need t to complete training 2. Clarification on Form 15
02-002F	1. Clarification on Form 15

Table 3. Stipulations sent back for corrections.

CHAPTER IV.

INTERNSHIP EXPERIENCE

DESCRIPTION OF INTERNSHIP SITE

Baylor University Medical Center (BUMC) at Dallas was established in 1903 [11]. The goal of BUMC is to serve all people by providing care, education, and research as a Christian ministry of healing and a non-profit organization [12].

In 1984, Baylor Research Institute (BRI) was established [13] and led by Michael Ramsay MD [14]. BRI was renamed Baylor Scott and White Research Institute (BSWRI) in 2015 [13]. BSWRI is the governing body that oversees all research in the Baylor Healthcare System and the administration behind the IRBs at Baylor [15]. The purpose of BSWRI is to find prevention therapies and treatments for diseases and illnesses [14]. BSWRI has Full Accreditation from the Association of the Accreditation of Human Research Programs (AAHRPP) in 2003 and 2006 [14].

There are two locations for BSWRI: Dallas and Temple [16]. The site in Dallas consists of eight departments: grants and contracts, financial services, marketing, iRIS support, ClincalTrials.Gov support, regulatory affairs, quality assurance, and IRB specialists. The departments work together and they are all located in the same area for easy communication.

The vice president of the BSWRI is Elizabeth Cothran M.S., CIP, CHPC. The IRB Team that I worked with are Heather Whitacre, Brittany Grimes, Dolores Juarez, Monica Lawrence, Mary deHaas, Gail Colbert, Latoysha Cox, and Francis Kanayo.

JOURNAL SUMMARY

When I first started working for BSWRI IRB department, I knew a little bit about how the IRB works. However, throughout the experience, I was able to read about how the Baylor IRB works, attend many IRB meetings and learn about the process of study submission, process paper work and deal with serious adverse events, read and understand different types of studies, and learn about IACUC and how animals are protected more than human subjects. I was also able to look around and help with the inspection for the animal facilities that Baylor owned with the manager of the animal facility.

Other than learning about work, I was also able to work closely with the IRB team to learn what they do. There are two main groups, the regulatory team (the team I am on) and the financial/legal team. The regulator team deals with the ethical parts of the study. The team would regularly process paper work on serious adverse events, and monitor studies. The financial/legal team works with contracts, billing compliance, and funding of the research. Each member of the IRB team is vital for the BSWRI IRB to work, and I was impressed by how well every one works together.

Finally, I was able to develop an idea into a protocol and carry out the study with the pharmacy residents. I never thought I was capable of writing a thesis until my internship started. My committee members gave useful feedbacks and shaped my writing throughout the internship. I definitely have more confidence in myself compare to before.

Overall the experience at Baylor was educational and amazing. The co-workers here taught me many lessons from the IRB to what to do when I face challenges in life. They had taught me to be more knowledgeable in the regulatory field of the study, and also how to be a better person in life.

APPENDICES

APPENDIX A.

FORM 1

Baylor Research Institute
Institutional Review Board
Supplemental Application

Project Title: _____.

Principal Investigator: _____

	Protocol Summary: The answers to the questions in this section should be included in an attached research protocol. Simply provide the page number and paragraph within the protocol where this information is included. DO NOT copy this information into this document. If the protocol does not include this information in detail, please put in a separate document and attach to the submission.
1	**Study Objectives:** (Page #/Paragraph in Protocol)_____If not included in protocol (or other supporting documents), please explain why: _____
2	**Study Design:** (Page #/Paragraph in Protocol)_____If not included in protocol (or other supporting documents), please explain why: _____
3	**Scientific Rationale:** (Page #/Paragraph in Protocol)_____If not included in protocol (or other supporting documents), please explain why: _____
4	**Historical Information/Animals:** (Page #/Paragraph in Protocol) _____If not included in protocol (or other supporting documents), please explain why: _____
5	**Historical Information/Humans:** (Page #/Paragraph in Protocol) _____If not included in protocol(or other supporting documents) , please explain why: _____
6	**Physical Risks:** (Page #/Paragraph in Protocol) _____If not included in protocol (or other supporting documents), please explain why: _____
7	**Psychological Risks:** (Page #/Paragraph in Protocol) _____If not included in protocol (or other supporting documents), please explain why: _____
8	**Social Risks:** (Page #/Paragraph in Protocol) _____If not included in protocol (or other supporting documents), please explain why: _____
9	**Legal Risks:** (Page #/Paragraph in Protocol) _____If not included in protocol , (or other supporting documents) please explain why: _____
10	**Economic Risks:** (Page #/Paragraph in Protocol) _____If not included in protocol (or other supporting documents), please explain why: _____
11	**Potential direct benefits to research subjects:** (Page #/Paragraph in Protocol) _____ If not included in protocol(or other supporting documents), please explain why: _____
12	**Potential future benefits to individuals with the condition being studied:** (Page #/Paragraph in Protocol) _____If not included in protocol (or other supporting documents), please explain why: _____
13	**Potential benefits to society in general:** (Page #/Paragraph in Protocol) _____If not included in protocol (or other supporting documents), please explain why: _____
14	**Potential benefits to others involved in the research:** (Page #/Paragraph in Protocol) _____If not included in protocol (or other supporting documents), please explain why:

	_____
15	**Provisions in place to protect confidentiality of research related information:** (Page #/Paragraph in Protocol) _____Additional provisions specific to your department : _____
16	**Provisions in place to protect the privacy of the research subjects:** (Page #/Paragraph in Protocol) _____Additional provisions specific to your department : _____
17	**Provisions in place to protect the PHI collected during the study:** (Page #/Paragraph in Protocol) _____Additional provisions specific to your department: _____
18	**Risk to benefit analysis:** (Page #/Paragraph in Protocol) _____If not included in protocol, please explain why: _____
	Study Subjects
19	**Inclusion/Exclusion Criteria** (Page Number/Paragraph in Protocol): _____
20	**Protocol specific rationale for the exclusion of any group of individuals for whom this treatment could potentially benefit (i.e., women, children, non-English speaking):** _____
21	**Age Range:** (must include specific age in days, months, or years) _____ to _____
22	**Gender:** ☐ Male ☐ Female ☐ Both
23	***Special Populations – Children*** ☐ Section N/A – Children Excluded
A	If the age range above includes individuals less than 18 years of age, please provide the following information:
B	Enrollment of children in research requires that the research meet specific criteria. Please choose the category that best fits your proposed research project and provide protocol specific rationale for why your study meets this category: ☐ Category 1 ☐ Category 2 ☐ Category 3 ☐ Category 4 Provide Protocol Specific Rationale for your chosen category _____ • Category 1 - Research involving no greater than minimal risk (NO drug or device studies). Category 2 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The risk is justified by the anticipated benefits to the subjects and the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. • Category 3 - Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. The risk represents a minor increase over minimal risk; the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations and the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition. Category 4 -Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (requires special approval from the federal government and only applies to federally funded studies).
C	Are any (or all) of the potential subjects in this study considered to be Wards of the State? ☐Yes ☐ No. If you answer yes to this question, special provisions must be made to comply with 45 CFR 46.409. Please contact the IRB Office Directly for further guidance.

