CLINICAL TRIAL MANAGEMENT ANALYSIS AND

INTEGRATION OF NEW POLICIES AND PROCEDURES

INTO A RESEARCH DEPARTMENT

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CLINICAL TRIAL MANAGEMENT ANALYSIS AND INTEGRATION OF NEW POLICIES AND PROCEDURES INTO A RESEARCH DEPARTMENT

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the Graduate School of Biomedical Sciences

University of North Texas Health Science Center at Fort Worth

In Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE

By:

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Fort Worth, Texas

February 2013

ACKNOWLEDGEMENTS

This practicum and report would not be possible without the support of my thesis committee, comprised of Dr. Ladislav Dory, Dr. Ray Page, Dr. Patricia Gwirtz, and Melissa Sottosanti. Thank you for your hard work and dedication to this project. Also, the encouragement and reassurance from the research staff at The Center for Cancer and Blood Disorders: Melissa Bagwell, Robin Rutt, and Brandi Halstead, was instrumental to the success of the internship and made the experience a positive one. Finally, this could not have been done without the love and support from family, friends, and especially, Geoffrey Hannan, who pushed me through, even when I thought I could go no further. Thank you all for your time and support.

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CHAPTER 1

INTRODUCTION

The purpose of this practicum was to increase productivity and efficiency in the clinical research department at The Center for Cancer and Blood Disorders (CCBD) in Fort Worth, Texas. The CCBD is a facility housing a research department committed to clinical research and good clinical practice guidelines. Starting in 1999, CCBD set out to become a benchmark for clinical research in the greater Fort Worth area and has become a leader in cancer care and cancer research in Fort Worth. Over the last few years, the research department has grown exponentially. The rapid growth has been stressful, because the department can no longer keep up with the study list or patient load using processes from the past.

The department needed a change to deal with the increased patient load and demands of the growing facility. Using new organizational techniques and increased computer literacy, the research team's ambition was to decrease the time it took to complete tasks. The objective of the practicum was to create a set of databases and spreadsheets to achieve this goal. Over the course of the internship, it was theorized that there would be an increase in productivity and tasks accomplished and a decrease in the number of protocol deviations filed by the research staff.

The significance of these updates to the research department was two-fold. First, increased efficiency and effectiveness equaled decreased stress and tension. The use of updated

processes was designed to make each job easier. Secondly, there was an increase productivity, which subsequently increased patient care. In the exam room, the research nurses were more prepared because they had more time to prepare for the appointment. Additionally, it was feasible to increase the number of clinical trials offered at CCBD. Offering a greater variety of studies provides the patients more treatment options.

The organizational tools developed for this practicum project consisted of multiple worksheets. The Principle Investigator (PI) Update Form, PI Patient Log, the Drug Inventory Log, the Research Database, and the Data Tracker were the implements created to quell the unnecessary tasks performed on a daily basis. These worked together to increase output, and decrease the time required to update the research staff on patient related events. To track certain aspects of the progress of the research staff and the validity of these worksheets, formulas were derived to track the number of tasks performed by each member of the department. Also, deviation reports were requested from the contract research organization (CRO) denoting the trend in protocol deviations over the course of the data collection. Finally, data acquired from internal sources were used to denote trends in patient screening and enrollment.

Based on the results of this practicum study, there was a slight overall increase in patient screening and enrollment over the course of the data collection period. There was also an increase in the number of tasks completed by each of the positions held within the research department, resulting there was an increase in productivity and efficiency. The analysis suggested that the organizational tools was effective in increasing the productivity within the research department.

CHAPTER 2

BACKGROUND AND LITERTURE REVIEW

Clinical research is research conducted in human subjects for the purpose of obtaining medical knowledge (clinicaltrials.gov, 2012). There are three types of clinical trials currently being conducted: drugs, medical devices, and combination products (these combine medical devices and drugs). These are tested in five phases. The pre-dose and clinical phases involve human participation during phases I, II, III, and IV. Phase I is designed to test the safety and appropriate dose of a product. Phase I trials are typically smaller trials with only a few dozen patients. Phase II studies, which usually have less than 200 patients, are designed to determine the efficacy of the product in a given disease state. Phase III trials test the product using a larger population and are generally a randomized study that compares a novel agent showing safety and efficacy in Phase I/II studies against standard-of-care treatment. Finally, phase IV trials are considered "after market" research. These trials are conducted after the Food and Drug Administration (FDA) has approved the product. The purpose of a phase III trial is to examine the effect of the approved product on the mass market. Due to the danger and ethical considerations of testing on humans, the FDA has instilled a set of guidelines for safety and efficacy in performing clinical trials. The FDA Code of Federal Regulations (CFR) ensures research institutions and entities engage in proper ethical treatment of patients throughout the research process (Food and Drug Administration, 2012).

The Center for Cancer and Blood Disorders (CCBD) is a facility committed to patient treatment and research. Since 1994, the facility has worked with patients diagnosed with cancer to restore their health and maintain their daily lives (The Center for Cancer and Blood Disorders, 2012). Due to the better understanding of the biology of cancer in recent years and advances in medical knowledge and technologies, oncology research is a field with exponential growth. CCBD began conducting clinical trials in 1999. Since then, the research department has grown to include a research manager, two clinical research coordinators, a regulatory coordinator/research assistant, and a medical assistant/data coordinator. The staff works to ensure excellent patient care, compliance with FDA guidelines and sponsor requests, and continuing education of oncology staff on the importance of clinical research. Despite the success of CCBD's research department, the addition of new staff resulted in disjointedness with task delegation and communication.

Clinical research in the beginning was not the heavily monitored industry it is today. Prior to the Nuremberg Code, "those involved in horrible crimes attempted to excuse themselves by arguing that there were no explicit rules governing medical research on human beings" (Vollman & Winau, 1996). For example, in Nazi Germany, Holocaust prisoners were subjected to numerous experiments that resulted in torturous pain and death. "The medical experiments listed under the heading of 'crimes committed in the guise of scientific research,' include 'high-altitude experiments; freezing experiments; malaria experiments; mustard gas experiments; Ravenbrueck experiments concerning sulfanilamide and other drugs, bone, muscle, and nerve regeneration and bone transplantations; sea water experiments; epidemic jaundice; sterilization experiments, typhus and related experiments; poison experiments; incendiary bomb experiments; and Jewish skeleton collection" (Leaning, 1996). The "participants" were forced into these

experiments without informed consent or the right to refuse. These acts led to the Nuremberg Code, which was the first code of ethics for research.

