Implementation of an Updated Standard Operating Procedure For Investigational Product Management

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To ensure the highest validity of clinical trials, the safety and efficacy of the investigational products that are used in the studies must be of highest priority. This task is accomplished through the use of a research site’s standard operating procedure.

This practicum study addressed the standard operating procedure for the handling of investigational products at The Center for Cancer and Blood Disorders. A survey was used to assess the knowledge and perception about the standard operating procedure from those that are involved in the handling of investigational products. Information from this survey was used to adjust and make changes to the existing standard operating procedure to better ensure the safety and efficacy of the investigational products that are being studied at the site.
IMPLEMENTATION OF AN UPDATED STANDARD OPERATING PROCEDURE FOR
INVESTIGATIONAL PRODUCT MANAGEMENT

Johnny Van Dang, B.S.

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Ray Page, D.O., Ph.D., Committee Member

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Graduate School of Biomedical Sciences
IMPLEMENTATION OF AN UPDATED STANDARD OPERATING PROCEDURE FOR INVESTIGATIONAL PRODUCT MANAGEMENT

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the Graduate School of Biomedical Sciences University of North Texas Health Science Center at Fort Worth in Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE
IN CLINICAL RESEARCH MANAGEMENT

By
Johnny V. Dang, B.S.
Fort Worth, Texas
November 2016
ACKNOWLEDGEMENTS

I would like to thank Dr. Ladislav Dory for serving as the major professor for this practicum study. I would also like to thank Dr. Joseph Warren for being a member of my committee. Their input was very crucial and helped guide me throughout the duration of this internship.

I would like to extend my gratitude to those at The Center for Cancer and Blood Disorders. As site mentors, Dr. Ray Page and Ms. Melissa Pool have shown me the amount of work that it takes to conduct and oversee a successful research site. In addition to his guidance in my experience with research, Dr. Page also gave me the opportunity to shadow him at one of the satellite sites in Weatherford, Texas. This showed me the importance of providing the most cutting-edge, and up-to-date care to those populations on a community level. Working alongside the different coordinators in the research department, I have learned about each role and the amount of coordination that is needed to successfully conduct a study. For that, I would also like to thank Brian Franklin, Rene Chaisson, Jo Ann Gilbert, Deanna Philips, David Enenebeaku, and Jennifer Joseph.
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CHAPTER I
INTRODUCTION

This practicum project was conducted at The Center for Cancer and Blood Disorders (TCCBD). The key mentors from TCCBD included the clinical research director, Ms. Melissa Pool, and the president and director of research, Dr. Ray Page, DO, Ph.D. Dr. Ladislav Dory served as the major professor for this project.

Investigational products are the drugs that are tested in clinical trials to determine if they are a viable treatment for a disease. This practicum updated the standard operating procedure (SOP) used for handling investigational products at TCCBD, along with the other satellite sites in the surrounding areas that are associated with TCCBD. It addressed the problems that were associated with the lack of uniformity in the way investigational products were transported, received, and stored. This study also examined the employees’ knowledge and attitudes towards the SOP. With the assistance of the investigational product coordinator, the SOP was updated and implemented to set guidelines that must be followed by everyone that is in contact with the investigational product.

Before this practicum, the SOP that was in place was one that was provided to the site from the Sarah Cannon Research Institute, which is TCCBD’s associated clinical research organization. This SOP was not created for the specific characteristics that make up the main site, or the satellite sites, which caused employees that deal with investigational products to be unsure about whether or not a certain process/procedure was to be completed by them. This resulted in a lack of uniformity in the handling of the investigational products, which could have possibly caused loss of efficacy of the
research drugs, a decrease in the validity of the studies being conducted, and most importantly poor patient care.

A questionnaire about this SOP was given to all personnel involved in the handling of the investigational products. This initial questionnaire was done to gauge employees’ current adherence, and attitudes toward this version of the SOP, and revealed what aspects of this document needed to be adjusted to better fit TCCBD and the satellite sites. After obtaining those results, new procedures and tasks were implemented and communicated to the employees. The questionnaire was then given again to assess the change in knowledge and attitudes of those associates that are involved with investigational product handling.
CHAPTER II

BACKGROUND

The purpose of research studies is to generate knowledge, and in the case of clinical trials, products and therapies for the benefit of society (Methot, J., 2012). The way to do this is to adhere to the study’s protocol that sets strict rules and guidelines on how to perform the study. Failing to follow this protocol increases the chances of deviations that can occur, which increases the chances of false results and conclusions. A research site must do its best to avoid protocol deviations. This is accomplished by following a document known as the “Standard Operating Procedure”. A standard operating procedure (SOP) is defined as detailed, written instructions used to achieve uniformity in the performance of a specific function and is used to maintain consistent quality control and quality assurance, support data quality, and ensure compliance (Benedict-Blue, M., 2014). This document is necessary to make sure that the resulting data and conclusions are valid, (Garattini, S., 2016) The SOP document is essentially a teaching and communication tool (Moret, L., 2012) that gives those involved in conducting the study a “to-do list” that states exactly what must be done, and when and how this should be accomplished.

Pertaining to the management of investigational products, the SOP document will address processes for the receipt, storage, dispensing, reconciliation, and return or authorized destruction of the investigational product. Those trusted with handling the investigational products must do everything that they can to maintain its safety and
sustain its efficacy. By addressing the oversight and monitoring of the temperature of the investigational products during its transportation and its storage, a site can minimize the risk of having a temperature excursion (Ammann, C., 2013). A temperature excursion occurs when the investigational product is stored outside of the specified temperature range that is required. This could possibly affect the quality, efficacy, and safety of the investigational products. (Foreman, S.) When an investigational product is kept at a temperature higher than the specified range, its quality decreases. This occurs because degradation of the active ingredient in the medication is taking place. The longer the drug is kept at this higher than optimal temperature, the more degradation is occurring and the degraded components could have toxic effects (Ammann, C., 2013). Most importantly, this affects the patients that are involved in the study. The patients are participating in the research trial so that they could receive the possible benefit of the drug. If the investigational drug is compromised in any way, then so is the treatment that the patients are receiving. If the investigational product may have been affected by the temperature excursion, the patient is no longer allowed to receive this medication, as the safety of the patient is first and foremost. If this medication has to be reordered, the patient experiences a delay in their treatment (Foreman, Shawn), causing stress, anxiety, and angst in the patients. Not only does the SOP minimize the chances of having the investigational product fall out of its temperature range, it maximizes the patient satisfaction that is experienced by those that are receiving treatment.

Implementing an updated SOP has its difficulties, which arise for multiple reasons, such as, “individualism and lack of team spirit, lack of transparency, lack of commitment of management, or lack of education.” (Moret, L. 2012). But, as evidenced
by Rognås, adherence notably increases when the implementation of a SOP is successful and the benefits that result from it are worth the necessary time and effort. Dejan Kosutic (2011) offers some insight and outlines 7 steps that can be taken for implementing policies and procedures. The basic tenets of this approach are to have an understanding of what the SOP is being used for, figure out what is most pertinent to include on this document, so that when anyone refers to it, there is no confusion or extraneous pieces of information, and lastly, to make sure there are no conflicting pieces of information. Training and communication after implementation are also important to make sure that the changes in the SOP are expressed to all of those involved and give them the rationale for these changes. This gives those involved a chance to understand the changes and gives them time for adjustment to the new procedures because those involved can not work under rules with which they are not familiar (Methot, J., 2012).
PROBLEM

There are specific instructions that state the conditions that need to be met to keep the investigational products in compliance with the protocol of the study. These tasks are accomplished by following the SOP that is set by the site. This procedural document may be even more important when there are multiple people performing the same procedures for the study, as is the case of TCCBD and its satellite sites. These sites are located in Weatherford, Arlington, and Hugley, Texas, and they all have their own characteristics that differ from the main site. One major difference between TCCBD and the satellite sites is that at the main site there is an investigational product coordinator, which is a position specifically devoted to take care of the tasks involving the investigational products. At the satellite sites, this position does not exist, and these responsibilities fall on the shoulders of the chemotherapy nurses that are working at that site, thus spreading the responsibility to multiple people. I propose that in the updated SOP, this responsibility is to be delegated to someone, or a specific set of people, so the TCCBD has a way of holding their employees accountable for the procedures that are being completed. Another difference is that TCCBD is the only site that is using a TempTracker, a device that is used to monitor the temperature of the investigational products as it is being transported from site to site. The use of this device is not mandated in the current SOP, so the satellite sites are not aware of its usage. By making it known in the SOP that employees handling the investigational products must monitor the temperature while investigational products are being transported, including the use of this device to help achieve this goal, temperature monitoring will increase, ensuring the safety of the drug throughout its transit. The storage of the investigational products is also a
noted difference between the main site and the satellite sites, as the main site has a procedure that it uses to monitor the temperature of the investigational products on a daily basis, while being held on site. By adding this requirement to the SOP, better oversight of the investigational products can occur while at the satellite sites
HYPOTHESIS

Because of these discrepancies between the main site and the satellite sites, whenever investigational products are shipped to these satellite sites, the chances for deviations increased. By taking into account the differences between TCCBD and the satellite sites, and updating the SOP to a version that was applicable to everyone that is involved in handling the investigational products. This will create a heightened sense of responsibility and awareness to what tasks must be completed and increase uniformity in performing tasks that deal with the handling of the investigational products.
SPECIFIC AIMS

• Aim 1: Delegate the responsibility of the oversight of investigational products to a single person, or set of people.