D	If any of the child subjects are considered to be neonates, please identify which categories apply (see BRI Policy 856 for guidance)
E	☐ **Viable Neonates** ☐ **Non-Viable Neonates –** Contact the IRB Office for Special Instructions ☐ **Neonates of Uncertain Viability –** Contact the IRB Office for Special Instructions
24	***Special Populations – Pregnant Women*** ☐ Section N/A – Pregnant Women Excluded
A	If your study population includes women who are pregnant, provide the following information. It is acceptable to reference specific sections within the protocol to support this claim. Please attach supporting documentation where appropriate.
B	• Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and data provided for assessing potential risks to pregnant women and fetus. _____ • The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means. _____ • Any risk is the least possible for achieving the objectives of the research. _____ • No inducements, monetary or otherwise, be offered to terminate a pregnancy. _____ • No individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. _____ • No individuals engaged in the research will have any part in determining the viability of a neonate. _____
	Pregnant Teenagers…….
25	***Special Populations – Non English Speaking*** ☐ Section N/A – Non-English Speaking Excluded Rational for exclusion of this group must be provided. _____
A	**Spanish speaking subjects.** Due to our geographic location and potential patient population, we do not allow exclusion of this group of subjects except in unusual situations. Additionally, to allow for an equitable consent process for these subjects, we prefer that the full consent document be translated into Spanish. If you have a unique situation which you would like considered for an exception to allow use of the short form document, please contact the IRB Office directly. ☐ Spanish translation of the entire consent document (preferred) ☐ Spanish version of the short form document –bilingual witness required (provide justification) _____. *With either of these documents you must also have a translator available who will facilitate the translation process. This translator can NOT be a family member/friend of the research subject. It can be a member of the research team, physician practice group, certified translator from the hospital guest services department or other comparable individual.* Translator: _____
B	**Other non-English speaking subjects.** There may be individuals who are non-English

	speaking with primary languages other than Spanish. If this population is anticipated to be a part of the potential subject pool, we expect that adequate provisions will be made to enroll them in the study. Please outline the provisions you will make for these subjects and obtaining consent. See BRI Policy 841 for regulatory requirements for this process. ☐ Translation of the entire consent document ☐ Translated version of the short form document –bilingual witness required Specify language(s): _____ *With either of these documents you must also have a translator available who will facilitate the translation process. This translator can NOT be a family member/friend of the research subject. It can be a member of the research team, physician practice group, certified translator from the hospital guest services department or other comparable individual.* Translator: _____
26	***Special Populations – Elderly*** ☐ Section N/A – Elderly Excluded (If your study has no upper age limit, this section must be completed)
	☐ **Elderly (>64) – Please remember age specific competencies and special needs of this age group when answering these questions.** **Protocol specific rationale for enrolling these subjects: _____** **Special provisions to protect these subjects: _____**
27	***Special Populations – Unable to Consent*** ☐ Section N/A – Unable to Consent Excluded ***(Cognitive Impairment or Physical Illness/Injury)***
A	☐ **Cognitively Impaired (mentally challenged, alzheimers, etc)** (See BRI Policy 857 for guidance) **Protocol specific rationale for enrolling these subjects: _____**These subjects should only be enrolled if their condition is directly related to the purpose of the research. **Special provisions to protect these subjects: _____** **How will you assess the capacity of these individuals to provide informed consent: _____** **Special Consent Requirements (both are required)** • Informed consent will be obtained from legally authorized representative. Please outline process _____ (See BRI Policy 857 for individuals who qualify under Texas Law) • Assent of the subject will be obtained. Provide specific information on method and timing: _____
B	☐ **Medically Unable to Consent (comatose, head trauma, etc)** (See BRI Policy 857 for guidance) **Protocol specific rationale for enrolling these subjects: _____**These subjects should only be enrolled if their condition is directly related to the purpose of the research. **Special provisions to protect these subjects: _____** **Special Consent Requirements (both are required)** • Informed consent will be obtained from legally authorized representative. Please outline process _____(See BRI Policy 857 for individuals who qualify under Texas Law) • Informed consent will be obtained from the subject as soon as they are physically

	able to provide such and they will be informed that they can withdraw from the study if they so choose. Provide specific information on method and timing: _____
28	***Special Populations – Employees & Students*** ☐ Section N/A – Employees & Students Excluded
A	☐ **Employees (Employees of any BHCS entity and/or the individual investigator)** **Protocol specific rationale for enrolling these subjects: _____** **Special provisions to protect these subjects: _____**(at minimum, supervisors or individuals in authority may not approach and/or consent individuals into the study)
B	☐ **Students (this only applies to students from institutions working with BHCS)** **Protocol specific rationale for enrolling these subjects: _____** **Special provisions to protect these subjects: _____** (at minimum, supervisors or individuals in authority may not approach and/or consent individuals into the study)
29	***Special Populations – Others*** ☐ Section N/A – Special Populations
	☐ **Educationally Disadvantaged** ☐ **Economically Disadvantaged** ☐ **Terminally** ☐ **Other (be specific): _____** ☐ **Other (be specific): _____** ☐ **Other (be specific): _____** If any of the above is checked, then the following two items must be completed. Ensure that the site's special provisions to protect the vulnerable populations is appropriate for that group. **Protocol specific rationale for enrolling subjects from these groups (include all groups): _____** **Special provisions to protect these subjects (include all groups): _____**
30	***Special Populations – Prisoners*** ☒ Section N/A – Prisoners Excluded
	Baylor Research Institute does not have a Prisoner Advocate on either IRB, therefore, we do not allow the inclusion of Prisoners on any study reviewed at this institution. If you have a research subject who becomes a prisoner while on the research study, they must be removed from the study, except for follow up activities to assure safety. Please contact the IRB Office immediately if this occurs during the study for guidance.
	Justification of Risks
31	Based on your knowledge of the subject matter, do you believe that this study involves the alternative of least risk for the potential subjects to be enrolled in the study? ☐Yes ☐ No If no, provide justification for conducting the study**: _____**
32	Have evaluations of less risky alternatives been done? ☐Yes ☐ No If yes, summarize: _____
33	If the study has the potential for research related injuries or problems (physical or psychological) – please describe any procedures that are in place to provide medical/psychological care to the subjects if these problems occur. This explanation should not simply address who will pay for the care, but should address how the care will be provided: _____
	Informed Consent Process

34	Provide information regarding **specific location** of obtaining informed consent. This would include clinical area, surgical suite, etc. If multiple locations are a possibility, please list all. Keep in mind that this should be one in an environment to minimize coercion and to lead to subject being comfortable with asking questions and making a truly informed decision. _____
35	Provide information regarding **timing** of obtaining informed consent. Include specifics and details such as when in relation to the beginning of the procedures that you will obtain informed consent, the amount of time provided for making the decisions. It is important that subjects are provided as much time as possible to make the informed decision. If the nature of the study allows for only a minimal time to make a decision and/or requires decisions be made immediately prior to the study, please explain why this is needed and acceptable for the particular study: _____
36	Please describe how you will manage consent as an ongoing process. This includes such things as providing new information to subjects while study is ongoing, reminders at follow up visits regarding the study, etc. : _____
37	Describe steps taken to minimize the possibility of coercion or undue influence. : _____
38	Does your study involve only the completion of surveys? ☐Yes ☐ No If yes, your study may qualify for a waiver of documentation of consent. This process allows for you to utilize only a survey cover letter explaining the study without collecting written informed consent. Please see BRI Policy 843 or contact the IRB Office with questions. If your study qualifies for Waiver of Documentation, please use the template Survey Cover Letter Consent and upload a document with this submission.
39	If additional tools, handouts, other written materials are used (other than the IRB approved consent forms) these must provided to the IRB for review and approval prior to their use. Will you use additional tools during the study? ☐Yes ☐ No If yes, these must be uploaded electronically and attached to the IRB application.

APPENDIX B.