In the United States, attention to ethics had been increasing even prior to the Nuremberg Code. In 1906, the Pure Food and Drug Act, which covered the safety of food, drugs, and liquor was adopted into law (United States Statutes at Large 59th Congress, 1906). The Food, Drug, and Cosmetics Act was enacted in 1938 and mandates safety in food preparation, drug research, and cosmetic manufacturing (Borchers, Hagie, Keen, & Gershwin, 2007). After the Nuremberg Trials and the subsequent international code, ethical research continued to evolve. In 1964, the Declaration of Helsinki stated ethical principles to provide guidance to medical research staff involving human subjects. "Principles of the Declaration of Helsinki include: to conform the accepted scientific principles, to have clearly formulated protocols, to have a positive cost to benefit ratio, and to safeguard subjects rights and integrity" (World Medical Organization, 1996). Finally, the Belmont Report noted more specific codes for human research with its three basic principles: Respect for Person, Beneficence, and Justice (Belmont Report, 1979).

With the evolution of all of these codes, two entities were developed to enforce these principles. On a global scale, the International Conference on Harmonization (ICH) was created to monitor human research in all countries involved in research (International Conference of Harmonisation, 2013). The ICH allows for one set of guidelines for all countries to follow for the use of human subjects in research. Having one set of guidelines to follow increases the validity of international studies, because all countries obey the same laws. Conduct of human research in the Unites States follows the guidelines of the ICH as well as guidelines set forth by the FDA. Research involving human subjects conducted in the United States must adhere to the regulations set out by the FDA and the ICH. "A quality clinical trial research site is one that is

compliant with the ICH's Good Clinical Practice (GCP) guidelines, … Compliance with [these standards] provides public assurance that the rights, safety, well-being, and confidentiality of those participating in clinical trials are protected and that the results of the clinical trial are valid" (Zon, Meropol, Catalano, & Shilsky, 2008).

Using the guidelines set out by the FDA and ICH, the team at CCBD set out to maintain a superior level of compliance. The addition of an organizational system will assist the staff in the endeavor of clinical research.

SPECIFIC AIMS

With the addition of recent staff and new Standard Operating Procedures (SOPs), the research department at CCBD has been busy training and maintaining patient care with the increased volume of studies and patients. Everyone in the research department had a set of specific tasks to be performed per their job descriptions; however, these designations were outdated due to the transition to a larger staff. The reorganization and new task delegations led to some confusion as to whom the task belonged and inadvertently led to inefficiency. For example, two people were performing a task that only required one person because there was confusion with how to execute the task. Other areas of concern included gaps in communication between the staff and between the staff members and outside organizations [i.e., sponsors, investigational review boards (IRB), and CROs)].

The addition of new databases and spreadsheets designed to simplify data searches and ensure compliance was paramount in reaching the goal of this practicum project. The aim of this internship practicum was to develop and successfully implement a set of management tools to increase productivity and communication in the research department. Therefore, the hypothesis states that adoption of the new guidelines, utilization of the organizational tools, and increased compliance with task delegation would result in increased efficiency, organization, and productivity in the research department.

SIGNIFICANCE

The significance of the implementation of new processes in the research department was to increase productivity, reduce errors and deviations, and to produce a more efficient system at an investigative site. Additionally, the tools created would assist in integrating research into the repertoire of the clinic staff. Some specific solutions to increasing organization and productivity in the research department included enhanced team training, weekly meetings, and a more organized system.

The Research Database and Data Tracker made it simpler for all members of the research staff to find information at a glance. The spreadsheets helped minimize the time it took to find information and allowed the staff to focus on more valuable tasks. The ease and simplicity applied to the Pharmacy Inventory Log. According to recent audits and clinical research associate (CRA) monitoring visits, investigational product (IP) and drug accountability were deficient. In order to monitor which drugs were low in volume and which were about to expire, the use and maintenance of a list was initiated. Finally, the use of new PI Update Forms helped to keep the PI abreast of his/her status in clinical research. These updates not only showed the physician the progress of their trials, but also showed the research staff items to be rectified. The goal of these organizational tools was to decrease deviations (data outside the accepted norms set by the sponsor) by consistently monitoring each trial and to keeping the PI in the loop so he or she can interject their ideas, thoughts, and comments.

Due to the increased productivity, the patient care level was to increase as well. This would allow for better access to treatment for patients needing treatment alternatives and options. The goals of these proposed improvements was to increase overall time management and

productivity, as well as to decrease undue stress and frustration throughout the research department. However, the most important reason for adding these trackers and logs was for accountability. These tools require the staff to be accountable for the tasks they perform.

METHODS AND MATERIALS

This practicum project analyzed current procedures in use at CCBD and allowed for the proposal and implementation of new processes and tools into the research department with the assistance of the research manager. Over the course of six months, the goal was to increase productivity in the research department through communication, task delegation, organizational instruments, and a thorough understanding of each job description. Once ideas were discussed and finalized, they were implemented for use.

Materials

The organizational tools to be created became the backbone of this project. The initial form created was designed to increase PI oversight. The FDA considers PI oversight an important aspect of the clinical investigation process. The FDA CFR Title 21 states that the primary reasons for PI oversight are, "ensuring that a clinical investigation is conducted according to the signed investigator statement for clinical investigations of drugs, including biological products, or agreement for clinical investigations of medical devices, the investigational plan, and applicable regulations, protecting the rights, safety, and welfare of subjects under the investigator's care, controlling drugs, biological products, and devices under investigation" (21 CFR 312.60, 21 CFR 812.100).

The PI is the physician who is fully responsible for everything that happens during the course of the study. He or she may delegate roles within the study to sub-investigators (other physicians participating in the clinical trial, who are not the principal investigator), nurses, and the research staff however, if mistakes are made during the course of the study, it is ultimately the responsibility of the PI. In order to ensure supervision over each study, the PI Update Form was established. This form, located in Appendix A, gave the PI a clear view of the study at a glance and allowed him or her to see every task completed, as well as any potential mishaps that have occurred during the course of the study. The PI Update Form was a form already being considered for use by the research staff at CCBD; however it had to be modified to include only information relevant for PI oversight.