• Aim 2: Implement temperature monitoring of the investigational products while they are being transported to and from satellite sites.

• Aim 3: Implement temperature monitoring of investigational products while they are being stored at the satellite sites.
SIGNIFICANCE

The SOP of a clinical trial plays a major role in clinical research because it allows for proper investigational product management. This procedural document ensures that the method of therapy that is going to be given to the patient is not compromised in any way. If one does not adhere to the SOP, the chances for deviations from the study’s protocol increases. When these deviations occur, patients may experience delays in their treatment, causing an unnecessary stress that the patients do not need. There are also monetary factors to consider, as drugs that are not used or that are compromised must be destroyed, which is a waste of resources. By creating a SOP that takes the characteristics of the site in mind, a clear and concise set of guidelines will be given to everyone involved with handling the investigational products. This ensures that those individuals involved in the study know exactly what they must do and when they must do it, making sure that the medications are being handled in the correct way.
MATERIALS AND METHODS

A questionnaire was generated via Survey Monkey, an online survey generator, and distributed to volunteer participants through email. This online survey method assures anonymity of the participants. The questionnaire addressed the SOP and was given to the participants twice. The first questionnaire addressed the SOP document prior to the updates, and the second questionnaire was given after the changes and updated version of this document was in use. The types of questions that were asked evaluated the awareness and understanding of the SOP document.

The survey was communicated by e-mails and through face-to-face interactions during site visits. The site visits allowed for viewing of the personalized needs of the satellite sites. The questionnaire was given to all those involved in handling of the investigational products that are working at TCCBD and the satellite sites that are associated with it.

The questionnaire is made up of the following 10 questions:

1. I have worked for The Center for Cancer and Blood Disorders for..

2. I am aware of the process that is involved in receiving the investigational product.

3. I am aware of the process that is involved in the storage of the investigational product.

4. I am aware of the process that is involved in the dispensation of the investigational product.

5. I am aware of the process that is involved in the return of the investigational product.
6. The Standard Operating Procedure with regards to handling the investigational products pertains to my daily duties.

7. Following the Standard Operating Procedure with regards to handling the investigational products helps ensure quality of care.

8. Following the Standard Operating Procedure with regards to handling the investigational products hinders my ability to tend to patients.

9. I have been a part of a situation where an investigational product was found out of its specified temperature range (temperature excursion).

10. (Only answer if “slightly agree” or “completely agree” to #9) I am aware of the process that is involved in reporting a temperature excursion of the investigational products.

A Likert scale was used to assess the responses from the questionnaire. The associates were asked to rate the level to which they agree with a statement. This was determined to be the most appropriate method to use to assess personality, attitudes and behaviors (Cherry, K., 2016).

The values of the Likert scale is as follows:

- Completely Disagree = 1
- Slightly Disagree = 2
- Neither Disagree/Agree = 3
- Slightly Agree = 4
- Completely Agree = 5

After the questionnaires were answered, a mean score was calculated for each question and this was the measurement that is compared to assess a difference, if any, in the respondents’ answers.
This first survey was used to find out what adjustments need to be made in the new SOP by addressing any areas of weakness that would have been shown through a low score. After making the changes to the SOP, the second questionnaire was used to assess if there was any change, more specifically an increase in the knowledge of the employees that handle the IP. It was the hope that by making the SOP clear and defining what the person’s responsibilities were, the employees would have a better understanding of what must be done, and understand the importance of the SOP document with regards to its role in providing the highest levels of patient care.
RESULTS AND DISCUSSION

After obtaining data from the initial questionnaire, changes were made to the pre-existing SOP. As mentioned before, this SOP was given to TCCBD to use from the Sarah Cannon Research Institute, which is The Center’s associated clinical research organization. This organization helps oversee multiple research sites, and because of this, the SOP that they suggest to use is very generalized and does not take into account specific characteristics for the research sites. In this version of the SOP, it states that the person responsible for handling the IPs is either the on-site pharmacist or the IP coordinator. At the main site in Fort Worth, the IP coordinator takes on all of the responsibilities for handling of the IPs. Because this position does not exist at the satellite sites, the responsibilities are dispersed among the multiple chemotherapy nurses that are there. The new SOP was adjusted to designate that the IP coordinator or any one that received training on the research drugs, were responsible for carrying out the procedures that involve IP handling. Another adjustment that was made to the new SOP was the reference to the correct forms and documents that needed to be filled out and completed when procedures were completed. The documents that were referenced in the SOP provided by the Sarah Cannon Research Institute were not being used by The Center, and for the documents that were being used, there was no mention about them in the SOP. The documents that were not being used were removed in the new SOP, replacing them with documents that were being utilized by The Center. It was also mandated that the documents be signed upon completion of a certain procedure. 2 such documents that were added to the SOP to help with handling the IPs were the “Drug Transportation Sheet” (Figure 1) and the “Monthly Storage Calendar” (Figure 2).
To address the processes in shipment of the investigational product, the Drug Transportation Sheet (Figure 1) that is sent out along with the drug shipment has been updated and its completed has been made mandatory. These forms contain information that is specific to the patient and the research medication that they will be receiving. It has information that identifies the drug vial and the expiration date of the medication. Information about the drugs storage conditions is also kept on these transportation sheets, along with the stability of the medication. This document has different sections that need to be filled out anytime that the investigational product is being handled. Information that needs to be completed includes the date, time, and temperature of the investigational product. It also asks for the initials of the person handling the investigational product. On this form there is a section labeled “Drug pulled at MCO”. This section is to be completed by the investigational product coordinator at the “Magnolia Center Office” in Fort Worth. This ensures that the investigational products are in proper conditions when they leave the main site. The section labeled “Drug Arrived at Site” is to be completed by the nurse that is receiving the investigational product shipment. This ensures that the investigational product was maintained in proper storage conditions throughout its transit. After receiving the investigational product, the nurse that receives the shipment is to place it into its appropriate storage area, until it is given to the patient. At this point, the nurse that takes the investigational product from storage to prepare for the patients will fill out the section “Drug pulled at site for patient”. This ensures that the investigational product was stored in the proper conditions, and kept this way throughout the time there. This also allows the nurse to confirm that the patient is receiving the medication that was designated for them. Also, on this sheet is a section “Drug pulled for return to MCO”. If
for whatever reason, the patient does not receive the investigational product, it is to be sent back to the main site in Fort Worth. After the investigational product returns to the main site, the IP coordinator will fill out the section labeled, “Drug Arrived at MCO”. By filling out these last 2 sections, it can be confirmed that the investigational product that was not used is still as safe and efficacious as it was when it first left the main site. This gives the IP coordinator the ability to send out this specific investigational product again. Regardless of whether or not the investigational product was used, the drug transportation sheet will return to the main site in Fort Worth with all of the appropriate sections filled out. All of this information is kept in a master log at the Fort Worth site.
Figure 1.

Drug Transportation Sheet

<table>
<thead>
<tr>
<th>Pt Name/#:</th>
<th>Study:</th>
<th>Cycle:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</table>

| Drug: | Cytotoxic: | Y / N |
|       |           |       |
|       |           |       |

<table>
<thead>
<tr>
<th>Kit #(s):</th>
<th>Lot #:</th>
<th>Expiry:</th>
</tr>
</thead>
<tbody>
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</table>

Drug Pulled at MCO

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Temp</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
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<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Drug Arrived at Site

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Temp</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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</table>

Drug Pulled at Site for Patient

<table>
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<tr>
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<th>Time</th>
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Drug Pulled for Return to MCO

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Temp</th>
<th>Initials</th>
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Drug Arrived at MCO

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Drug Storage Conditions

- Frozen Normal Range: -15° to -25°C or -13° to 5°F
- Refrigerated Normal Range: 2° to 8°C or 36° to 46°F
- Ambient Normal Range: 20° to 25°C or 68° to 77°F

Please notify Research if drug temperature is outside of the above ranges.
To address the process in proper storage of the investigational products, the Monthly Storage calendar (Figure 2) was sent out to each of the satellite sites. This calendar was to be placed in the storage area that housed the investigational products. Once daily, a nurse was to check the ambient temperature of the room and record this temperature on the calendar. This was also to be done with the refrigerated and freezer drugs as well. This helps ensure that the drugs are kept in their stable storage conditions.

Figure 2.
To address the process in the dispensation of the investigational products, admixture sheets and chemotherapy sheets are being sent to the satellite sites. The admixture sheet has directions and steps on how to properly prepare the treatment. They come along with check off areas, where the nurse that is administering the medication is to check off the step that they performed. After completion of this form, the nurse is to initial the sheet, confirming that they did all the steps. From the site visits, it was expressed that it would be helpful if the nurse were provided more information about the medication itself. The purpose of the chemotherapy sheets is to provide a quick reference to information that is important to administering the medication. This sheet will have information such as infusion rate, adverse events to look out for, and instructions on what to do in case infusion needs to be stopped or delayed.

After making the adjustments to the SOP, this document was electronically sent out to every employee that was involved in the handling of IPs. This information was also verbalized to the employees during site visits. Site visits were made during regular working hours, so this information could not be passed along to all of the employees that handle the IP. It was asked of employees that we were able to speak with to spread the message, and to be prepared to receive the SOP document. After implementation and use of the new SOP, follow-up questionnaire was then sent out to assess if there was a change in employees’ knowledge about the SOP and what their perceptions were to this new version.