FORM 15

Baylor Research Institute
Institutional Review Board
Supplemental Application – Form 15
Review of Existing Records or Tissue Only

Project Title: _____

Principal Investigator: _____

1	What type of information will be reviewed for research? Please check all that apply: ☐ Medical Record/ Chart Review ☐ Films/X Rays ☐ Computer/Database ☐ Hospital Administrative/Billing Records ☐ Quality Improvement Records ☐ Other types of records (please specify) _____ ☐ Existing Specimens – specify specimen type and source (tissue bank, etc.) _____
2	**NA**
3	Will any individuals other than those listed as Key Study Personnel be given access to the research data? ☐ Yes ☐ No If yes, please list individuals and provide reason for the access _____
4	Briefly describe the purpose and description of the study. This should include the rationale for conducting this research as well as the methods of analyzing and protecting the data. **You are required to attach a short project summary to this document to supplement this form**. _____
5	Does this study involve the analysis of existing specimens? ☐ Yes ☐ No If yes, what is the source of the specimens (i.e. clinical pathology, tissue/blood bank, etc.): _____ If yes, how many specimens will be analyzed? _____
6	Does this study involve review of medical records and/or databases? ☐ Yes ☐ No If yes, which charts and/or databases will be searched? _____ If yes, how many charts (paper or electronic) will be reviewed? _____
7	Will data be sent outside of the BHCS facility? ☐ Yes ☐ No If no, please note that subsequent release of data outside of the BHCS facility requires approval. Investigators will need to update the request. If yes, where will data be sent? _____ Why is it necessary to send data outside the BHCS facility? _____

8	How will data be sent? (Describe actual methods and include plans for coding and/or encryption): _____
9	Provide the date range for creation of clinical data: These dates should reflect the date that the information became (or will become) a part of the medical record or database. This date is not intended to identify the dates that the researcher will be conducting the reviews. Provide specific dates that include month, day and year. _____ to _____
10	This data is to be used for (check all that apply): ☐ Publication ☐ Presentation ☐ Other _____
11	Please check all categories of data that will be obtained during the record/database review: ☐ Demographics (age, sex, address) ☐ Drug/Device Utilized ☐ Diagnosis ☐ Length of Stay ☐ Lab Values ☐ Service Location (OR, ER, Inpatient, Outpatient) ☐ Radiology Testing ☐ Clinic Notes ☐ Procedures/ Treatment ☐ Provider of record (who saw pt, signed d/c note) ☐ Billing/Charges ☐ Other _____
12	The following information is considered identifiable under the Privacy Rule regulations. Please choose all of the following will be obtained. For purposes of this question, it is all data that is collected for data analysis, not necessarily the publication. So if it is gathered on the data collection sheet, it should be indicated here. If any of these elements are check off, under Privacy Rule provisions it cannot be considered de-identified and authorization from the subject or a waiver of authorization granted by the IRB is required. If none will be obtained, check that box. : ☐ Subject Name ☐ Address Street Location ☐ Address Town or City * ☐ Address State * ☐ Address Zip Code * ☐ Elements of Dates (except year) related to a subject. For example, date of birth, admission or discharge dates, date of death * ☐ Telephone Number ☐ Fax Number ☐ Electronic mail (e mail) Address ☐ Social Security Number ☐ Medical Record Numbers ☐ Health Plan Beneficiary Numbers ☐ Account Numbers ☐ Certificate/License Numbers ☐ Vehicle Identification Numbers and Serial Numbers Including License Plates ☐ Medical Device Identifiers and Serial Numbers ☐ Web URLs ☐ Internet Protocol (IP) Address ☐ Biometric Identifiers (finger and voice prints)

	☐ Full Face Photographic Images ☐ Any Unique Identifying Number, Characteristic or Code ☐ Link to Identifier (code) ☐ None of the above listed items will be recorded (Skip to the signature section) * These items may be included and considered a "limited data set." Use of data under the provisions of a "limited data set" require the signing of a data use agreement by the recipient (this includes researchers) or a request for a waiver of authorization or authorization is required. **You must also attach a copy of your data collection sheet. This could be the blank spreadsheet which includes the headings of data points that will be collected from the medical records.**
13	If links to identifiers are used, please describe the coding mechanism: _____
14	You are required to only obtain the minimum necessary data in order to achieve the goals of the research. Please justify why the data you are obtaining is the minimum necessary to achieve the goals of the research. _____
15	Federal regulations require that informed consent and authorization to use private health information be obtained for all research involving human subjects, including medical record/chart/database reviews. However, the IRB is allowed to waive this requirement for consent and authorization for private health information if the following conditions are met. If you wish to request a waiver of consent/authorization, please provide the justifications as listed below. (attach additional pages if necessary). This section must be completed if any identifiers in #12 are being collected OR if either date in #9 is in the future. (a) The proposed use of this data/document/record presents no more than minimal risk to the privacy of individuals because: _____ (b) The research could not practicably be conducted without the waiver of informed consent and authorization because: _____ (c) The research could not practicably be conducted without access to and use of protected health information because: _____ (d) Waiving informed consent will not adversely affect the subject's rights or welfare because: _____
16	Please describe the steps taken to assure privacy and confidentiality of subject data and to protect the identifiers/ links to identifiers from improper use or disclosure: _____

17	You are required to destroy identifiers (or links) at the earliest possible time. Please describe this plan and specify when this will occur. If there is a justification for retaining the identifiers, please provide this information: _____

APPENDIX C.

SKELETON NOTES FOR FORM 1 AND 15.

Skeleton Notes for Form 1 and 15

Please take notes during presentation to help you on your study application submission. The forms will need to be filled out correctly in order to be approved. If any part of the application needs correction, it will be sent back and it will delay your approval (which might potentially delay your projected completion date for your study). If you have any question, please do not hesitate to ask any of the IRB specialist to help you after the presentation. Please pay special attention to any error-prone sections that are mentioned! They will help you along the way.

FORM 1

Project Title:

Principal Investigator:

Question 1 – 5: Research information

Question 6 – 10: Risks

Question 11 – 14: potential benefits

Question 15 – 17: Provisions

Question 18: Risk-benefit ratio

STUDY SUBJECTS

Question 19 – 22: subject information

Question 23. SPECIAL POPULATION – Children

A. Age Range

B. Category

1:

2:

3:

4:

C. Wards of the State

D. Neonates

E. Type of neonates

Viable Neonates

Non-viable neonates

Neonate of Uncertain Viability

Question 24. SPECIAL POPULATION – Pregnant Women

A.

B.

Pregnant Teenagers:

Question 25. SPECIAL POPLUATION – Non English Speaking

A. Spanish speaking subjects

B. Other non-English speaking subjects

Question 26. SPECIAL POPLAUTIONS – Elderly

Protocol specific rationale for enrolling these subjects:

Special provisions to protect these subjects:

Question 27. SPECIAL POPULATIONS – Unable to Consent

A. Cognitively Impaired

Protocol specific rationale for enrolling these subjects:

Special provisions to protect these subjects:

B. Medically Unable to Consent

Protocol specific rationale for enrolling these subjects:

Special provisions to protect these subjects:

Question 28. SPECIAL POPULATIONS – Employees & Students

A. Employees

Protocol specific rationale for enrolling these subjects:

Special provisions to protect these subjects:

B. Students

Protocol specific rationale for enrolling these subjects:

Special provisions to protect these subjects:

Question 29. SPECIAL POPULATIONS – Others

Protocol specific rationale for enrolling these subjects:

Special provisions to protect these subjects:

Question 30. SPECIAL POPULATIONS – Prisoners

Baylor Scott & White Research Institute does not have a Prisoner Advocate on either IRB. Thus, we do not allow the inclusion of Prisoners on any study reviewed at this intuition.