The procedure for using the PI Update Form was a simple process. The regulatory assistant examined all the regulatory documents to ensure they were up to date (i.e., verified that all sub-investigators have signed the FDA-mandated Financial Disclosure forms provided by the sponsor, etc.). The regulatory assistant then added pending issues onto the sheet for the PI to view. Once all of the regulatory affairs were in order, the data coordinator added information to the form that required the PI's attention, such as patient adverse events and data locks in the electronic data capture (EDC) system. Finally, the research manager attached a report of all protocol deviations occurring since the last time the PI update was reviewed, a list of all patients on the clinical trial, and their treatment status. Once all of the information was added to the form, the research manager reviewed the form with the PI during their weekly meeting. The PI then signed off the information and the PI Update Forms were housed in the regulatory assistant's office. These documents are used as evidence that the PI was aware of every aspect of the study and to ensure PI oversight in every study in which he or she was chief clinician.

The second item created for the organizational toolbox was the Pharmacy Inventory Log. This log was devised to keep track of all of the research pharmaceuticals used, called investigational product (IP). Appendix B provides an example of how a drug is inventoried. The spreadsheet provided the information needed for the pharmacy technician to do his or her job: it contained information regarding the lot numbers, kit numbers, batch numbers, expiration dates, and dosages for each vial of IP. Additionally, a column denoted the course of action for drug shipment. In some cases, the drug was automatically shipped once a patient was enrolled onto a clinical trial, while other studies required a manual supply order form in order for the IP to be shipped to the site for the study. This section showed the pharmacy technician, at a glance, whether the drug he or she was processing needed ordering, or if the sponsor automatically shipped it.

Third, the PI Patient Log was a spreadsheet designed to provide the physicians a color-coded worksheet to show the process of patient enrollment for each of the trials in which they are the lead investigator. As seen in Appendix C, the log presented the PI all of the patient information relevant to the study he or she was overseeing. The information on the PI Patient Log included the patient status (In Prescreening, Screening, Active, In Follow-Up, or Screen Fail) and identifying information, including the date the patient signed informed consent and their randomization number. A randomization number was the number given to the patient by the sponsor to ensure patient confidentiality and to increase the validity of the study. The intent of this log was to present it with the PI Update Form to offer the PI oversight of all areas of the study, from regulatory issues to patient events.

Once a patient was screened into a clinical trial, the main focus of the research staff was then collecting data and relaying it to the sponsor. This was a massive task requiring knowledge

and skill. To help the research employees with the data capture process the Data Tracker was created. This tracker was designed with two functions in mind. First, the goal of the Data Tracker was to house a log of patients' visits. On the day the patient visited the clinic, the coordinator filled in the study-specific data tracker with the date of the visit. Second, after the information from the visit was entered into the electronic medical record (EMR) by the medical staff, the data coordinator extracted the information and entered it into the EDC. Once the data were entered, the data tracker was updated to reflect the process of data collection via a color-coded system; green indicated that all data were entered and the visit was completed, yellow indicated that data were missing from the EDC, and blue denoted a CRA query.

Finally, the Comprehensive Research Database was created as a catchall for relevant study information to be stored. The goal of the Comprehensive Research Database was to list any valuable data for each clinical trial (Appendix D). Once a list of all of the studies conducted at CCBD was created, data were added to the list. Examples of the data stored here included the dates for study start up, study close out, and data storage information for closed trials, and data destruction date. It also housed barcode data corresponding to boxes that contained the data. After the first few months of use, the staff noticed that the Comprehensive Research Database was not useful. During the course of data collection, the Comprehensive Research Database was revamped and renamed the Research Database.

The Research Database was an organizational tool designed to house all information needed to run a research department on a daily basis. As seen in Appendix E, the Research Database incorporated multiple tools already being used at CCBD. The parts Research Database included a list of studies and pertinent information, a full patient list, physician accrual statistics, data storage information, and the patient screening log. Prior to this project, separate

spreadsheets were used for the patient list, physician accrual statistics, and patient screening log. Each spreadsheet was updated independently of each other. This was time-consuming, and it was never clear whether they were up to date. The Research Database combined all of these logs. As the data was entered onto the logs, the physician accrual numbers were automatically updated, thus eliminating the task of updating the physician accrual numbers manually. Additionally, the Research Database was able to filter patients by study, treatment status, screening date, and physician referral. The ability of manipulate the data was valuable because it could now run reports for data analysis. This saved the department time, because the reports did not have to be created by hand.

With the use of these tools, there should be an increase in productivity, efficiency, and output as the tasks decrease in scope and length. The practicum evaluated whether this did indeed occur.

Methods

To track improvement, review of the departments logs and reports will yield data to monitor the progress. The parameters of data collection were:

- Number of patients prescreened for a clinical trial
- Number of patients screened for a clinical trial
- Number of patients enrolled onto a clinical trial
- Number of tasks completed by the regulatory staff
- Number of boxes containing research data in storage

- Number of monitor follow-ups from a monitor visit
- Number of protocol deviations
- Number of tasks completed by the coordinators and data personnel

The number of patients prescreened, screened, and enrolled onto a clinical trial are housed in a log titled Patient Screening Log (Appendix F). The research assistant updated this log daily to ensure all patient activity was monitored and up-to-date. The Patient Screening Log was the source used for the determination of the number of patients that have been prescreened, screened, and enrolled. To be considered "prescreened," two events occurred. First, a physician had to refer the patient to the research department. Once a physician referred the patient, the research coordinator examined the protocols to determine whether the referred patient is eligible to partake in any of the trials offered. A patient is then considered prescreened by the research staff. A "screened" patient is any patient who was prescreened and found to be eligible for a clinical trial. Once the patient has signed an informed consent form to enter the trial, he or she is considered "in screening." Though the patient volunteered for the trial and affirmed their interest by signing the informed consent form, the patient is not yet enrolled into the study. Once the patient has been randomized by the study and given a patient number, a patient is now "enrolled" in the study. The process from screening to enrollment varies from study to study; most clinical trials require baseline values, such as lab values (i.e., chemistry, hematology) and radiology scans (i.e., bone scans, computerized tomography [CT], magnetic resonance imaging [MRI]).