The following figures displays the initial questionnaire and the follow-up questionnaire:
Figure 3. Initial Survey: I am aware of the process that is involved in receiving the investigational product.

![Bar chart for Initial Survey]

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
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<td>0</td>
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<td>2</td>
<td>3</td>
<td>7</td>
<td>3.86</td>
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</table>

Figure 4. Follow-Up Survey: I am aware of the process that is involved in receiving the investigational product.

![Bar chart for Follow-Up Survey]

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
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<td>0</td>
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<td>0</td>
<td>3</td>
<td>3</td>
<td>5.00</td>
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</tbody>
</table>
Figure 5. Initial Survey: I am aware of the process that is involved in storage of the investigational product.

<table>
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<tr>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (0%)</td>
<td>2 (28.6%)</td>
<td>0 (0%)</td>
<td>3 (42.9%)</td>
<td>2 (28.6%)</td>
<td>7</td>
<td>3.71</td>
</tr>
</tbody>
</table>

Figure 6. Follow-Up Survey: I am aware of the process that is involved in storage of the investigational product.

<table>
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<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
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<tbody>
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<td>0 (0%)</td>
<td>0 (0%)</td>
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<td>0 (0%)</td>
<td>3 (100%)</td>
<td>3</td>
<td>5.00</td>
</tr>
</tbody>
</table>
Figure 7. Initial Survey: I am aware of the process that is involved in the dispensation of the investigational product.

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>1</td>
<td>7</td>
<td>4.14</td>
</tr>
<tr>
<td>Percentage</td>
<td>(0%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td>(85.7%)</td>
<td>(14.3%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 8. Follow-Up Survey: I am aware of the process that is involved in the dispensation of the investigational product.

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4.67</td>
</tr>
<tr>
<td>Percentage</td>
<td>(0%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td>(33.3%)</td>
<td>(66.7%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 9. Initial Survey: I am aware of the process that is involved in the return of the investigational product.

![Bar chart showing responses to the initial survey.]

<table>
<thead>
<tr>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (0%)</td>
<td>1 (14.3%)</td>
<td>1 (14.3%)</td>
<td>4 (57.1%)</td>
<td>1 (14.3%)</td>
<td>7</td>
<td>3.71</td>
</tr>
</tbody>
</table>

Figure 10. Follow-Up Survey: I am aware of the process that is involved in the return of the investigational product.

![Bar chart showing responses to the follow-up survey.]

<table>
<thead>
<tr>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>2 (66.7%)</td>
<td>1 (33.3%)</td>
<td>3</td>
<td>4.33</td>
</tr>
</tbody>
</table>
Figure 11. Initial Survey: The Standard Operating Procedure with regards to handling the investigational products pertains to my daily duties.

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely Disagree</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (14.3%)</td>
<td>3 (42.9%)</td>
<td>3 (42.9%)</td>
<td>7</td>
<td>4.29</td>
</tr>
</tbody>
</table>

Figure 12. Follow-Up Survey: The Standard Operating Procedure with regards to handling the investigational products pertains to my daily duties.

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely Disagree</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (33.3%)</td>
<td>2 (66.7%)</td>
<td>3</td>
<td>4.67</td>
</tr>
</tbody>
</table>
Figure 13. Initial Survey: Following the Standard Operating Procedure with regards to handling the investigational products helps ensure quality care.

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>2 (28.6%)</td>
<td>5 (71.4%)</td>
<td>7</td>
<td>4.71</td>
</tr>
<tr>
<td>Disagree</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slightly</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>3 (100%)</td>
<td>3</td>
<td>5.00</td>
</tr>
<tr>
<td>Disagree/Agree</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slightly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agree</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completely</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>3 (100%)</td>
<td>3</td>
<td>5.00</td>
</tr>
<tr>
<td>Agree</td>
<td>71.4%</td>
<td>28.6%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 14. Follow-Up Survey: Following the Standard Operating Procedure with regards to handling the investigational products helps ensure quality care.
Figure 15. Initial Survey: Following the standard Operating Procedure with regards to handling the investigational products hinders my ability to tend to patients.

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>7</td>
<td>2.86</td>
</tr>
<tr>
<td>(%)</td>
<td>(14.3%)</td>
<td>(28.6%)</td>
<td>(28.6%)</td>
<td>(14.3%)</td>
<td>(14.3%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 16. Follow-Up Survey: Following the standard Operating Procedure with regards to handling the investigational products hinders my ability to tend to patients.

<table>
<thead>
<tr>
<th></th>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>2.33</td>
</tr>
<tr>
<td>(%)</td>
<td>(0%)</td>
<td>(66.7%)</td>
<td>(33.3%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 17. Initial Survey: I have been a part of a situation where an investigational product was found out of its specified temperature range (temperature excursion).

<table>
<thead>
<tr>
<th>Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely Agree</td>
<td>1</td>
<td>2.14</td>
</tr>
<tr>
<td>Slightly Agree</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neither Disagree/Agree</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Slightly Disagree</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Completely Disagree</td>
<td>4</td>
<td>57.1%</td>
</tr>
</tbody>
</table>

Figure 18. Follow-Up Survey: I have been a part of a situation where an investigational product was found out of its specified temperature range (temperature excursion).

<table>
<thead>
<tr>
<th>Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely Agree</td>
<td>3</td>
<td>1.00</td>
</tr>
<tr>
<td>Slightly Agree</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neither Disagree/Agree</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Slightly Disagree</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Completely Disagree</td>
<td>3</td>
<td>100%</td>
</tr>
</tbody>
</table>
Figure 19. Initial Survey: (Only answer if input to #9 was “Slightly Agree” or “Completely Agree”) I am aware of the process that is involved in reporting a temperature excursion of the investigation products.

<table>
<thead>
<tr>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>2 (100%)</td>
<td>2</td>
<td>5.00</td>
</tr>
</tbody>
</table>

Figure 20. Follow-Up Survey: (Only answer if input to #9 was “Slightly Agree” or “Completely Agree”) I am aware of the process that is involved in reporting a temperature excursion of the investigation products.

NO CHART DATA TO DISPLAY

<table>
<thead>
<tr>
<th>Completely Disagree</th>
<th>Slightly Disagree</th>
<th>Neither Disagree/Agree</th>
<th>Slightly Agree</th>
<th>Completely Agree</th>
<th>Total Respondents</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (0%)</td>
<td>0 (0%)</td>
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<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0</td>
<td>0.00</td>
</tr>
</tbody>
</table>
SUMMARY AND CONCLUSIONS

Due to the low number of responses on the follow-up survey, making the comparison of the initial survey and follow-up survey was not possible, thus making it inappropriate to make any statistical conclusions as to how the SOP has been received by those involved in the handling of investigational products. However, trends in the right direction can be seen from the data that was obtained.

Questions 2 – 5 addressed the specific processes that are used in the handling of IPs. By looking at the figures, it can be seen that mean score of each of these questions has increased. For question 2 (figures 3 and 4), the response scores increased from 3.86 to 5.00, respectively. For question 3 (figures 5 and 6), the response scores increased from 3.71 to 5.00, respectively. For question 4 (figures 7 and 8), the response scores increased from 4.14 to 4.67, respectively. For question 5 (figures 9 and 10), the response scores increased from 3.71 to 4.33, respectively. Although there is no way to statistically make conclusions about this increase, this would suggest that there has been an increase in the knowledge of the employees in regards to the process that are involved in the handling of the investigational products, specifically, its receipt, storage, dispensation, and return.

Questions 6-8 were asked to gauge the associate’s attitudes towards the standard operating procedures. These were asked so that TCCBD could get a better understanding of how their employees feel about the SOP for handling investigational products. Looking at question number figures 11 and 12, employees’ response scores of 4.29 and 4.67, respectively, do suggest that they believe following the SOP for IP handling is a part of their daily duties. Furthermore, taking a look at figures 13 and 14, it can be seen
that with the response score of 4.7 and 5.0, respectively, the employees do believe that the SOPs do help ensure the highest levels of patient care. However, with that being said, in response to question number 8, figures 15 and 16, with the response scores of 2.8 and 2.33, there are employees that believe that following all of these guidelines hinders their ability to care for their patients. This could perhaps be do to the amount of time that they are not spending with the patient, or time that is taken away from making good notes and annotations on the visits. It was important to note that the steps and procedures that were brought forth were to ensure that the medication that the patients were receiving is safe and efficacious, thereby increasing patient care and satisfaction.

Lastly, in regards to the questions about the temperature excursions, questions 9 and 10, it seems that although there are not a lot of instances in which this occurs, whenever it does occur, the associates do understand what the proper procedure is.