JUSTIFICATION OF RISKS

Question 31 – 33:

INFORMED CONSENT PROCESS

Question 34 – 39:

FORM 15 – Review of Existing Records or Tissue Only
Project Title:
Principal Investigator:
Question 1. Type of information reviewed

Question 2. N/A
Question 3. Key Personnel

Question 4. Purpose and Description of the Study
Question 5. Analysis of existing specimens

Question 6. Review of Medical Records?

Question 7. Data being used outside of BHCS facility

Question 8. How will the data be sent (following question 7)?

Question 9. Date range for creation of clinical data

Question 10. Data is used for

Question 11. All categories of data will be obtained

Question 12. Identifiers

Question 13. Links of identifiers

Question 14. Minimum necessary data

Question 15. Waiver of informed consent

a) The proposed used of this data/document/record presents no more than minimal risk to the privacy of individuals because:

b) The research could not practicably be conducted without the waiver of informed consent and authorization because:

c) The research could not be practicably be conducted without access to and use of protected health information because:

d) Waiving informed consent will not adversely affect the subject's rights or welfare because:

Question 16. Steps taken to assure privacy and confidentiality of subject data

Question 17. Plans to destroy identifiers

Reminders for myself:

APPENDIX D.

STUDY APPLICATION OUTLINE.

Study Application Outline

Please take notes during the presentation to guide you through your submission process on iRIS. Also, pay special attention to any error prone sections mentioned – they are the main reasons why study applications were sent back for corrections.

Part 1: Section View of Application

1. General Information

2. Setup Department(s) Access

3. Grant Key Personnel access to the study

4. Type of Application*

5. Type of Project*

6. Funding Information*

7. Scientific/Scholarly Review

8. Research Team Members

9. Administrative/Clinical Oversight

10. Use of FDA Regulated Products

11. Drugs

12. Devices

13. Subject Recruitment*

14. Data Safety Monitoring Board

15. Use of Radiation

16. Supplemental Review

Part 2: Attaching Forms

1. Study Application

2. Consent Forms

3. Other Study Documents

Notes for myself:

APPENDIX E.

IRB APPOVAL LETTER.

UNT | HEALTH SCIENCE CENTER

Office of Research Compliance

DATE: August 4, 2016

TO: Patricia Gwitrz, PhD
with CRM student Yuhung Holy Chou
Clinical Research Management
Graduate School of Biomedical Sciences

FROM: Brian Gladue, PhD
Executive Director, Office of Research Compliance

SUBJECT: **Not Human Subject Research Determination of "Submission to the IRB: Will Individualized Training Improve Successful Submission of IRB Protocols"**

The Office of Research Compliance (ORC) received and reviewed the Exempt Application submitted for the above named Clinical Research Management project. Based on the information provided, the ORC determined the activity (involving the review of IRB records from Baylor Research Institute) to be **quality assurance** and subsequently does **not** meet the federal definition **human subject research**. More specifically, the activity does not meet the criteria of being a systematic investigation and does not appear to involve human subjects (data collected / reviewed are related to IRB submission history) as defined by federal regulations. Therefore, further review of this specific activity by ORC and/or the IRB is not needed at this time.

Please note that *in the event* that any *other* qualitative data collected *about* an individual and for non-human subject research purposes becomes of interest (i.e., identify systematic trends and patterns that create generalizable knowledge), and you would like to use it for human subject research purposes, please contact the ORC / IRB for appropriate guidance and review before the data are used in publications, presentations or in any human subject research forum.

As always, if you have any questions regarding UNTHSC policies and/or federal regulations, please feel free to contact the Office of Research Compliance (817-735-0408).

We wish you good luck with this activity.

APPENDIX F.

JOURNAL ENTRIES.

JOURNAL ENTRIES

First Week

05/31/2016 – First day

Today was my first day of internship, and I arrived at 8:30AM to start my day. I was greeted warmly by Lisa at the front desk. After a moment, Latoysha, the executive assistant, showed me around the office helped me organized my personal desk. I also read through infectious substance shipping training materials while waiting to get my badge. After I got my identification, I was reading and preparing for the upcoming meeting for Baylor Scott and White Research Internal Review Board (IRB) Blue - which is a committee that meets monthly to hear recommendations and review research proposals. I will be working on my proposal tomorrow, since I do not have my login information today.

06/01/2016

I had an interesting day because I got the chance to sit through a biosafety meeting with Elizabeth. According to Elizabeth and Heather, the meeting only happens twice a year. A biosafety meeting approves or sends back studies that involves recombinant nucleic acid. At the meeting, I noticed that the committee members were careful and thoughtful. When the cases were presented, people were aware of inconsistencies and potential missing elements. I was impressed by their attention to details. During the process, I learned the meaning of mixed phases of clinical trials. After the meeting, I did some online training for new employees. I feel like a staff here already. Lastly, I met up with Elizabeth to talk about the day. I got my login information through Elizabeth, but my desktop computer was not able to connect to the internal network. I am betting on my computer to work tomorrow so I can start on my proposal.

06/02/2016

The first thing I did when I came into the office was to contact the technician. I hope I will be able to use the network soon for my proposal project by the end of the week. Before the IRB Blue meeting, I was reading today's agenda. About 11AM, Heather, Elizabeth, and I started walking toward the hospital. The meeting was located at the seventeenth floor of the Baylor hospital. During the meeting, I was able to observe how the IRB meeting goes. In a typical IRB meeting, there has to be a certain amount of voters present (quorum) in order to start a meeting. There was also an educational reading that the voters had to do, which was "Regulating Research with Human Subjects – Is the System Broken?" The writer stated that the system is not broken – it is just hard to adjust old standards with new types of research that is going on in modern era. The writer proposed that we should just modify the regulatory rules instead of revamping the whole process. The IRB committee then continued the meeting by discussing clinical trials. During the discussion, they were concerned about how the informed consent was written, and they mentioned risk-benefit balance of each trials before approval. The committee was very detailed about what each study was missing. Overall, the IRB Blue meeting was very similar to the biosafety meeting that I had yesterday. After the meeting, the technician came and fixed my computer. Lastly, I had a meeting with Heather about the IRB meeting that happened today. She talked me through the IRB system – iRIS – step by step. Heather and I also talked about my proposal in a more detailed manner. I was glad that I got more instructions on my proposal. I cannot wait to start the research.

06/03/2016

My login information finally logged me into the Baylor system! I was excited to start working. Since most of the team went to the Fort Worth Conference, it was basically Elizabeth and I today. She assigned three readings for me to do: Expedited Review Process, Review by the Fully Convened IRB, and IRB administration. I only completed the first two – the last one will be completed on Monday. In the afternoon, I had a meeting with Elizabeth to talk about the upcoming week. I definitely look forward to next week!

Second Week

06/06/2016

The office was quiet and busy at the same time. Since Elizabeth and Heather were both fully occupied today, I decided to sit in my office and read the IRB administration paper that Elizabeth assigned me last week – total of fifty-six pages. Other than that, I set up my email signature to make it more official that I now work as an intern for Baylor Scott & White Research Institute.

06/07/2016

I had been working on my proposal online today. I went on the UNTHSC website to look for papers, but the return was minimal. I also read more supplement materials that Latoysha gave me on the first day of work. I will be having a meeting with Elizabeth and Heather tomorrow! I hope to get more directions to how to work on my proposal.