After a patient has been enrolled onto a clinical trial, it is the responsibility of the research department to guarantee all of the protocol-specific assessments are completed

according to the timetable presented by the sponsor. If the assessment is not completed correctly or in the time allotted by the sponsor, a protocol deviation is filed with the sponsor. Protocol deviations are "any other unplanned instance(s) of protocol noncompliance. For example, situations in which the investigator failed to perform tests or examinations as required by the protocol or failures on the part of study subjects to complete scheduled visits as required by the protocol, would be considered protocol deviations" (Food and Drug Administration, 2011). Once the staff is aware of a protocol deviation, it is the responsibility of the research coordinator in the department to file a deviation report with the CRO and/or the sponsor. This can be a particularly useful assessment because there typically is an inverse correlation between the number of protocol deviations filed by an investigative site and how efficiently and productively a department performs.

Multiple techniques were used to calculate and determine task productivity for the research assistant. The research assistant performs many tasks: regulatory affairs and IRB correspondence, lab kits preparation and processing, and any other task that is not performed by the research nurses, data coordinator, or manager. Because of the diversity of the tasks the research assistant performs, only certain aspects will be counted. The following formula was used for the calculation of the data collection efficiency for a portion of the research assistant's responsibilities:

Tasks = [(# monitor visits) * 4] + [(# Tumor Board Meetings) * 3]

The first portion of the formula was multiplied by a constant of four, because four tasks were required every time a clinical research associate (CRA) visits. First is the preparation for

the CRA monitoring visit, which includes pulling patient charts and regulatory binders. The second task executed by the research assistant is adding the patient information into the EMR for the monitor to access. Thirdly, answering clinical research associate monitoring questions is another timely task which involves stopping the flow of the day's events in order to answer any immediate questions the CRA may have. Finally, answering follow-up letters from the CRA rounds out the four tasks. This number is then added to the tumor board tasks. Tumor board is the weekly meeting in which physicians meet to discuss difficult cases and get opinions of colleagues. The research department runs tumor board. There are three tasks the research assistant accomplishes per tumor board meeting: meeting attendance, scheduling of sponsors, and transcribing the notes. As previously discussed, this calculation only accounts for a small portion of the responsibilities of the research assistant.

In addition to the tasks just mentioned, the collection and retention of data no longer accessed due to study closure was a task delegated to the research assistant. The redistribution of the data from their original housing to the storage boxes was a large task. The data, patient case report forms and regulatory documents were housed in binders sitting on bookshelves behind shower curtains. This was a violation of patient confidentiality; the data had to be moved. With addition of studies and personnel, additional space was needed; the removal and storage create more time and space for the research assistant to complete other things. Additionally, the use of a database to house the stored information decreases the time it takes to find specific information, thus increasing efficiency.

The other aspects of the regulatory affairs and research assistant position were more difficult to quantify. Listed below are the tasks performed by the research assistant not

previously justified in calculations; these tasks were accounted for by estimation and approximation, in consultation with the research assistant:

- Finance and invoicing
- Lab kits
- Supply orders
- Tumor tissue requests
- Portal updates
- Patient information updates
- IRB correspondence
- Regulatory filing
- Study start up paperwork
- Amendment and mid-study regulatory paperwork
- Study close out paperwork
- Sponsor correspondence
- Physician licensing for studies
- Organization/retention of screen fail patient informed consent forms
- Investigational new drug safety reporting
- Research department meeting minutes and preparation
- Notes to file
- Protocol training for all individuals
- Delivery/package and mail receipt

The tasks completed by the research assistant are typically on an "as needed" basis; therefore, it was difficult to quantify the specific number of times a job was completed. To account for the effort on the part of the research assistant, estimation based on discussion and first-hand experience was used.

Monitor follow-up discrepancies were lists of unresolved issues accumulated during a CRA monitoring visit. After a CRA completed a monitoring visit, he or she sent a letter to the research department discussing areas of concern during the monitoring visit. Examples of discrepancies included: missing or outdated regulatory documents, missing data for patients, and a lack of PI oversight. Monitoring follow-up discrepancies track the productivity of the department. CRAs' oversight requires the research staff to stay on task; if the staff does not stay caught up, it will show up on the monitor follow-up letter showing little progress in the study.

To track the number of tasks completed within the research department, a formula was developed and used. This calculation allowed the data to be compared over months. The formula accounts for shortened months and increased workload in other areas. The first section of the formula is listed below:

$$\text{Tasks} = \frac{(\#\text{ patients} * 4) + \#\text{ patients prescreened for trial} + \#\text{ patients consented to trial}}{\#\text{ working days}}$$

This formula was used to track the coordinators' tasks for each month. It tracked how many tasks the research coordinators and the data coordinator performed. The "number of patients" category was multiplied by a constant of four because with every active patient visit, four tasks needed to be completed. The first task was the preparation for the upcoming patient visit. This

task included ordering labs that needed to be performed and scheduling radiology scans for the patient.

The second task considered in the formula was the actual patient visit. For the majority of patients, the research coordinator/nurse met the patient and collected data for that particular visit. The third task factored into this equation was the task completed following the appointment. The patient follow-up included charting the visit into the electronic medical record system (EMR). Once the clinical research coordinator completed the addition to the patient's information in the EMR, the task of charting was complete. The last task included into this calculation was the data entry into the EDC. Once these four tasks were completed, the sponsor considered the patient visit complete. The goal of the formula was to compare the number of tasks completed by the research coordinators for each month.

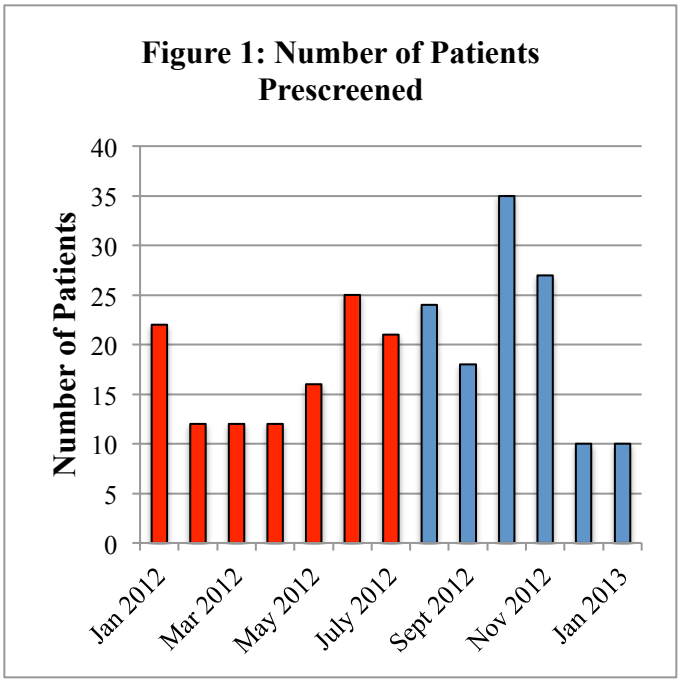
The data was examined in two ways. The overall trend of the data was a source of information. In addition, data obtained prior to the initiation of the organizational tools were examined. Because the organization began within the first weeks of the internship, the cut off between before and after the reorganization was August. Therefore, the 'before" section included data from January 2012 to July 2012, while the "after" data spanned August 2012 through January 2013.