Regarding the aims and goals of this practicum project, the following addresses what was achieved. As previously stated, the lack of responses on the follow-up survey leads to the inability to assess the changes in the understanding and sense of responsibility in those that are handling the investigational product. Although this practicum project was not able to achieve this goal, because of the initial survey and the information that was obtained, it allowed the framework for what needed to be addressed in SOP and helped achieve some of the other goals. A specific goal of this practicum project was to identify a standard to delegate the responsibility of the oversight of investigational products so that it is attributed to a single person, or set of people. By requiring associates to initial what procedure was completed on the drug transportation
sheet, TCCBD now has a way of holding those handling the investigational products accountable. Another goal that was accomplished was implementing a procedure that allows for monitoring the temperature of the investigational products while they are being stored at the satellite sites. With the use of the temperature-monitoring calendar at the satellite sites, the associates are now able to monitor the conditions that the investigational products are being stored in. Another goal that this practicum project aimed to achieve was to implement a procedure that allows for monitoring the temperature of the investigational products while they are being transported to and from the satellite sites. Although, the use of such a procedure has not been implemented, steps have been made to in the direction towards having this. By having the SOP in place, whenever the use of this device begins, those using it will understand why it is being used and how to integrate that into the process of handling the investigational products.
LIMITATIONS

A major limitation of this practicum project is the low response rate to the questionnaire, which made the comparing data not possible, thus the findings less significant. A possible explanation for the low response rate was due to the population that was asked to participate in the questionnaire. The pool of potential participants were made up of chemotherapy nurses that are constantly moving and busy throughout the day tending to patients, making notes, and completing all of the other tasks that are asked of them. Because of how busy they are, the chances of them forgetting to do the questionnaire were high. Another possible reason for the low response rate was that maybe the employees do not think that handling investigational products is a part of their daily tasks and because of that, viewed the questionnaire as something that was just as extraneous to what they needed to do, thus prompting them to not respond. In attempts to minimize the problem, multiple efforts were made to get their input. Participants were notified when the questionnaire was opened, and multiple announcements were made telling them how many days are left before the questionnaire closed. Announcements were also made on my behalf from the IP coordinator, Jo Ann Gilbert, and site mentor, Melissa Pool. For the possibility of a better response rate from the participants, I could have made personal visits to the satellite sites. By possibly showing them that I took the time out of my day to drive and ask them to complete a questionnaire, the employees would feel more inclined to help by responding. Another method of communication that could have been utilized was possibly handing out hard copies of my questionnaire to the satellite sites and asking for their return through the mail.
Another limitation was the inability to fully implement the updated SOP by the time the second questionnaire was given. Those involved might have felt that they have not had enough time to fully experience the updated version of this document and felt as if they could not truthfully answer the questions about perception and understanding. This was addressed in the outlining and planning of the standard operating procedure. By making it as clear, and concise as possible, the standard operating procedure should have allowed for quick adaptation and usage.

A limitation also came with using a Likert scale because the results could have been influenced by the need to appear socially desirable or acceptable. People may not have been entirely honest with their answers or may have answered items in ways to make themselves appear better than they really are. This effect can be particularly pronounced when looking at behaviors that are viewed as socially unacceptable (Cherry, K., 2016). To help alleviate this problem, the results of individual questionnaires were kept anonymous and the participants of the study were told this from the very beginning. By letting them know that their identities were not linked to their answers, their responses hopefully reflect their true feelings and honest knowledge.
FUTURE RESEARCH

With the realms of healthcare and technology making advancements every day, TCCBD will have to be able to do the same and try to adapt so that they are able to provide the best type of care that they can. With the SOP in place, whether it is a change in the technology being used, or new personnel that come to work at TCCBD, there will be a set guideline for how certain procedures are completed. It would be of the site’s best interest to research any barriers that could lead to poor understanding of these adjustments. Learning from those barriers, TCCBD will be able to come up with a strategy to effectively communicate these changes to all those involved in the handling of investigational products.
BIBLIOGRAPHY

Ammann, Claude. "Handling Temperature Excursions and the Role of Stability Data."


http://michr-resources.org/23087-what-are-sops/181469-writing-standard operating-procedures-for-clinical-trials. 07/14/2016


CHAPTER III

INTERNSHIP SITE

This practicum project was completed at the Center for Cancer and Blood Disorders, located in Fort Worth, Texas. Since 1998, under the research leadership of Dr. Ray Page, TCCBD has participated in almost 200 critical clinical trials involving over 60 experimental drugs, of which many have achieved FDA approval for standard of care use today.
In the first month of my internship, I was able to shadow and observe everyone that works in the research department. By doing this, I was able to introduce myself to all of the different aspects that are involved in the management of a clinical research site. The investigational product coordinator is the one that is responsible for the handling of all the research medications that are being studied at the site. I was able to help out this position by helping out with tasks that included receiving shipments of investigational products, keeping up with the inventory, with investigational product accountability, and working to update the SOP that used for the handling of the investigational products. The data coordinator is the person that is responsible for entering the data for the studies that are being conducted at the site. I was able to help this position by entering data from patient visits, answering queries that were asked from the sponsors of the research studies, and making sure that the source documents for patients were kept in the proper places. The regulatory coordinator is the person that is responsible for that the study is being conducted according to protocol by making sure that the proper documents are up to standard. This includes having the most up to date protocols and informed consent forms that are IRB approved, making sure that the personnel have the required training,
organizing site visits, and making sure that the guidelines that the sponsors of the studies have set are being adhered to. I was able to help this position by helping anytime the sponsors of the studies wanted to perform an audit for specific documents. The lab coordinator is the person that is responsible for conducting the procedures that collect the samples and data points that are asked of the study. I was able to help this position by making sure that the proper lab kits were always on hand and ready for the patient whenever they have their visits. I ran inventory on the lab kits and made sure that lab kits that were expired were disposed of and that new lab kits were ordered to replace them.

In summary, working as an intern has allowed me to see all the roles and tasks that need to be completed at a clinical research site. It has taught me about the amount of coordination and communication that the research team needs to be successful, and it has taught me about the struggles that research studies can face. Most importantly, working here has shown me the importance of bringing research to the community level, providing this service to those that have not previously had the opportunity to receive such treatments.
Dear potential study participant,

I am a graduate student at the UNT Health Science Center in Fort Worth, Texas, and I am asking for your participation in a study that involves the standard operating procedure (SOP) for handling research investigational products. Specifically, I am studying the SOP as it currently stands, and assessing what areas are lacking in clarity and understanding. The hope of this project is to update the SOP, so that all of those involved in handling of the investigational products will follow the procedures ensuring complete compliance with the research protocols. The title of this practicum is, “Implementation of an Updated Standard Operating Procedure For Investigational Product Management”, and will be conducted under the guidance of Ladislav Dory, who will serve as the principle investigator.

If you choose to participate in the study, you will be asked to complete a 10-question survey that will assess your understanding of the SOP for investigational products. It will take approximately 5 minutes to complete. This survey is conducted with complete anonymity, so your responses will not be linked to your identity. After making the updates to the SOP, the same survey will be given again. This is done to assess the change, if any, in your understanding of the SOP.

If there are any questions or concerns regarding your participation in the study, please contact me at johnny.dang@my.unthsc.edu, or the Dr. Ladislav Dory, the principle investigator at lad.dory@unthsc.edu.

Thank you for your time and consideration,

Johnny Dang
APPENDIX B: DAILY INTERNSHIP PRACTICUM JOURNALS

5/31/2016

On my first day here, I was introduced to everyone in the research department where I would be working. I was told that I was going to be shadowing Jo Ann, who is the investigational product coordinator. She gave me a tour of the facilities to familiarize myself with the building and the different labs that are located throughout the center. I was asked to read 2 studies to familiarize myself with the type of language that is used in a research brochure. I read the “Standard of Procedure” for the facility to understand the rules that they have to follow when carrying out a research project. This was important, as I needed to know the order of how an investigational drug is tested and used in treating patients. I got to go into the admixture room, and I was able to watch the process that is performed when drugs are to be sent out to the smaller satellite sites. I was able to help organize drugs into their respective storage areas.
06/01/2016

I was told that a monitor for one of the studies would be coming later in the week to check up on the research study, so I read the associated study to familiarize myself with the material. I was able to help prepare the binder for the study that was going to be presented to the monitor. I helped take inventory on drugs and checked drugs in that were delivered to the center. Each drug that is delivered has a specific number associated with the identity of the drug. This data is logged into their respective research binders. Some drugs were in the inventory were expired and I was able to help get rid of drugs that were out of date. For these medications, I helped make sure that they were the correct drugs that were supposed to be destroyed. This is important to actively make note and look for these drugs as we do not want to give an expired drug to patients. This is also necessary to clear up space and it allows the facility the ability to keep the research drugs in an orderly way so that they are available to get in a quick, orderly manner.
06/02/2016

I performed a temperature log as we were preparing for a close out visit from a clinical research assistant that day. This was important to do because the investigative drug needs to be stored in the correct environment, so that it can maintain its efficacy. I went to the admixture room so that I could observe medications that were going to be delivered to Weatherford. After doing this, I saw how Jo Ann made documentation in the master accountability logs. This is a document that we use to account for all of the research drug that is delivered to the center and what is being distributed out to the patients. I was able to observe the documentation in the destruction sheet whenever we received word from a monitor of a study to destroy a drug that we had on site. This is a document that is used to show that we disposed of the correct drug. I helped check in a drug that was delivered to the site and I was able to put them away to their correct places. At the end of the day, I helped prepare for a monitor meeting that was set for the next day.
Today, I was able to shadow Rene, the lab coordinator for the investigative products. One of the first tasks that I performed today was reviewing patient’s logs so that we could determine the necessary actions for follow-ups. This is an important step in the process, as this makes sure that the patients come in and get whatever labs they need done, to make sure that they are compliant with the research protocol. This also allows us to take out the patients who are no longer participating in the study, either due to toxicities or now being deceased. Of those that were suspected to have expired, we made calls to confirm this so that we could obtain proper documentation to keep on file. The next task that I observed her perform was the preparation of the labs for the next week. We went into the centers database and saw the patients that were scheduled to come in to have labs done, or to receive treatment. We prepped the actual lab that was being performed and laid out the materials that were going to be used. This was an important step because it allows us to be efficient whenever the time comes for the patient to get their tests or treatment done. A part of the preparation was to make sure that the labs were paid for either by the patient’s personal insurance, or the research company. I helped
destroy lab kits that were expired and ordered new drug kits to replace them.