06/08/2016

I was late to work today because my cat threw up when I was about to leave my apartment. Our crew had "Coffee Talk," which was a casual breakfast meeting to hand out birthday cards, and to talk about recent updates. We all had a great laugh, and I enjoyed meeting the whole crew for the first time. Afterward, I went to the fourth floor to attend the new employee orientation. I learned about cost analysis, budget training and billing compliance, recruitment and retention during the morning session. In the afternoon session, we went over informed consent process, investigational product, study assistant highlights, and complete study start up process. After the meeting I was able to meet up with Elizabeth briefly to get some more concrete details on my proposal before she leaves for Temple the next day. It was a very educational day!

06/09/2016

Today I was learning from Francis because Elizabeth and Heather were not present. Francis taught me how to navigate around iRIS – which stands for "integrated Research Information System" – and how to process IND (investigational new drug) safety reports and SAE (serious adverse event) reports. For the rest of the day, I was working on my proposal to get most of the details down. I am hoping to finish this (at least to a certain extent) by next Monday when I meet with Elizabeth and/or Heather.

06/10/2016

I spent the whole entire day working on my proposal. I looked up some more papers and found five potential sources that could be part of my thesis. All the readings that Elizabeth assigned me last week were super helpful on writing about the IRB at Baylor. Other than that, it was a

productive and peaceful day. I cannot wait to talk about my proposal more with Elizabeth and Heather next week!

Third Week

6/13/2016

This Monday was peaceful as usual. I spent today catching up on my proposal. I am hoping to get more information from Heather this week. She came into the office in the afternoon, but she still did not look well. I hope she feels better soon. I also had an opportunity to meet up with Elizabeth to sign my journal entry and read over my first rough draft. Elizabeth wrote some corrections and told me that I was making some good progress. I am so elated to hear that. I am definitely looking forward to the rest of the week.

06/14/2016

This morning, I received an email from Dr. Millar on my first rough draft. After reading his comments, I had many things to work on. Dr. Millar really helped me on organizing my thoughts and brainstorming for more ideas. He also asked me to clarify some things that I wrote in my draft. I spent the whole day trying to look up more papers and adding more information. I am thinking about asking to meet up with Heather tomorrow or Thursday to get more information on the training materials and dates.

06/15/2016

Elizabeth is out of town today and tomorrow, so I decided to ask Heather to meet up sometimes today or tomorrow. Heather looked so much better today, and I was happy to see that. The

schedule says that I would be meeting up with her tomorrow, so I am hoping to have more stuff to work with starting tomorrow. I spent the whole day trying to find more papers and grammatical errors in my proposal. Tomorrow is the IRB white meeting, and I am so excited to learn more about the pending studies!

06/16/2016

The office was quiet this morning, and I was able to read through today's agenda for the IRB white meeting. During the meeting, we had guests coming to answer questions about the study. I think it was beneficial for the lab members to come in and answer questions because it cleared up a lot of confusion. In the afternoon, I was able to meet up with Heather to talk about the study materials. I now have a lot more things to work on! Gail also set up my iRIS account today, so I will be able to work on my research application. I cannot wait to get this started!

06/17/2016

The first thing I did when I came into my office this morning was working on my proposal. I finally got my draft updated. I also found more background information about BUMC and BSWRI online. Before noon, I had the chance to meet up with Elizabeth again to talk about my proposal and sign off on my journal entry this week. I left work after the meeting to go back home to Houston. I look forward to next week to get my proposal finalized!

Fourth Week

06/20/2016

I spent today rewriting and correcting my proposal. Dr. Gwirz was able to send me her comments on my first draft, so I was able to brainstorm more. I am still waiting on that critical

detail for my proposal in order to move forward. Other than that, I was working on the iRIS training materials that we will be using for the training. I did not really like the packet format, so I might change the format without taking out any material contents. I think attaching a sheet with definitions on there would also be beneficial for the pharmacy residents to understand more. Tomorrow is the BRI staff monthly meeting, and I look forward to it.

06/21/2016

I attended the monthly BRI meeting today, and it was about meeting patient healthcare learning needs in the digital world. The speaker was Bridget Browder! I was really happy to see her because she was my instructor for Clinical Research Management class last semester. During the presentation, I learned that the transition from paper records to electronic records is still a process. Today, only about 50% of trials are run electronically. I also learned about the pros and cons of electronic records. Bridget also did a social demonstration that reminded me that some people do not know things that I know. Bridget asked someone to teach her how to make a peanut butter sandwich. The volunteer, at first, was vague about the instruction. When the volunteer asked Bridget to “open the bread,” Bridget tore the bag open instead of opening it through untwisting the bag. Later, the volunteer told Bridget to put the knife “down.” Instead of putting the knife down on the table, Bridget dropped the knife on the ground. The experiment taught me that we have to be aware of what people know, and always be thoughtful. Bridget related the experiment back to teaching technology to another person. The person can be old or young – he or she may not know how to use a mouse or a keyboard. Overall, the meeting today was fun and educational.

06/22/2016

While still waiting for the critical information for my proposal, I came across IACUC – which stands for "Institutional Animal Care and Use Committee." Heather told me that IACUC has a stricter regulation compared to the IRB, because animals cannot give informed consent. During the IACUC meeting, the investigators may not show up to the meeting at all. Other than that, I spent the day reading the IACUC Guidebook that Heather gave me and brainstorming for the proposal.

06/23/2016

Today, I was working on my proposal. Heather told me that the pharmacy school representatives finally got back to her. The good news was that there were two different institutions. The bad news was that we will not have two separate training due to small numbers of students from each institution. After hearing that, I was able to move forward with my proposal. I think the study is going to be a comparative study between this year's and last year's class. We want to see if the result would be better (or would be the same) from a personalized training versus the generalized training from last year. Dr. Gatch told me that I needed to send my final draft tomorrow. I hope I will be able to make it.

06/24/2016

I spent the whole day working on my draft to meet my deadline. I also got to meet up with Elizabeth and Heather to look at my final draft. In the afternoon, we had a party for Deborah, who is transferring to Temple, Texas soon. I wish her the best!

Fifth Week

06/27/2016

The morning started out with lots of modifications and editing my draft with Dr. Gatch. After a couple submissions, Dr. Gatch allowed me to send to the committee members. However, I still will not be able to meet the deadline because Dr. Millar is out of town until July 5th. I hope Dr. Gwirtz replies soon and grants me the extension!

06/28/2016

I was waiting for Dr. Gwirtz's response today, but still no reply. I spent the whole day looking over more papers for proposal. I also got a chance to talk to Heather about my next step, and she proposed that I could learn how to process some forms. She was not feeling well so she left early. My meeting with Elizabeth is tomorrow, so I am hoping to learn more!

06/29/2016

I spent the morning looking over some self-taught lessons from BLN, which stands for "Baylor Learning Network." According to Latoysha, I could register myself and learn more things on my own. In the afternoon, I had a chance to meet up with Elizabeth. We talked about the proposal and the current situation about Dr. Millar. Elizabeth told me the final draft looked good!

06/30/2016

We had our office lunch meet up today. We went to a Mexican restaurant together as a team. It was my first time going out to lunch with them, and it was fun! I finally got to see the whole

team come together and chat about their lives. The lunch experience was great and it made me happy. For the rest of the day, I spent time doing self-study.

07/01/2016

Heather still did not show up today, so I was unable to meet up with her to talk about my research project. I hope she feels better soon. Like yesterday, I spent majority of the day doing self-study. This upcoming Monday is July 4th, and I am excited for the weekend.

Sixth Week

07/05/2016

After a long, restful break, I was ready to come back. Heather was here today, and I was happy to see her. I also got an email back from Dr. Millar about my proposal. I spent majority of the day putting in corrections, and emailing Dr. Gatch and Dr. Gwirtz for any writing tips. I am glad that I have a full staff supporting me.