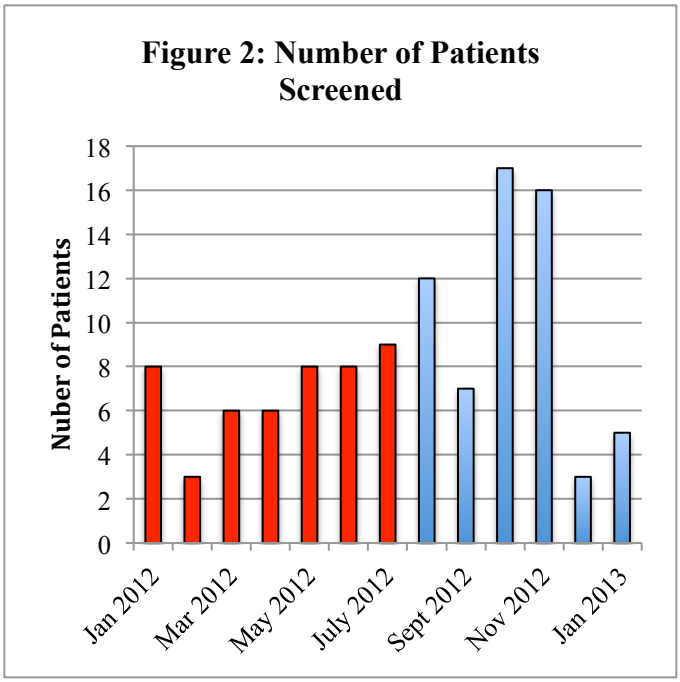
RESULTS

This practicum project was designed to increase the output and efficiency of the research staff at CCBD. Several forms and logs were developed to improve productivity at the research site. These included the PI Update Form, The Pharmacy Inventory Log, Data Tracker, and the Research Database comprised of the new patient screening log, the study information database, the physician accrual and referral log, and data storage information. To evaluate whether the goals were achieved, formulas were developed and data were collected from CCBD research site.

Patient Enrollment

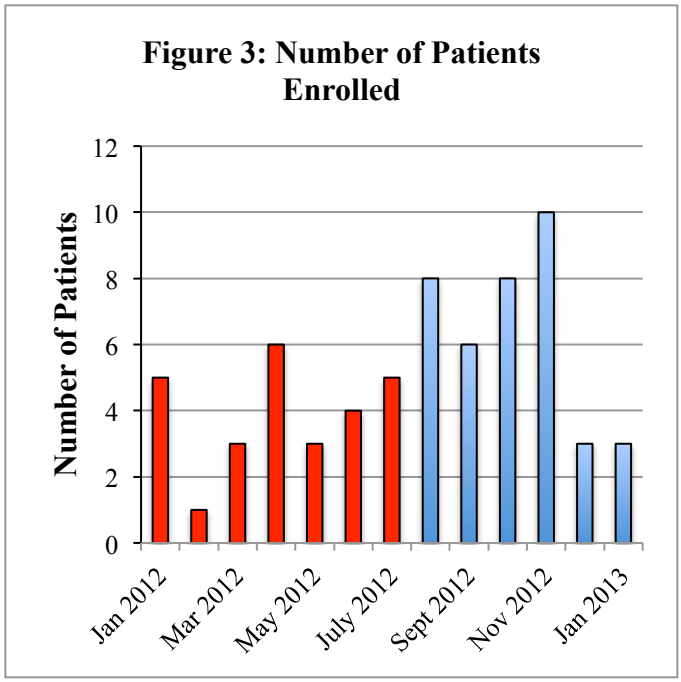
An indication of the increased productivity shown by the research department at CCBD was the increased number of patients prescreened, screened, and enrolled for clinical trials. As shown in Figure 1, the number of patients considered by research personnel increased over the course of the data collection period. The numbers of patient prescreened prior to the use of the productivity tools were: 22, 12, 12, 12, 16, 25, and 21 for the months from January 2012 to July 2012, respectively, with the average number of patients prescreened





being 17 patients with a standard deviation of 5. As the organizational tools were put into place, the number of patients prescreened increased to 24, 18, 35, 27, 10, and 10 for the months of August 2012 through January 2013, averaging 21 patients per month with a standard deviation of 10.

To be considered a patient in screening, the patient had to have signed an informed consent form for a clinical trial offered at CCBD. The number of patients who signed informed consent forms increased. For the months of January 2012 through July 2012, the numbers of patients screened were: 8, 3, 6, 6, 8, 8, and 9 patients screened per month, respectively. The average number of patients signing consent prior to August was 7 with a standard deviation of 1. However, August 2012 through January 2013 saw increased patient screenings with 12, 7, 17, 16, 3, and 5 patients signing consent. This averaged 10 patients per month with a standard deviation of 6.