Whenever we destroyed the kits, we recycled some of the materials so that we could save them for other uses.

6/6/16

The first task that I performed for the day was record temperature logs. This is a weekly task that is performed every Monday to ensure that all of the drugs that we have on site are kept to the storage standards that will maintain the drugs ability to work. I was able to work the computer and actually run the program myself, and I documented the recordings. There was a deviation that was found, so I had to notify the monitor of these findings and waited for word about what to do about it. Later that day, we received word to make a “note to file” so that we had this documented. It was deemed that the drug was still able to use as the deviation was over a short period of time. One of the main tasks of the day was to account for a missing drug that we needed to find before destroying the set of drugs for the study. We were notified that there was a new patient that consented to be involved in a research project, and we had to make sure that there was enough of the drug on site so that the patient could receive their treatment as soon as possible. I observed Jo Ann as she created a cheat sheet for a protocol for a research study. This is important to do so that we can streamline the process of getting information and get an easy
reference. For an end of the day task, we asked permission from the monitor to destroy the drug.

6/7/16

Today we were allowed to address the temperature excursion that occurred more than a month ago. It ended up being that the drugs were not compromised and that we could use it. The CRA took a long time to respond and we were not allowed to do anything until we got word from him. I see this as big problem because the study was basically put on hold until we were told otherwise. Jo Ann explained to me the importance of timely correspondence with a hypothetical example where a patient was enrolled in the study and had to receive treatment. The facility would not have been able to give this treatment because we are unsure about the status of the drug until we got confirmation from the study’s monitor. The next task that was addressed was destroying drugs that were expired. Again, this is an important step to do so that there is not too much clutter, allowing for better organization and accessibility for the drugs that we do need. We dispensed drug that was to be sent out to satellite sites. I read a protocol for a blinded study. This was my first exposure to the protocol for a blinded study and I was able to see how the process is a little bit different with regards to who gets to see what. I read IP management for the drug
that is involved in the study and this showed me the details that Jo Ann has to look for when dealing with these medications, as each one will have specific instructions that need to be in compliance with. Received drug in the mail and processed it in the system.

6/8/16
The first task of the day was receiving the morning shipment. We discovered that the boxes were wet and we notified the monitor to ask about possible precautions that needed to be taken. We basically wanted to know if the drug was compromised because of this. The next thing that I did was create a cheat sheet for a protocol. This streamlines the info that is in the protocol so that we can have a quick reference to the information that we need. In the afternoon, we had a Meeting with Melissa Pool. This meeting was done so that we could touch base with everyone in the research department and to address any problems or shortcomings that we had during the week.
6/9/16

We started the day by dispensing drug to satellite sites. Afterwards, we filled out the corresponding master accountability logs. The next thing that we did was complete the actions from a follow up letter that we received from a monitor visit. It was found that there was a discrepancy in the dates of shipments of drugs that we received and this caused a mix up regarding the total number drugs that we had on site. We had to go through the shipment logs and fixed dates to verify shipments and to account for the total amount of drug that the facility was receiving. I saw the importance of keeping good meticulous notes on this type of information, as we never would have been able to solve this issue if we were not careful with the documentation. We made modifications to the SOP to fit the Texas center. We are part of a bigger branch of networks. For the drugs that got wet from the previous day, we received word that we were able to open the boxes to see if the actual drug was okay. It was deemed that we could keep the drugs. We updated the transportation sheet, so that the correct temperature ranges that we want the drugs to be kept. This is an important document because this is essentially a transfer of
stock, so this helps keep both locations accountable. I helped Consolidate important forms within a new protocol so that they are in one place. The binder was too big and inconvenient to go through again every time that we need a copy. There was an amendment to a study, so I read it to see what types of changes were made. The purpose for this amendment for a study design change. Went from a phase 3 to a phase 2. This was done to see if the drug in question could be used for something else. Allows the drug to be tested so that we could possibly use it for a wider range. Through this I learned about the phases of a study design and the different study phases that a drug goes through before it goes out to market and even after that

6/10/16

Started off the day by dispensing drug to satellite sites. I filled out the appropriate forms, which included the accountability logs and the transport forms with updated temperatures. I filled out the dispensation forms myself for the drugs that had to be done the next week. This helps make sure that we are ready whenever the patient comes in. Created a cheat sheet for study. There is going to be an SIV next week, so I read the protocol so that I could familiarize myself with the information.
Today was the beginning of my time shadowing Deanna, the regulatory coordinator for the research department. We started off the day by answering emails that she received regarding the studies that were being conducted. As we went along, she explained to me the importance of the different forms that were in question. She showed me how important it is for proper communication between her and the rest of the research department to fulfill the requirements that are set out by the sponsors of the studies. One of the biggest tasks that we did for the day was updating training logs. This makes sure that everyone that is working on the study has the proper training to do so. This is important so that the site can avoid any deviations that would be caused do to a lack of training/knowledge.
Today, we started the day by preparing binders for a monitor meeting that was occurring later today. This involved us going through the monitors notes, making sure that everything that they needed would be accessible to them. This is important to do so that the follow up letter from the site visit is limited in its content. With regards to follow up letters, Deanna went through a previous one to show me how she addresses the problems that were mentioned by the monitor. This must be done to let the monitor and sponsor know that the site is diligent and takes these matters seriously. Again today, we made sure that the proper personnel had the training that they needed to work in the study. Doing this properly meant that we had to send out notices to those that haven’t done the training and giving them a deadline for when it needed to be done.
6/15/16

The first task that we did was run a safety report for a monitor meeting later in the day. Deanna showed me the importance of this form because it shows all the serious adverse effects (SAEs) that were involved with the study from all over the world. This is important because this informs the physicians that are involved in the study of what side effects could possibly occur with their patients at their respective sites. On a serious event that happened today was that we were notified that one of the patients signed a faulty informed consent form (ICF). This form was missing important information that need to be told to the patient, so this means that the patient needs to be re-consented after the problems are resolved. We then had a meeting with Melissa. We talked to her about the ICF problem and we were told that it had to be recorded as a deviation. This was a serious problem that needed to be addressed so that we can recognize where along the process this mistake occurred, and how it can be prevented in the future. We updated the delegation of authority (DoA) logs. This lets those involved in the study know what their responsibility is. This is important to do so that everyone knows what his or her duty is. This also
allows Deanna to send the proper training notifications to those that actually need it.

6/16/16
The first task of the morning was to prepare a study binder for a monitor visit. This included running the SAEs report and getting the deviations log that is accompanied with the study. We updated more DoA logs so that the most up-to-date requirements were being met. Putting together the binders helped stress the importance of communication in the chain of command from the sponsor, to the CRO's, and then finally to the site.

6/17/16
Out due to a family circumstance

6/20/16
Today was the beginning of my shadowing time with Brian, the data coordinator for the research department. We met with Melissa and we were told that the Sarah Cannon Research Institute was running an audit on all of the studies that were being done at the site. I was told that it would be my job to obtain all the information that
is required so that the site could be reimbursed for everything that we doing for the studies. My task for the rest of the day was inputting data from monitor visits into the master spreadsheet that needed to be completed.

6/21/16
In continuation of to the previous days task, I was asked to go through patient histories and keep track of the studies that they were involved in. This included any scans/tests that they had performed to meet the requirements of their study. For each patient, I took note of what scan/test they received, when they received it, and input the data that I found into the audit spreadsheet.

6/22/16
For the audit, the Sarah Cannon Research Institute required a list of all SAEs. I went through every study that had an SAE and made note of which patient had what adverse effect, to what extent did the patients experience this adverse effect, and when the problem started and finished. I then created a document for my data and then transcribed that into the master spreadsheet that needed to be filled out. For the second half of the day, Brian showed me how to input a patient’s data into the site’s electronic medical records, and I was able to do this for multiple patients.
6/23/16

Today was a continuation of the audit that needed to be done. The information that I was obtaining today was the dates that the patients re-consented to the study. The reason why this is required is because there was a change in the study, which could be anything from a procedural change, a new adverse effect, etc. The patients need to be notified of these changes and are once again, allowed to make the decision on whether or not they want to participate in the study. The reason this is in the audit and is reimbursable is because the study coordinators at the site are required to redo the informed consent process, which is something that they can be paid for. I took this data and transcribed it into the audit's spreadsheet.

6/24/16

As I did not finish obtaining the data from all the patient’s re-consent from the previous day, as soon as I got to the center, I continued to record the dates that the patients re-consented to the studies. I was able to finish this task before lunch. In the
afternoon, I was able to go through patient records and helped input data from their records into the sponsor’s electronic data capture.