07/06/2016

Today was my first IACUC meeting. During the meeting, I noticed the procedures for animal testing were even more meticulous compared to the procedures for human research. The reason why is because animals do not have the ability to give consent. Thus, we have to take extra precaution to ensure the animals are being well treated. After the meeting, I had the chance to look around Baylor's animal facilities. The hospital has two facilities that work with mice and rats. I was able to join Albert, the manager of the animal facilities, to watch the inspection process. Two IACUC members went with us, and they were looking for things that were expired or things that may cause safety concern for animals and humans. During the inspection, they

found a lot of things that were expired (Heparin, sanitary wipes, and isopropyl alcohol). They also pointed out one of the tables on wheels being too close to the door (which obstructed the only entrance if there was a fire going on). They both also inspected the fume hood used, and found two of them were expired (fume hoods need to be inspected by a specialist once in a while). I thought the whole process of interesting, and I was definitely excited to learn about our animal facilities.

07/07/2016

Elizabeth was out of town today. I went to work in the morning, and went to school in the afternoon to meet with and obtain signatures from Dr. Gatch and Dr. Millar. I was nervous at first because I did not think I did well on my proposal. I was afraid that my writing ability was not to standard or my idea for the project was not well thought out. I met with Dr. Gatch first, and he was very supporting and encouraging when I was asking him questions about my thesis. Since I have never written a thesis before, I was not sure if I was on the right track. Dr. Gatch was attentive to my concerns and questions, and he also gave me good tips on how to improve. Dr. Millar was also helpful and supportive when I told him my concerns. I am thankful for my committee members.

07/08/2016

I was twenty minutes late this morning because my cat made a huge mess in the kitchen. I also failed to realize that I had a meeting with Elizabeth at 8:30AM. I felt really bad because Heather and Elizabeth waited for me, and they were worried about me. They were also understanding of

the situation when I told them what happened. I was thankful yet ashamed at the same time. I spent the rest of the day catching up on my diary entries and doing self-study.

Seventh Week

07/11/2016

I made a trip to school today to turn in my proposal. After my submission, I drove back to work and studied for the rest of the day. It was a good day.

07/12/2016

Since Elizabeth was out of town, I went to Heather for any work to do. Heather sat me down and gave me details and history of Form 1 and Form 15. The forms are supplemental application that any researcher will need to fill out when they submit their research application to the IRB. Form 1 is for any research that involves human interaction. Form 15 is for any research that does not involve direct human interaction but uses their tissues, medical history, etc. Heather also talked about vulnerable population, and she pointed out the most important ones are pregnant women and children. Since they are both protected extensively, pregnant women and children do not have variety of treatments available due to lack of research. At the end of the day, I was able to process a lot of information that Heather had gave me. I learned so much today!

07/13/2016

Heather was not in this morning because her headache came back last night. I spent some time reading over what Heather gave me yesterday (Form 1 and Form 15), and I also got the sign-in sheets for the pharmacy iRIS training from last year and the year prior from Latoysha. It seemed

like there were only five people from last, and seven from the year before that. Other than that, I spent the rest of the day studying.

07/14/2016

I made a trip to school today because my MacBook charger finally came in! My cat chewed up my cord so the IT department from UNTHSC placed an order last week. Other than that, I spent my day researching about how to calculate Welch's t-test.

07/15/2016

Elizabeth is back in town, and I had a chance to meet up with her. We talked about our week and updated her about my progress. I am excited to start moving forward on Monday!

Eighth Week

07/18/2016

This morning was busy because class registration opened for fall. I managed to register myself to the right class. I also filled and signed my intent to graduate. For the rest of the day, I was filling out paper work for UNTHSC IRB (expedited form, conflict of interest, and IRB protocol synopsis). I am still waiting for an approval from the graduate school on my proposal. For my project, I decided to use the students from 2014 instead of 2015 due to three reasons:

1. 2014 is more similar to this year on the number of staff members. During 2015, Elizabeth told me that they were understaffed. In terms of resources and time, they were not able to provide as much in 2015 compared to 2014.

2. There is one person that had attended the iRIS training in 2014 and 2015. In order to eliminate any outlier, I decided to use the data from 2014.
3. There were only 5 people in 2015 whereas there were 7 people in 2014. I decided to use the year with more pharmacy residents.

I hope to present this to Elizabeth and Heather. I am sure I will get more ideas from them!

07/19/2016

I was able to meet up with Gail today to pull data for me. I told her that I need the whole submission history for the pharmacy residents that attended the iRIS training in 2014. There are total of eight people. For the rest of the day, I created an excel sheet to perform Welch's T-test and I studied.

07/20/2016

I spent majority of the day studying and preparing for the IRB White meeting tomorrow. There are fewer new studies and a lot more revisions this time. I wonder how the meeting is going to be tomorrow.

07/21/2016

The IRB White meeting was quiet. Most of the studies that we reviewed were good to go or just require minor corrections. After the meeting, Gail emailed me the data that I needed for my proposal. I organized the data and found five people (out of eight) that submitted their initial study application after attending the iRIS training in July 2014 without prior submission history. I also noticed that only one person was not the primary principal investigator. Other than that,

they all submitted their initial application around September/October and was reviewed by the same board (IRB Red). The data looks good for now. I am happy with it!

07/22/2016

Today was our iRIS training for Clinical Research Coordinator and Clinical Research Associates. I sat in and learned the training materials. I was also able to generate more ideas throughout the meeting. After the training, I got to meet up with Heather to talk about the iRIS training for the pharmacy residents next week. I hope there will be enough people who shows up next week! I also got to meet up with Elizabeth to talk about our week.

Ninth Week

07/25/2016

Today was busy. During the weekend, I did some research over how to maximize memory retention by modifying the note-taking process. When a person is learning during a lecture, s/he is using his/her working memory to retain information. However, if that person takes note on a blank piece of water, more of person's attention will be shifted to writing the materials down instead of processing the information. In order to increase memory retention of the information, skeleton notes will be used to facilitate this process. Students can write down less and still be engaging during the lecture, and they will be able to process and retain more information throughout. I modified supplemental forms (Form 1 and Form 15) and study application presentation into skeleton outlines. After making some minor corrections, Heather approved my outlines and they are going to be used for the training on Wednesday. I am beyond excited! I will

also be working on my IRB submission for UNTHSC. I am hoping to turn everything in by Thursday or Friday this week.

07/26/2016

I spent the whole day filling out the IRB forms and preparing for tomorrow's training. Dr. Gwirtz suggested that I should submit my study to the Baylor IRB first, and then to the UNTHSC IRB. I hope I will be able to finish my forms this week so I can submit it as soon as possible. I am also hoping for tomorrow's training to go well.

07/27/2016

The pharmacy training was today, and I was slightly nervous. The training did not go according to plans because FDA made a surprise visit to BSWRI and Heather had to step out in the middle of the presentation. However, Dolores, another IRB specialist, took over and did a good job on presenting the materials. The pharmacy residents seemed more engaged when they were handed the skeleton outline. I was glad that we finished in time and they seemed receptive to the information that was given. I cannot wait to find out what happens when they submit their application! But first, I need to finish my IRB submission.

07/28/2016

Today was relaxing. I was able to sit down and type my thesis out. I was also preparing to turn in my intent to gradate and IRB submission to UNTHSC. Since I made some modification to my research, it was under exempt 1 or expedited 5 instead of expedited 7. I hope my study qualifies for exempt 1.

07/29/2016

I spent the morning perfecting my IRB submission. My plan was to submit my research as exempt 1. If that does not work, I will submit as expedited 5 study. I left during lunch to go to school and repair my car. I hope I will be able to turn everything in by next Friday.