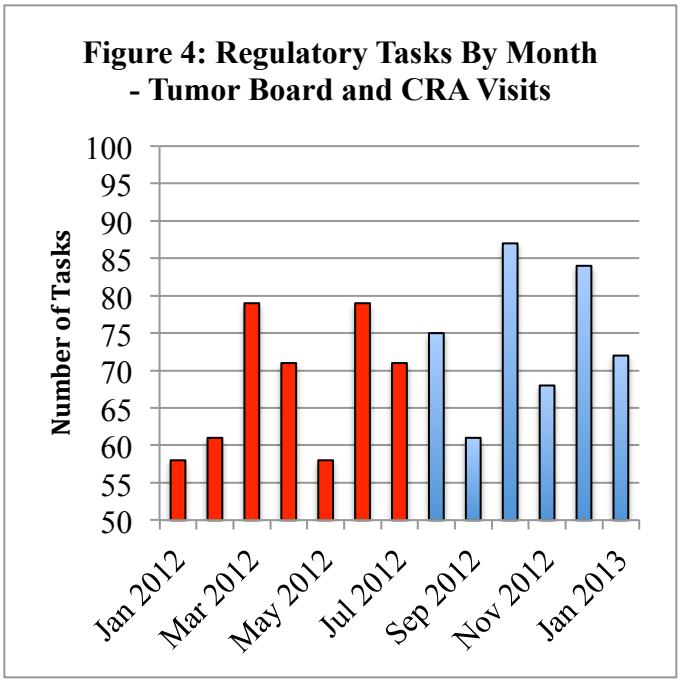


As for patient enrollment onto a clinical trial, Figure 3 also showed an

increase; from January 2012 to July 2012, the numbers of patients enrolled onto a clinical trial at CCBD were: 5, 1, 3, 6, 3, 4, and 5 with the average being 4 patients per month (standard deviation= 2), while for the later months, the patient enrollment increased with 8, 6, 8, 10, 1, and 3 patients enrolled from August 2012 to January 2013, with the average number of patients enrolled onto a clinical trial being 6, with a standard deviation of 3.

Regulatory Affairs

The position of the research and regulatory assistant was more difficult to assess. As previously noted, only some data could be quantified. Figure 4 shows the improvement of the quantified tasks. Between January 2012 and January 2013, the number of tumor board and CRA monitor visit tasks increased. Between January 2012 and July 2012, the average number of tasks performed in these two categories was 68 while from August 2012 to January 20123, the average increased to 75. The standard deviations were 9 and 10, respectively.



The non-quantified data was assessed differently. Based on discussions, observations, and direct participation, the number of tasks performed by the research assistant increased over the course of six months. Overall, the research assistant stated that she was more organized and had better time management. The time required for the research assistant to update the patient

logs when a new patient was screened and enrolled decreased sharply with the addition of the new Research Database. The number of places the new patient needed to be added and accounted for was immense.

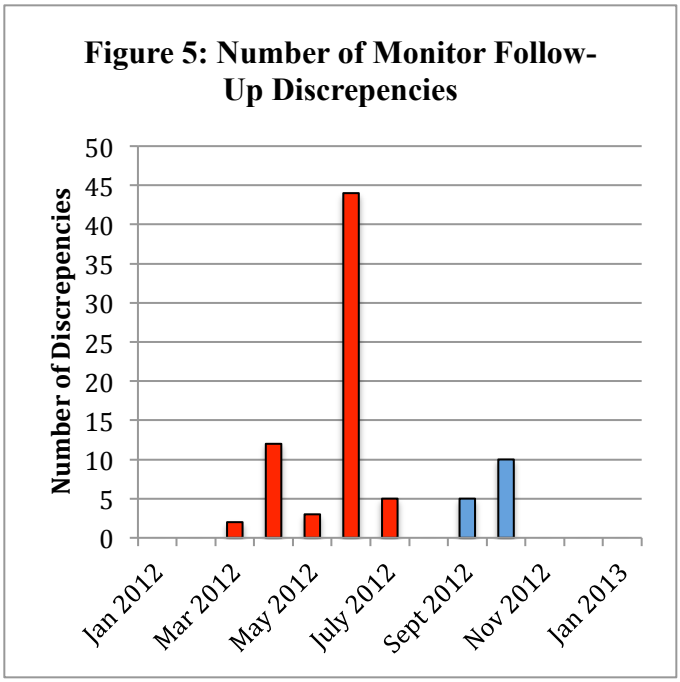
Table 2: Patient Screening Logs	
Before Research Database	**After Research Database**
Running Follow-Up Log	Research Database
Follow-Up Log By Study	Research Meeting Minutes
Physician Accrual Log	CRO Log (If needed)
Yearly Accrual By Month Log	Study Specific Log- Screening
Physician Referral Log	Study Specific Log- Enrolled
Research Meeting Minutes	
CRC Screening Log	
CRO Log (if needed)	
Study Specific Log- Screening	
Study Specific Log- Enrolled	
Patient Accrual Log	

Prior to the Research Database, a total of 11 documents required updating for every patient enrolled onto a clinical trial (Table 1). The Research Database performed the function of many of those logs, and so once the database was operational, the number of documents to be updated by the research assistant decreased to five. In general, the time required to complete tasks decreased. This was mainly due to the reorganization of the office space, better time management skills, increased awareness of computer capabilities, the expansion of computer literacy, and the data storage organization. These items allowed for an increase in the number of tasks completed by the research assistant. For example, prior to the reorganization, the regulatory filing system consisted of one bin. Anything to be added to study regulatory binders was placed in the filing bin. Once a week, the research assistant spent approximately two hours to sort, separate, and file all of the papers in the bin. Two hours to file documents was a time-consuming task. During the reorganization, a new filing system was employed. Instead of

having one bin housing every document to be filed, the research assistant now had a filing tower consisting of 48 slots to house all documents needing to be filed. Each study received a slot, so study materials were no longer mixed together. This increased productivity in two ways: 1) by decreasing the time it took to place the files in each study regulatory binder, and 2) by decreasing the chance of documents getting misplaced or misfiled. Now, the research assistant files by CRA visit to ensure there is no paperwork let to file prior to the CRA monitoring visit.

Other tasks that benefited from the reorganization were central scan requests and tumor tissue requests. Both of these tasks require requesting information and then waiting for the corresponding item. Before the reorganization, the paperwork for these tasks was set on a shelf and left indefinitely, which made it difficult to determine the progress of the task, and it was easy to misplace the relevant documents. After the reorganization, trays were set up with dry erase folders. These folders now house the paperwork and additional items, such as reports and CDs. The surface of the folders allowed the research assistant to write any information on the front for easy viewing, plus the bright colors of the folders made is easy to track.