6/27/16

When I first got to the center, I was told that I was going to be working on an ongoing, observational trial. This type of study is one where they follow patients to obtain information and observe how they are doing on their current medications. No manipulations are involved and nothing is given to these patients. Brian told me that this type of study is performed so that the study can know what current standard of care regimens is working. This type of study requires constant upkeep so that none of the data is lost, and to make sure the records are up to date. Without this type of oversight, the amount of material and data that comes from the study can pile up, making work a lot harder than it needs to be. I helped catch up this study for most of the morning and the early afternoon. For the rest of my day here, I helped input data for a patient from a different study and I helped file away patient documents into their respective folders.
When I arrived this morning, Brian told me about a situation where a physician needed to enroll a patient, but there was a circumstance that could possibly stop her from enrolling because it didn’t comply with the written protocol. The physician wanted to get the patient started as soon as possible, so the solution was to get in contact with a medical monitor of the study to make sure that she could do it, as this was deemed to be the best opportunity to help her patient. Brian explained to me that the site didn’t have all the medical monitors’ contact information ready and on hand, so it was my job to compile a master list with this information. In the afternoon, the research department had a meeting with Melissa, where we talked about things that had to do with regulation, upkeep of data, and the importance of communication within the department.
As I was not able to finish the task yesterday, I continued to update medical monitoring logs. I was able to finish this task before the afternoon. After lunch, Brian showed me another sponsor’s EDC and showed me how to answer queries about the data that we inputted into the system. I had some difficulty navigating through the system as I was not used to the verbiage that was being used and it was hard for me to locate certain pieces of information. I was able to get through a decent amount of queries before leaving for the day.

6/30/16

The first task of my day was to continue entering patients’ data into the EDC. Today went by a lot smoother as I was able to acclimate to the system being used. I still had trouble finding things, but after some trial and error, I was able to successfully find the necessary information for the patients. In the afternoon, Brian showed me another sponsor’s EDC so that I could see the different interfaces that they use. Again, I had a hard time at the beginning trying to figure out how to navigate through the system, but I was able to figure it out after some time. I was able to input data for 2 patients before leaving for the day.

7/1/16

Today, there were 2 study monitors that were coming to the site. The first thing I did was I gave the monitors access to their respective studies. They could now see all the patients and their information that are associated in their study. This makes
sure that the monitors get all the relevant information that they are there for and nothing more. For the rest of the morning, I put away patient files and updated them with new documents that were sent to the site.

7/5/16
Did not return to work because of a problem that occurred over the weekend

7/6/16
Today was my week to follow the study coordinators, Jennifer and David. I got introduced to the overall process of the following patients through their studies, and had a conversation with how the study coordinators work within the flow of a research department. I was told that it was important to work ahead of schedule to make sure that everything for the research patients are in order whenever they come get their treatment. I followed David as he went to visit his morning patients. I got to interact with the patients as David asked them questions about how they felt since their last visit, such as any adverse effects that have happened. This is important to do so that the physician can be notified before they come and speak to the patient. This allows the physician to be prepared and able to address any questions or concerns that the patient might have. SOV’s are filled out afterwards to make sure that the interaction was done to protocol. The rest of the morning was filling out paperwork and writing notes into the electronic medical records. The
importance of this was stressed to me because doing this step in a timely manner helps ensure accuracy of the patient’s visits. In the afternoon, I was able to observe David and Jennifer as they prepared for their patients that were coming in the next couple of days.

7/7/16

In the morning, David showed me how he screened patients. For each study, there are inclusion and exclusion criteria that are placed so that an appropriate patient will be selected for the study. This makes sure that the study can get accurate results and that the patient is possibly going to receive the promised benefits of the drug. This is an important step because it makes sure that the patients that are interested in research trials are put into studies that will help alleviate their symptoms. The other side of this is that this allows those patients that don't have the inclusion criteria or those that have the exclusion criteria to not waste their time and energy on having this conversation. This helps the research department with workflow and efficiency as screening patients is what allows the patient to either go on study, or not. By being proactive and screening patients, the study coordinators ensure that the research department is able to do its job and get patients on potential study
trials. In the afternoon, we saw patients and made annotations and notes just as we did yesterday.

7/8/16
In the morning when reviewing a patient’s notes, David found a potential problem that would delay the patient from continuing to the next phase in the trial study. The patient was going to be coming in today to sign her informed consent documents to start a trial, but the problem David found would stop her from being able to do so. It was important that the patient be notified of the situation and that she would not be allowed to start a new treatment without first consulting the primary investigator. David decided it was best to wait for them to come in and have a face-to-face conversation instead of a phone call, and I believe this was the correct route of action. By sitting down and having a conversation, David was able to make sure that the patient understood everything and was completely informed about the process that would be taking place in the next couple of weeks. We spent the rest of the time speaking with the patient about upcoming treatment options and what steps need to
be done moving forward, so that they would continue to receive treatment. In the afternoon, David and Jennifer prepared for the following week, by setting up phone calls and meeting times with patients, so that they could talk to them about possible clinical trials that they would be interested in.

7/11/16

Today, I was told that I would be helping out Deana with an audit. The audit was for informed consent documents, so this required me to go through a list of patients to make sure that their informed consents were signed. I went through each regulatory binder and had to locate each person on the list to make sure that the original hard copies were present. This was important to do because it makes sure that the agreements are on hand and ready in case they are called into question. Another thing that I did was to make sure that the most recent informed consent document was available in the binder, meaning that the most up to date version of the informed consent form was on file. This is important because by being proactive in this way ensures that any new patients for studies will sign the correct ICF. This helps save the site and patient a lot of time and energy by making sure that the informed consent process doesn’t need to be done more than necessary.
7/12/16

For the first part of the morning I continued the audit from the previous day. I found a couple that were missing from the day before, and had them filed in the correct place so that they would be easier to find next time. In the afternoon, I was able to help out Jo Ann with tracking a patient's accountability by reviewing their drug diary and making sure that their doses were taken at the correct time intervals. It was also important to do this because of the accountability of the drug as well. There was a delay in the dosing in the middle of the patient's treatment, which caused confusion both on their end, as well as our end when it came to the amount of drug that they should’ve had in hand. At the end of the day, I spoke with Jo Ann about the progress of my thesis proposal and my practicum project. I felt that this was important since I was going to be directly working with Jo Ann in the management of the site’s investigational products.
7/13/15

In the morning, I worked with David as he went through his list of possible research candidates to see if he could set an appointment time to either talk with them in person, or over the phone, to give them more information on the study that they could possibly be involved in. In the afternoon, Jo Ann gave me another drug accountability project to work on. I went through patient diaries, transportation logs, and master accountability logs to create a spreadsheet that allowed me to have a timeline where I could refer to, to find the missing data.

7/14/15

In the first part of the morning, I spent more time on the drug accountability assignment from the previous day. I then reconsolidated study binders so that the information was organized. I also did this for the temperature logs that the site keeps on hand, separating the information by the type of storage that was needed (ambient, refrigerated, or freezer) and by the year.

7/15/15

Today was a designated “research/thesis day” where I worked on my research proposal.
7/18/15

Today was a designated “research/thesis day” where I worked on my research proposal.

7/19/15

For the first part of the morning I worked on my proposal for my research/thesis project. Towards the end of the morning, I helped Jo Ann plan for the research department moving to a different part of the facility. The biggest part of this task for me was to gather material safety data sheets for each of the drugs to make sure that the new area has all of the necessary equipment, ensuring that all of the drugs will be kept in an environment where they would remain safe and efficacious.
In the morning, I sat in on a meeting with Jo Ann and a monitor, where they discussed IP management and how to improve upon it. There was a list of materials that the monitor wanted to take a look at and Jo Ann and I spent the morning obtaining the pieces of information that the monitor was looking for, so that we could minimize the amount of information in the site’s follow-up letter. In the afternoon, I watched a demo on a possible system that could be implemented into TCCBD. This system is called Vestigo and it is essentially, an investigational product manager. It does everything that the IP coordinator would need to make note and write down by hand. This system would take down a lot of the paperwork that the IP coordinator would have to do. One of the biggest benefits that I got out of this system is that it promises correct and accurate accountability. Another benefit is that Vestigo has the possibility of being able to work within other interfaces. This
would be ideal and advantageous for TCCBD as they are about to employ Onco-Trials, a clinical trial management system, who is missing this aspect. After the demo, Jo Ann, John (Pharmacy director of TCCBD), and I went and talked with Melissa about the demo. We discussed the positives and negatives of the system and talked about the feasibility of implementing the system.

7/21/16

I performed various tasks throughout the day, which included preparing binders for the site-monitoring visit, putting away patients’ documents into their respective folders and proceeded to file them, and I was able to help Jo Ann as she went through the accountability for a research medication. Throughout the day, I worked on my research/thesis proposal’s accompanying questionnaire.

7/22/16

I was asked to look at the current temperature trackers that we have on site, and I recorded when they were manufactured and when they are set to expire. By doing this, we know when we need to get them re-calibrated, so that we can ensure their functionality. This ensures the safety of the drugs that we have in transit. I called the supply company and made inquiries about the pricing of the temperature loggers.
and got a price quote for the needs of the site. I then proceeded to figure out the next steps in possibly ordering more of these temperature loggers, and sending them back in for re-calibration.

7/25/16

Today, Brian showed me the process of reconciling patients’ medical histories and their accompanying adverse event logs. It is important to do this because it lets us know if any adverse events that happen throughout the time the patient is in the study is attributable to the study drug, or if it was because the patient had a condition in their medical history. This allows the study to know what actual side effects their study medication is causing, so to better describe their medication when it becomes available to the public. After, doing this with Brian, I was able to work on this project on my own and proceeded to do this for the rest of the day.