Tenth Week

08/01/2016

I was trying to find out which site I should submit my IRB forms to today by emailing my professors and Heather throughout the day. I was able to locate the IRB forms on the UNTHSC website. It was kind of confusing at first but I eventually decided to submit to school. I hope they will take my forms.

08/02/2016

I took a day off today to go to school to turn in my IRB forms and obtain signatures for my intent to graduate form. I met up with Dr. Gwirtz to talk more about my submission, and she gave me tips on how to write my thesis. After that, I went straight to the school IRB office to submit my documents. Although the process of talking to the school IRB was tedious, I got everything turned in today. I was grateful for Elizabeth, Heather, and Dr. Gwirtz's help and support. Today was Elizabeth's birthday as well! Sadly, I didn't get to celebrate with her because I was on campus. I will bake a batch of cupcakes tomorrow.

08/03/2016

Today, I learned how to process IND forms. They report serious adverse events that happened on other clinical sites. I processed some forms and I hope I get some feedback from Heather today. Other than that, I baked some chocolate cupcakes for my team, and they were gone by noon.

08/04/2016

Today was the IRB Blue meeting, and it was the longest meeting up to date for me. There was one particular study that seemed like the risks outweighed the benefits. The study was based on a foreign study, but there were no concrete data or safety information available. It was interesting for me to watch the members discuss the study. I also received my letter from the UNTHSC IRB saying that my study does not involve human subject research. I am so elated to hear about the result! I can finally now move forward with my study.

08/05/2016

I spent the majority of the day studying and processing IND forms. Heather and Elizabeth will be out of office majority of the time next week. It looks like I am on my own. I am hoping to work with rest of the IRB team and learn to process more paperwork for them.

Eleventh Week

08/08/2016

I worked on one IND today, and I spent the rest of the day studying and typing up my thesis. I also asked Elizabeth to drive back to Houston this upcoming Friday due to Father's day (August 8th is Father's Day in Asia). Other than that, today was a bit slow because there were very little

IND's to do. I also received an email from Dr. Gatch and Carla about deadlines. My first draft of thesis will be due on August 22nd.

08/09/2016

I continued to work on more IND's and studied. I reviewed five studies today, and most of them had the correct documents. There was one study that submitted their reports under the wrong study (the PI had multiple studies). I am glad that I was able to catch that since there were two event reports submitted for the same study. I definitely think attention to details is really important for this job.

08/10/2016

I spent majority of time studying because there were no IND submissions today. However, I learned another form of submission other than the traditional IND reports. Yesterday I sent a report back for correction, but they told me that it was a DSMB summary. They are like IND's but instead of multiple reports, it is just one report. They do not require an event report summary like traditional IND's. After I learned the difference from Brittany, a specialist in IRB submission, I quickly corrected my action and completed the acknowledgement letter. I also signed up to take my MCAT in September, so my focus will be studying from now on.

08/11/2016

Today, I spent majority of the time studying again. There were three IND's, and I processed them accordingly. I will be out of office tomorrow because I am driving back to Houston to visit my family. I hope I will get some time to study and work on my thesis over the weekend.

08/12/2016

I drove to visit my family in Houston today.

Twelfth Week

08/15/2016

I processed one IND today. It was rainy today and I was tired from the drive from Sunday. I also met up with Elizabeth to talk about last week. Elizabeth suggested that I should follow up the residents from this year's training in the beginning of September. The follow up also serves as a reminder for the residents to submit their study applications. I am grateful that she was very supportive and caring.

08/16/2016

There were two new IND's today! I felt much better today compared to Monday. I studied for the rest of the day.

08/17/2016

I worked on my thesis today to elaborate more on my material and methods. I did not do very much today because I was not feeling well physically. I checked iRIS periodically for new IND's but there were none today. I was thinking about asking Heather if I could start processing other forms.

08/18/2016

Today was the IRB meeting for the white board, and I certainly enjoyed the meeting today. The reviewers were clear and concise when they explained their studies, and they caught a lot of little errors on the consent forms. I also noticed that I was able to catch on what they look for in a study. After the meeting, I studied for the rest of the afternoon.

08/19/2016

I was able to process three IND's today. I met up with Elizabeth to talk about future direction and some new things to do. I suggested monitor visits, and Elizabeth agreed to talk to Mary about that. I also worked on my thesis and asked Elizabeth to look at it before I turn it on Monday.

Thirteenth Week

08/22/2016

I spent the whole day working my thesis and setting up my defense date. Time is traveling quickly, and it is almost September. I hope I will get my data soon. My first draft of thesis was also due today, so I spent majority of the time refining and rereading my draft before sending it to Dr. Gatch.

08/23/2016

Today, I spent most of the day studying. I processed one IND today.

08/24/2016

There were no IND's today for me to process so I studied more.

08/25/2016

Finally – I was able to process two IND's. Other than that, I spent some time finding the email addresses of the pharmacy residents. I am thinking of emailing them on the first week of September to offer help on their applications.

08/26/2016

The defense date is finally set in stone – October 28th from 9AM – 11AM at CBH 220. I cannot believe that I will be getting my masters after that. I met up with Elizabeth to talk about my week as well. Dr. Gatch also sent me some corrections on my thesis format. He will be sending corrections for my contents next week. I cannot wait to improve my draft.

Fourteenth Week

08/29/2016

I met up with Brittany today to talk about how to process SAE (Serious Adverse Events), PD (protocol deviation), and other event forms. I was curious on how to process them, and they do not look very confusing. I am hoping to start processing some more forms soon! I also planned to turn in my intent to graduate this upcoming Friday.

08/30/2016

I processed two IND's today. Other than that, I spent the whole day studying. My committee members also replied to set up times to meet up on Friday. It looks like I will be busy in the morning.

08/31/2016

Today, I was able to process four IND's today! I also composed an email because tomorrow is the first day of September, and I am planning on following up with the pharmacy residents. So far, there are only two people who registered on iRIS out of seven people. I studied for the rest of the day.

09/01/2016

The IRB Blue meeting was today, and it was interesting as usual. One of the questions asked during the meeting by an IRB member was who determines the level of significant risk for a device. From my Clinical Research Management, I was able to murmur "the FDA" under my breath to answer the question (due to my timid nature in public). I am definitely glad that I decided to intern at BSWRI.

09/02/2016

I went to UNTHSC today to turn in my intent to defend. I met up with Dr. Gwirtz, Dr. Gatch, and Dr. Millar to talk about my thesis. I am excited for the upcoming month.

Fifteenth Week

09/05/2016 – Labor Day

09/06/2016

One of the residents emailed me back! The resident needed assistance to check her study application. Since the resident was still working on her application, I spent the whole day studying.

09/07/2016

Meanwhile waiting for the email, I was able to process one IND today. The resident later emailed me with his/her detailed study application. I was able to spend some time looking over them. I also met up with Heather to talk about the resident's application. I was able to learn about what to do and what not to do when the FDA shows up unexpectedly from Heather. She told me that it is important to contain the FDA crew in a quiet room, never let them leave your sight, and only give the FDA specific documents when they ask for them – no more, no less. I think I would be hyperventilation when they actually come. Finally, I got Heather's permission to process more paperwork! SAE (serious adverse events), PD (protocol deviation), and other forms here I come!

09/08/2016

Another resident emailed me back with his/her questions. I was happy to be able to assist them! I was able to be on a conference call with the first resident (my first call with someone else outside

of company). I spent the whole day assisting the first resident and getting ready for tomorrow's resident.