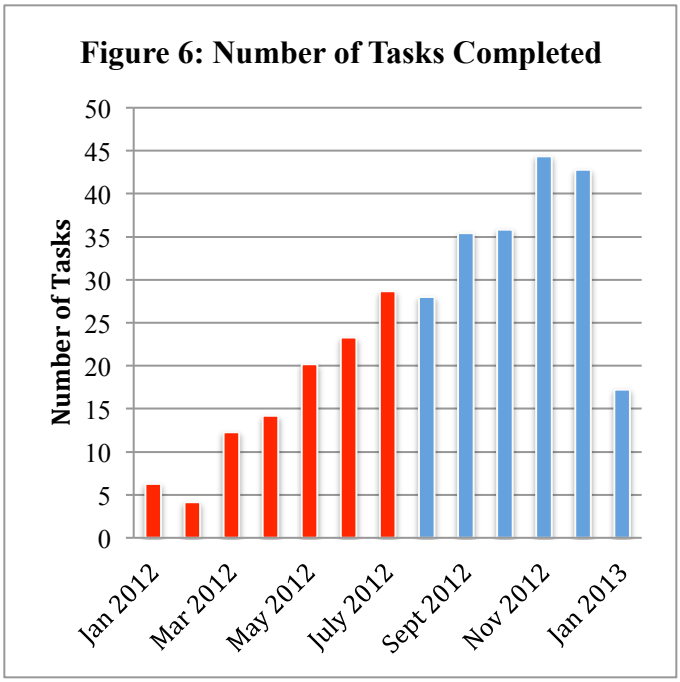
One area of regulatory affairs receiving special attention in the early stages of the office organization was the number of data boxes stored onsite. Because of the volume of data housed in the research department, there was no room for other types of storage. After assessing the data, it was determined that it was eligible to be boxed and stored. There were zero boxes containing data prior to the reorganization of the research space. Once the data were moved, the procedure of boxing data during study close out was implemented. Currently, 39 boxes contain archived data ready for storage.



Finally, the number of CRA follow-up discrepancies determined how prepared the staff was for the CRA monitoring visit from the sponsor. In Figure 5, the downward trend shows an increase in preparedness in CRA monitoring visits. Prior to August, discrepancies occurred every month from January 2012 to July 2013 with a mean of 9 per month and a standard deviation of 16, but starting in August there were some months in which no discrepancies were recorded. The mean for the latter period was 3, with a standard deviation of 4.

Clinical Research Coordinators

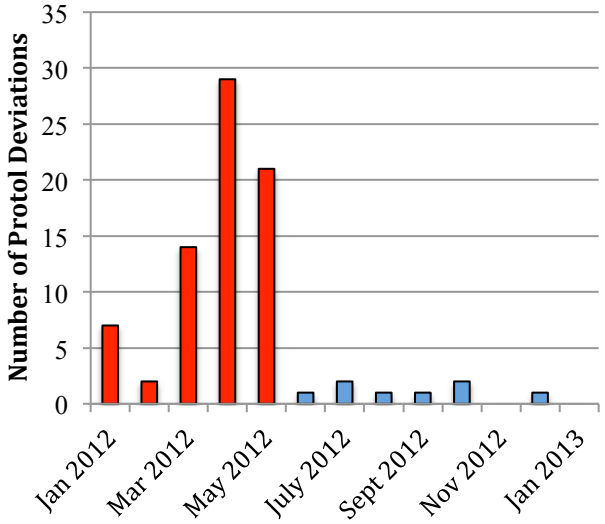
Using the formula previously described, the number of tasks completed by the clinical coordinators was calculated. As shown in Figure 6, the number of tasks completed increased over the course of the year. The implementation of the tools and procedures went into effect in a staggered format (i.e., some were put into place



before others), so the beginning of the improvement was not markedly noticeable. However, in the end, productivity increased from 6 tasks per month (January, 2012) to 43 tasks per month at its peak in December 2012. Additionally, the average number of tasks performed from January 2012 through July 2012 was 16 with a standard deviation of 9 tasks per month, while the average number of tasks completed between August 2012 and January 2013 was 34 with a standard deviation of 10.

Protocol deviations are instances when the protocol is not followed. These errors are reported to the sponsor for validity and oversight. The fewer the protocol deviations filed, the fewer mistakes being made by the research staff. Figure 7 shows the protocol deviations filed between January 2012 and January 2013. From January 2012 to July 2012, a total of 76 protocol deviations filed with the CRO. From August 2012 to January 2013, the total number of deviations filed dropped to 5. The average number of protocol deviations per month from January to July was 11 (standard deviation=11), while the mean from August to January was < 1 per month (standard deviation=1).

Figure 7: Number of Protocol Deviations



DISCUSSION

Based on the data and events that occurred during this internship experience, the combination of increased productivity and efficiency, and a determined staff were the main driving forces for improvement within the research department. The use of the tools was a factor in the improvement, but the modification in staff assignments aided in the increased productivity.

To begin, there was a continuous increase in the number of patients prescreened, screened, and enrolled into clinical trials at CCBD through this internship with the exception of the months of December and January. In all three categories, the number of patients seen by the research staff decreased noticeably. One possible reason stems from the time of year: it is during and right after the holidays. During and immediately following the holiday season, many physicians go on vacation. Because of the physicians' absence, the temporary healthcare person (i.e., filling in physician, nurse practitioner, physician's assistant, etc.) was less likely to put a patient into a clinical trial because he or she was not as familiar with the patient history. Additionally, the month of January typically sees less patient activity in the clinic due to co-insurance. Because of annual deductibles, many patients are reluctant to visit the clinic for any reason other than what is required due to cost. These not only affected the screening numbers, but also affected the number of tasks for the CRC. Another main reason for the decrease in CRC tasks for the month of January, in addition to the decrease in patient enrollment may have been related to "patient progression." In the month of December, numerous patients had to be taken

off of the clinical study because of disease advancement. Once a patient's disease worsens, he or she is no longer considered an active patient.

Between the months of August and December, a total of seven studies closed to patient enrollment. This decreased the range of studies offered in the research department and limited the patient population eligible for clinical trials. Furthermore, in the same time period, only two additional studies were added to the clinical trial roster, resulting in a net loss of five studies from August to December. But, with eight studies being prepared to be opened, there is likely to be increases in patient screening and enrollment in the coming months.

Because of the eight pending studies among other things, the regulatory and research assistant was busy throughout the internship time period. The tasks delegated to the research assistant were vast and not easily quantified. It was difficult to measure whether the tools developed affected the position of research assistant. There were only two tasks that were measurable: tumor board and CRA visits. These were logged and therefore could be calculated. The number of CRA visits increased between January 2012 and January 20131q . There two primary reasons for the surge in visits. First, there was an increase in the number of studies being conducted at CCBD. Each study should be monitored every 6 – 8 weeks, therefore, as the number of open studies increased, so did the number of CRAs visiting CCBD. Second, the number of patients accruing into clinical trials was increasing. While CRAs typically monitor studies every 6 – 8 weeks, the more patients enrolled onto the trial, the longer the CRA must monitor the study. In some cases, the CRA would monitor a single study for two or more days.