7/26/16

Today, I sat in with David, as he went into the EMR, making his notes on previous visits that he had with patients. He paid attention to close details, such as the
patients’ diets and habits that the patients had during the course of their treatment. This is done to assess how much of their daily life has been affected by the medication. I also went in with him as he saw his patients for the day.

7/27/16
MCAT study day

7/28/16
I was asked to put away a stack of different patients’ paperwork and file them into their respective folders. This included the patients’ labs, adverse events that were reported, and any correspondence that occurred in relation to the patient. After filing away all of the paperwork, I reorganized each of the folders so that each folder was organized in the same way. This allows for consistency across the entire system, allowing us to know where to look when we need to find information.

7/29/16
In the morning, I was asked to help with data entry. I was given a report that had pieces of information that was missing. The entry of data was incomplete without this information, so I was tasked with going through the patients medical records to
figure out the information that was needed. In the afternoon, I met with Dr. Warren to discuss my practicum project.

8/1/16

I spent the day working with data entry. I was given a study that I was familiar with, and was working with an EMR that I had previously worked on. I was able to successfully navigate through the patients information and answered queries.

8/2/16

I spent the majority of the day entering data for the study that I worked on the previous day. In the afternoon, I prepared regulatory binder for monitor audit, making sure that the necessary pieces of information were present, and retrieving any information/paperwork that was missing.

8/3/16
Today, I was given the privilege of shadowing Dr. Page at his Weatherford clinic. I was able observe as he visited with patients, enter his notes, and take care of his daily duties. I was able to ask questions whenever they arose.

8/4/16
Day off

8/5/16
MCAT

8/8/16
Shadowed Dr. Page in Weatherford.

8/9/16
I was given a list of studies that had been closed by the institution's IRB. I removed patient files, and any accompanying information to put away into storage boxes. These boxes are going to be sent to Weatherford, where they will stay for 2 years. This allows us the ability to go back and get any information that is requested by the sponsor, monitor, or any agency that has inquiries about the study. After removing these files, I rearranged and organized the area where the patient files are kept

8/10/16
Shadowed Dr. Page in Weatherford.

8/11/16

I sat with JoAnn and we read through the SOP that pertains to the handling of the investigational products. We talked about the best way to approach each of the aspects, determining how to address the problems that have resulted in inconsistencies in how the IP is being monitored. In the afternoon, JoAnn and I had a meeting with Melissa, discussing the ideas that we came up with earlier in the day.

8/12/16

I worked entering data for a study. I went through the patients’ records and entered data from their visits. I answered queries and addressed any inconsistencies with what was entered and what is found in the source data.

8/15/16

I spent the morning and early part of the afternoon entering data. It was a little more difficult today as I was working with a new study, and it had a different interface that I had never used before. I had to spend a lot of time learning how to navigate through the system, but I was eventually able to answer the queries that were presented. In the afternoon, Brian and I had a meeting with Melissa, and we discussed any problems that were present and Melissa told me about an upcoming...
task. Soon, I was going to go through the regulatory binders and audit the ICFs that we had for each patient. Melissa stressed the importance of this task, as many of the deviations that occurred at the site have been due to the ICFs and how they are being obtained and kept.

8/16/16

Personal day off.

8/17/16

I was asked by Rene to help her take an inventory of all the lab kits that came with each of the studies. I took note of the number of each type of lab kit and their expiration dates. This was important to do so that Rene can make the necessary orders, to make sure that the study won’t be delayed due to lack of supplies. By keeping note of the expiration dates, we know what needs to be ordered and when to order them. It is also important to keep track of this type of turnover because there is a limited amount of space at the site, and this ensures that the lab kits on site are going to be put to good use, and that they aren’t taking up space.

8/18/16
Because I was not able to take an inventory on all of the lab kits yesterday, I continued this task for most of the morning. After compiling my spreadsheets, I turned them into Rene, and she told me which ones she wanted to pull so that we could “destroy” them. Destroying the lab kits meant that we were no longer going to be using the materials found in the kits for the studies, but using them elsewhere, so that we are not wasting resources. I went through each of the “destroyed” lab kits and saved materials, such as needles, slides, and glass vials.

8/19/16
I started the task of auditing the ICFs. I made spreadsheets for each study, taking note of each patient that signed an ICF. This included patients that eventually enrolled in the study and those that eventually screen-failed.

8/22/16
Continued my task in auditing the site’s ICFs.

8/23/16
I started off the morning by cross-referencing the spreadsheets that I had created for each study with the clinical trial management system, FlatIron. Every ICF that is found on site should have data that is found in this system, and vice-versa. If information on the ICF is missing, then it must be found so that we can avoid deviations. After doing this, I gave my notes about the inconsistencies that I found and gave them to Deana, so that she could help figure out what needed to be done. In the afternoon, Rene asked me to help her with filing away packing slips and air
bills that she received. I had the paperwork into their corresponding studies and filed them away into their respective lab manuals.

8/24

For all of the morning, and most of the afternoon, I helped Brian with data entry on a study. I first filed away the paperwork into their appropriate sections, and then I proceeded to enter data into the EDC. After that, Brian asked me to help him try to find documentation on 2 patients that would have possibly been “loss to follow up”. This means that the patient had agreed to allow us to follow them after the conclusion of the study, so that we could get information about their survivorship, but for whatever reason, we were not able to contact them. Despite efforts from CCBD, the 2 patients that I was looking for had not been contacted in over 2 years. This means that we are allowed to officially document that the patients were indeed “loss to follow-up”
8/25/16

I started the morning by filing away patients’ paperwork into their shadow charts, making sure that they were being put into the right spots. Towards the end of the morning and the early part of the afternoon, I helped Brian with data entry for another study. This was a study that I had never previously worked with, so the EDC was a little tricky to use at first. Eventually, I was able to enter the necessary data and answered the queries that were asked.

8/26/16

In the morning, I helped with data entry. In this particular EDC, as I entered the data, automated queries would pop up that would ask for further clarification on what was being inputted. In the afternoon, I was given a list of queries on a different study that needed clarification/answering. Going through the EMR, I was able to resolve most of the issues that were on the list.
8/29/16

In the morning I filed patient source documentation, making sure that they were first scanned and documented into the EMR and then placed them in the correct places in patient shadow charts. In the afternoon, I helped Brian with data entry and answered queries.

8/30/16

In the morning I went with Rene when she went to pick up a tissue sampled from one of the associated labs in Fort Worth. Unfortunately, the tissue sample that was prepared was not “blocked”. Rene explained the significance of this because the tissue that was being sampled would be used by the study for “archived tissue”.
This means that anytime the study wants to go back and look at the original sample, this is the sample that they will be using. In the afternoon, we had the weekly research department meeting, where we talked about prospective patients, or any problems that had arisen throughout the week. The biggest highlight from the meeting was going through the process that we use when providing informed consent to patients. This was done to make sure that everyone is on the same page when it comes to this process.

8/31/16

JoAnn asked me to go through the investigator's brochure and protocol for a study so that I could create a cheat sheet for the study. This allows us to streamline the important information. A project that JoAnn is working on is creating data transportation sheets that are specific to the drug that is being transferred. Helping her with this, I went and found the stability conditions for certain drugs and this information was transferred to the transportation sheets. This helps the chemotherapy nurses by giving them a quick reference to the medication that they are about to administer, so that they can make sure that the drug is safe to give to the patient. In the afternoon, Rene asked me to help her fill out lab requisition
forms. This is done for proper record keeping, and accountability for what tissue samples the study should have.

9/1/16

Rene asked me to find expired lab kits and ones that are expiring at the end of September. She does this at the beginning of every month to ensure that patients aren’t using expired lab kits, and that she orders what is needed so that the correct kits are available. This makes sure that inventory is properly kept. In the latter part of the morning, JoAnn asked me to help fill out a temperature excursion form for an incident that occurred the day before. In the afternoon, I helped David set up his filing system for patients that are in follow up. Going through patient files, I went and found each of their upcoming visits and filed them accordingly to this date. This
helps David by making sure that he knows who he needs to schedule for their future visits.

9/2/16

Off Day

9/6/16

My first task of the day was to help prepare for a monitoring visit. I got the binders ready and gave the monitor EMR access for the patients that are involved in the study. After that, I filed away patient source data and made sure that everything was updated in the EMR. I then helped Brian with data entry by answering queries. We also had the weekly research department meeting. This was a rather short meeting as we discussed the training that would be occurring this Friday. We talked about what would be happening, what to expect, and what we needed to do to prepare for it.
9/7/16

From the monitoring visit yesterday, there was a list of tasks that was given to us so that we would know what to expect in the follow-up letter. I was given the task of addressing these issues, so that when the follow up letter was received, everything would be taken care of. By being proactive in this process, the site is able to make further scheduling appointments for monitors to visit, which ultimately reflects as adequate oversight of the study from the research site. After addressing these issues, Brian asked me to update the patient data schedule. This schedule is used so that the site is able to keep track of which patients are coming in on a weekly basis, and to make sure that appointments are kept, ensuring that the study is done in the time allotted per protocol.

9/8/16

I was given an ongoing project from Melissa and JoAnn. This project revolves around the adverse events and side effects that are involved in the study drugs that are given to patients. I am to go through each of the studies that are being conducted at the study, and note what the associated study drugs are, and what possible risks each of those drugs come with. Ultimately, I will be creating a spreadsheet that is used by the physicians of TCCBD, so that when they see their research patients, they will be able to better attribute certain ailments to the study drug that they are receiving. Overall, this is important to do as the development of the research drug
depends on proper identification of all the benefits and risks that come along with it. I spent the day going through the studies that are on site, and began to compile the information needed.