09/09/2016

I was surprised that it was Friday already. I went through the second resident's protocol before meeting up with the resident. The second resident came into the office around 2PM and met up with Heather and me. We talked about the protocols and additional suggestions for the resident. After he left, I continued studying for the rest of the day.

Sixteenth Week

09/12/2016

I was able to work on my thesis today. I elaborated more on materials and methods section. I met up with Heather today as well to talk about this upcoming week. I was hoping that both residents will be submitting their studies this week. I spent the rest of the day studying.

09/13/2016

This morning, I got an email from Dr. Gwirtz to complete Research Conflict of Interest for UNTHSC. I did the lessons and completed the requirement. For the rest of the day, I worked on my thesis more and studied.

09/14/2016

Today was peaceful – I was working on my thesis and studying for the most of the day. I spent some time looking at the agenda for tomorrow's IRB meeting. It looked short and sweet. I left early from work to the CRM meeting with Dr. Mathew. He mentioned that he used to work for a

pharmaceutical company back in India. I thought it was interesting that Dr. Mathew was exposed to many areas of clinical research when he was younger.

09/15/2016

The IRB White meeting was today, and it was short and sweet. Most of the studies were simply, straightforward, and well-formulated. Afterward, I went back to my office and started working on my thesis. I should be able to turn in my second draft in tomorrow to Dr. Gatch.

09/16/2016

I spent majority of the day writing my thesis draft and processing papers. Sadly, no one turned in their studies this week. I hope I will have some data by the end of this month. I also turned in my draft to Dr. Gatch this afternoon. I was not able to do much today because I was not feeling well physically.

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Seventeenth Week

9/19/2016

I got an email back from Dr. Gatch for my third draft of thesis. I was able to work my thesis and study for the rest of the day.

9/20/2016

Today was the BSWRI monthly meeting! The last one was a few months ago, and I was excited to attend the meeting. Heather was the presenter, and she talked about how to report different types of events such as SAE, AE, and UAP. I definitely learned a lot today from Heather. After the meeting, I was able to work on my thesis for a little bit. I also applied for some Baylor jobs as well.

9/21/2016

I worked on my thesis for the majority of the day. One of the residents emailed me to look over the protocols. It seems promising that the resident will submit this week or next week. I am hoping to get more than two residents this year for my data analysis. I also processed one IND today.

09/22/2016

I met up with Elizabeth today, and I was able to update her the last two weeks. She was extremely encouraging and warm as usual. I also applied for more jobs online as well. Other than that, I studied for the rest of the day.

09/23/2016

It was a peaceful Friday today. I was able to work on my thesis and study some more. Elizabeth was out of town today. I still did not hear back from the residents.

Eighteenth Week

09/26/2016

I got an email from Dr. Gatch this morning and he suggested that I start working on my defense presentation. I cannot believe that the defense is only a month away. However, I am more nervous about not being able to obtain any data before my defense. I am hoping that the residents would submit something soon. I spent majority of the day applying for jobs, working my presentation, and studying.

09/27/2016

I went to school today to pick up my laptop since it was broken a week ago. Afterward, I spent most of the day working on my defense presentation.

09/28/2016

Today was peaceful – I was able to work on my presentation most of the day. I finished majority of it, and I am hoping to polish it more before I hand my first draft to Dr. Gatch. I also had my first interview for Clinical Research Assistant for Baylor. Although it was a phone interview, I was still grateful for the opportunity. Tomorrow is the BSWRI's first retreat, and I am extremely excited!

09/29/2016

Today was the BSWRI retreat, and it was relaxing. We had some introduction on each department from its prospective leader. Elizabeth talked about the regulatory affair while Renee talked about the financial department. After the introduction, the guest speaker came in and

talked about how to lead other people. Bob talked about three different types of people - heart, square, and circle. Heart represent emotional people, square represent type A personality, and circle represent type B. Bob also spoke about how to communicate with people without them being defensive. After the talk, we all went to eat lunch. In the afternoon, we had activities that were related to the presentation this morning. An hour before we departed back to Dallas, we had activities such as archery, basketball, and volleyball. Overall, it was a nice relaxing experience. I also got to hang out with the IRB team and some of the finance team members.

09/30/2016

It was a good day today because I was able to polish and finish up my first draft of my presentation and send it to Dr. Gatch. I spent majority of the studying and processing paperwork. Unfortunately, there are still no submission from any of the resident from 2016. At least one more user got his/her user account on iRIS today!

Nineteenth Week

10/03/2016

One of my co-workers is leaving BSWRI tomorrow, and I was sad. We had a get-together lunch with Dolores. For the rest of the day, I worked on my thesis presentation, studied, and processed some paper work.

10/04/2016 – Dolores' Last Day

For the majority of the day, I worked on my thesis and the presentation. I got to say bye to Dolores before I left work. I am really happy for her that she got a new job with better pay!

10/05/2016

I spent the whole day studying and working on my thesis. A third resident emailed me for help! I was elated to help her. I might have three residents for 2016! I am definitely keeping my hope up for their submissions soon!

10/06/2016

Today was the IRB Blue meeting. Since we had an extra week last month, the meeting was long. However, I learned about atrial fibrillation patients tend to have blood clots in their left atrium if they are unable to be on a blood thinner. I thought it was very interesting. After the meeting, I an email from Dr. Gatch saying that I will need to complete my thesis by next Monday. For the rest of the day, I worked on my thesis.

10/07/2016

The thought of having my defense two weeks from today really scared me. I don't even have data to put on my presentation. I emailed the residents today and reminded them to submit their studies soon. I hope there will be some submission next week. I also got to meet up with Elizabeth this afternoon to talk about my week and progress.

Twentieth Week

10/10/2016

I spent majority of the working on my thesis and defense presentation.

10/11/2016

Again, I spent the majority of the day working on my thesis and defense presentation. However, I think I am starting to feel a bit sick.

10/12/2016

I had a meeting with Heather today because a resident submitted! However, the resident decided to retract the study application and wait until January 2017 to submit. I was kind of disappointed but I still have hope! I left early today because I was feeling sick and I was coughing a lot.

10/13/2016 – Sick day

I stayed home today because I was sick.

10/14/2016

Today was my first BSWRI Employee Appreciation day, and I got some amazing food, dessert, and prize! Afterward, I left for UNTSHC to practice my defense with Dr. Gatch. I was still sick so I could not practice a lot beforehand. I hope I will feel better next week.

21st Week

10/17/2016

After a weekend of rest, I still did not feel better. I stayed home and worked on my thesis and presentation. Tomorrow is my second practice run with Dr. Gatch. I hope I will be able to speak by then.

10/18/2016

First thing – two new residents submitted their study application! I finally got the data that I wanted! Heather was so kind and speedy – she was able to process both application quickly. Both resident had minor mistakes so the applications were sent back. I was so happy! My second practice run with Dr. Gatch went OK – I still could not stop coughing. Dr. Gatch was very help and encouraging throughout the practice run. I am very fortunate to have a wonderful group of people to help me throughout this project.

10/19/2016

I spent majority of the day working on my thesis. The two residents submitted again but their application was sent back. Welch's t-test projected the p-value to be 1. I am not surprised to be honest because there were a lot of confounding variables that may had caused this insignificance.

10/20/2016

I had a job interview with UTSW today, and I immediately got back to work afterward. Today was the IRB White meeting, and it was good as usual. I spent my free time typing and polishing my thesis today. I noticed that this year's residents had less stipulations sent back compared to the residents in 2014 for corrections. I was elated to find that my methods actually improved the quality of the submission. Although I cannot say for sure, I am still happy that Heather decided that she will be using the skeleton notes for next year as well.

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