9/9/16

Today was a whole day of training that was provided by the representatives from the Sarah Cannon Research Institute. These representatives came to the site so that they are able to help with the development of the site’s SOPs. Walking through the process with us and making sure that everything that needs to be mentioned is included. Topics discussed include the following: CAPA (Corrective and Preventative Action), research misconduct, SOPs for informed consent and reporting of adverse events, and how the research in lung cancer has shifted in recent years.

9/12/16

Brian gave me the task of updating the patient data schedule for an ongoing clinical study. The purpose of this study was to follow these patients after their treatment and note the survivorship and quality of life that they are having. My job was to go through each of the patients that participated in the study and note whether or not they had expired, and whether or not they were still allowing us to follow them. I then updated the patient data schedule with the information that I had gathered. Towards the end of the morning and early part of the afternoon, I spent time filing away patient shadow charts, making sure that the documents were in the right
places. For the rest of the afternoon, I answered queries for a study and updated the EDC with patient visits.

9/13/16
In the morning, I entered data and answered queries. In the early afternoon, I worked on the adverse events project that was given to me by JoAnn. In the last hours of the day, we had our weekly research meeting, where Melissa assigned the task of going through Flat Iron, the site’s clinical trial management system, and making sure that the information that they had matched correctly with the source documents. Melissa explained to me that this system generates reports that she uses to assess how the research department is doing, so the information must be accurate.

9/14/16
Today, I worked on the project that was given to me yesterday. My job to compare the information that was found in Flat Iron to the notes in the EMR and make sure that the information was transcribed correctly. If incorrect information was found, I went in and made note of them so that the correct changes could be made.

9/15/16
Today, I worked on the adverse event project that was given to me last week from JoAnn. In the afternoon, I had a meeting with Melissa and JoAnn regarding
investigational products and the SOP that accompanies them. Separate satellite sites were discussed and the problems that each of them faces. After the meeting with Melissa, JoAnn and I met with nurses’ manager to discuss some of the changes and notes of emphasis that would be occurring.

9/16/16

Today, I continued my task of going through flat iron and making sure that the information on there was correct. I was able to finish all of 2015 enrollment logs, and started on the data for 2014.

9/19/16

In the morning, and early part of the afternoon, I continued my project of from the previous day and finished it. Afterwards, I helped Brian with data entry and answering queries.

9/20/16

In the morning I helped Brian answer queries and I helped file away patients’ source documents. In the afternoon, the research department had a meeting with Melissa.
Topics of discussion included SOPs for the process of obtaining an informed consent, possible population analysis, and the working practice guidelines.

meeting with Melissa

9/21/16

Today I helped Rene receive a shipment of investigational products. I helped record the temperature of the drugs using the accompanying temp tale and helped make sure that the shipment had the correct identification numbers for the expected medications. I also helped Rene receive new lab kits and I helped break down and recycle old lab kits.

9/22

In the morning I helped Brian by answering queries. In the afternoon, I accompanied Melissa and JoAnn when they went to the Weatherford Clinic to assess the current storage conditions of the site. We discussed with the head nurse about what they think they needed to address, and asked how we would be able to help. We also looked at the space that the drugs were being stored and thought about ways we could better enhance the area, while staying in research compliance.
9/23

I helped Rene destroy and recycle lab kits. This task was a little different today, as I had to keep track of the lab kits that were being destroyed. Rene explained that this was because the study that the lab kits were for was now considered “closed” so this was a necessary task for accountability of what was on site. This sheet was placed inside of the regulatory binder.

9/26/16

I helped Brian answer queries that were sent from the study monitors. I was able to use the EMR and patient source documents to fix the inconsistencies that were noted.

9/27/16

I helped Brian answer queries that were sent from the study monitors. I was able to use the EMR and patient source documents to fix the inconsistencies that were noted. I also helped Brian by filing away patient source data that had been obtained from the most recent visits.

9/28/16
I helped Rene receive a shipment of new lab kits and placed them in their designated areas. I destroyed/recycled expired lab kits.

9/29/16

Today I was given the opportunity to prepare for my upcoming interview.

9/30/16

I was asked to organize patient checklists today. These are used to make sure that the study coordinators are doing everything that they need to for the patient during the visit. These are to be filed away so that the site can have record saying that such procedures were done for a specific visit. This is to make sure the site has a source saying whether or not something was done.

10/3/16

I helped Brian answer queries that were sent from the study monitors. I was able to use the EMR and patient source documents to fix the inconsistencies that were noted. I also helped Brian by filing away patient source data that had been obtained from the most recent visits.

10/4/16
I was given the task of entering data into the EDC for patients’ most recent visits. I also answered queries today.

10/5/16

I helped Rene receive lab kits and placed them in their designated areas. Throughout the day, I would be asked to perform various tasks, such as making copies, filing items away, or organizing certain areas.

10/6/16

Today was a slow day in the office, so I was allowed to work on other tasks that I needed to have done. Throughout the day, I would be asked to perform various tasks, such as making copies, filing items away, or organizing certain areas.

10/7/16

I was given the task of putting away items from a study that had been closed by the institution’s IRB. I removed patient files, and any accompanying information to put away into storage boxes. These boxes are going to be sent to Weatherford, where they will stay for 2 years. This allows us the ability to go back and get any information that is requested by the sponsor, monitor, or any agency that has inquiries about the study.
10/10/2016

I helped answer queries for multiple studies today. Monitors noted some inconsistencies with what was found in source data and what was being inputted in the EMR. I was able to fix this by going through the medical records of patients and making sure they were properly recorded in the EDC.

10/11/2016
I helped enter data for patients that recently had visits, and I helped answer queries that were presented by monitors. To find the information, I had to go through patients’ shadow charts and the EMR to make sure that the information that was being put in the EDC was correct. We had our weekly research department meeting to touch base with each of the coordinators to see if there were any problems or anything to make a note of.

10/12/2016
I helped Rene receive new lab kits. I made sure that what was being put into inventory matched the packing slips and noted any discrepancies. I was also able to help by ordering lab kits to replace ones that were already expired or soon to be expired. Afterwards I helped Brian pack away the patient data that I had collected from the week before. I put them in their respective boxes and made note of what was being put into each one, properly labeling the materials, so that if needed, it can easily be found. I also helped by answering queries today.

10/13/16
I performed a reconciliation of patients’ concomitant medications and their adverse events that they experienced while they were on a study trial. This required me to look at the adverse events that the patients had experienced, and made sure that there was a designated medication that was given to the patient to solve the issue. If there was no such medication, I was required to answer the reasoning as to why.
This required me to go into the patients’ medical history and progress notes to confirm any inconsistencies.

10/14/16

I helped enter data for patients who had recent visits. When entering these data points, I was prompted to answer queries about whether or not the values that I was entering were significant or not. Because this assessment had not yet been performed, I printed out the document that the PI of the study receives. Whenever the physician assesses whether or not the data is clinically significant or not, they return the document back to the data coordinator, and then they will be able to answer the prompted queries.

10/17/16

Traveling Day for Interview: Campbell University - Jerry M. Wallace School of Osteopathic Medicine

10/18/16
Interview Day: Campbell University - Jerry M. Wallace School of Osteopathic Medicine

10/19/16

I helped Brian with entering data into a study’s corresponding EDCs. By taking the information from the patients’ visits, I was able to fill in the appropriate fields that were required in the EDC. After completing this task, I then filed away patient’s source documents into their appropriate folders.

10/20/16

I helped Rene receive a new shipment of lab kits. I made sure that the lab kits that were sent to the site were the lab kits that were ordered by referencing the inventory sheet with the original order form. I then marked these lab kits and put them away into the appropriate areas. I then destroyed the old lab kits that were being replaced and recycled the parts from the lab kits that were reusable in other areas of the site.

10/21/16

I helped answer queries that were given to the site from different studies. Inconsistencies were noted from monitoring visits and I had to find the correct information to fix these problems. By looking at the notes from the patients’ visits
and the source documents that were obtained, I was able to find the correct information that was supposed to be recorded in the study’s EDCs.

10/24/16

Today, I helped Brian with multiple tasks. I started the day with data entry for a study that I had been working with for the duration of my internship. I entered all of the appropriate fields in the EDC and then filed away the patient’s source documents into its appropriate area. I helped put away documents that had been recently signed by the physicians, and placed them into the patients’ folders, showing proper oversight of the study on the end of the physicians. I spent the rest of the day answering queries from different studies, making adjustments to the EDC so that there were no longer any inconsistencies in the information that was being recorded.

10/25/16

I helped Rene receive a new shipment of lab kits. I made sure that the lab kits that were sent to the site were the lab kits that were ordered by referencing the inventory sheet with the original order form. I then marked these lab kits and put them away into the appropriate areas.

10/26/16

Designated “Thesis Day”

10/27/16
Traveling Day for Interview: Midwestern University - Arizona College of Osteopathic Medicine

10/28/16
Interview Day: Midwestern University - Arizona College of Osteopathic Medicine

10/31/16
I helped Brian with entering data into a study’s corresponding EDCs. By taking the information from the patients’ visits, I was able to fill in the appropriate fields that were required in the EDC. After completing this task, I then filed away patient’s source documents into their appropriate folders. I was then allowed to work on/practice my presentation for the defense of my practicum project.

11/01/16
Day of Defense.