The nature of the research assistant's position required other tasks delegated to her that were difficult to measure. To assess the improvement of these duties, discussions, observations,

and hands-on experience were used to determine whether the organizational tools were valuable in these tasks. Based on direct involvement in these processes, it was clear that the organizational tool was beneficial at increasing output of the research assistant. For example, the addition of a filing system aided in the organization of the regulatory filing. Before the new system was operational, all of the regulatory documents were put into one bin and combined. The large mountain of papers made it easy for items to misfiled or misplaced. It also took several minutes to find a single piece of paper. The filing process consisted of the research assistant organizing the pile prior to actual filing. Then, she would take every binder down and file the documents into the proper section. This was done one or two times a week for one to two hours at a time. Now, with the new filing system, the process is much simpler. As the documents are ready to be filed, they are temporarily filed into the organizer by each study. This decreases the chance of items getting lost because only one study occupies a bin. Prior to the CRA monitor visit, the research assistant files the paperwork into the regulatory binder and sets the binder out for the CRA. This allows for filing to be completed in minutes, rather than hours.

The research assistant's task of requesting central scans and tumor tissue is also reorganized. Space was made for tumor tissue requests and central scans, so that the paperwork accompanying the slides would not be filed away accidentally. This increased the efficiency with which these tasks were completed, because the paperwork was readily available. But, spatial organization was only a portion of the process. The Research Database discussed below reduced the length of time for certain tasks, such as screening log updates and information retrieval.

In the beginning of this internship experience, the major task of reorganizing the research office space occurred. All information pertaining to closed studies was boxed and stored. In

order to ensure that the information was easy to retrieve in the event that any of the documents were needed, a database was creating housing the barcode data of each box. This created an entire room of space for the expanding department. Without the clutter of old data, the current data are now much easier to access.

The Research Database

Over the course of the internship, there was constant need to update and refine the tools that were created in order to fully facilitate the research department. The initial goal was to create a set of spreadsheets and databases to make the department run smoother. During the early integration, it was clear that the multiple files were not user-friendly. After reconsideration, the multiple spreadsheets were reworked and incorporated into one cohesive database.

After testing the compilation of newly minted spreadsheets, it was evident that they would not suffice in the reaching the goal for increased efficiency. The spreadsheets needed to be an all-inclusive database housing all of the information from the Patient Screening Log, the PI Patient Log, the Follow-Up Log, and the Comprehensive Research Database. As seen in Appendix D, the Comprehensive Research Database was not comprehensive at all. The spreadsheet held information only pertaining to the storage of closed studies. Once it had been built, it was seldom used because it was rare to access the information regarding closed studies. To make the Research Database useful, the Follow-Up spreadsheet, containing a list of every patient on clinical trial at CCBD from the beginning, was added (Appendix G). Now that the Research Database has all of the information important for running a research department, it is now feasible to run reports to aid in the efficiency and productivity of the department.

Once the Follow-Up patient spreadsheet was integrated into the Research Database, it became evident that all aspects of patient tracking could be tracked through this database. Such statistics included the number of patients referred to research by the attending physicians and the number of patients enrolled into trial per physician. The research assistant was counting these numbers by hand; however, once the Research Database was operational, it was apparent that these statistics can also be housed in this database. Computer software was used to calculate physician referral and patient enrollment based on data entered into the patient list. This information is instrumental in showing physician involvement in research and in calculating patient enrollment for the quarterly reports. The task of gathering the data and putting into a meaningful presentation for the board members took many days to complete using the old database; the newly-developed Research Database cut down the amount of time needed to prepare for that presentation.

Other Considerations for Improvement

The increase in patient interaction from the research department can be accounted for by many reasons, not just the increased efficiency of the research department. First, the increase in the number of coordinators allowed the research personnel to see more patients without sacrificing patient care. Increased number of employees leads to a larger patient load. Second, the addition of a CRO with CCBD has decreased the time required for regulatory tasks. With their assistance and expertise, the role of regulatory coordinator has been easier to manage. The CRO took over some tasks that were time-consuming including, IRB submission of protocols and informed consents, study demographic completion, and management of study documents.

During the course of this internship experience, there was a lot of change within the research department. There were adjustments in personnel; the medical assistant/data coordinator left the organization to pursue other interests. This sudden change left a staff consisting of the research manager, who also coordinated with clinical research patients; a clinical research coordinator/research nurse, another clinical research coordinator and licensed vocational nurse (LVN) who focused on data entry once the data coordinator left, the research assistant and regulatory coordinator, and the research intern. The department's increase in patient load and productivity was invaluable during the time the staff was short staffed. Upon completion of this internship and report, the research intern will assume the responsibilities of the data coordinator; she will assist in regulatory matters to help take the load off of the research assistant.

Limitations

The limitations of the data collection for the research assistant's tasks made it difficult to determine the true benefit of the organizational tools. Without the ability to completely quantify the tasks performed, a full understanding of the value of this internship report cannot be known. And, due to the nature of the position, it was not feasible to measure how well the organizational tools increased productivity for the research assistant

The data collection for the CRC tasks used a formula created for this project. It encompassed every major aspect of the CRC's task delegation. The major limitation to it was that the formula was not all-inclusive. Though it accounts for the majority of the CRC's duties, it does not account for the extraneous jobs that the CRC does only on rare occasions.

The CRA monitor follow-up discrepancies were difficult to assess. Though they were a good indicator of the preparedness of an investigative site, they were not reliable. Because of the sporadic nature, not all studies send CRA monitoring letters to the investigative site discussing discrepancies, therefore some data were missing. Additionally, not all studies were monitored by the sponsor, and even more participated in remote CRA monitoring, which can be completed from the sponsor site. Another factor affecting the monitor follow-up discrepancies was that many letters had not been sent from the sponsor to CCBD, especially from the month of January, the data for those times are therefore incomplete. Finally, not all CRAs were the same; some were more thorough in their monitoring visits, consequently more discrepancies existed.

In similar fashion, despite being a good indicator, some of the data regarding protocol deviations may have been incomplete. The main issues were: not all deviations had been filed by the end of the data collection time period and that not all studies that CCBD participated in were a part of the CRO, thus those deviations were not accessible.

Finally, the loss of the data coordinator during this internship denied the staff the opportunity to attempt to use the Data Tracker. Once the data entry responsibilities were given to the CRC at another site, it was difficult to assess the effect the Data Tracker had on her performance. After a week of attempting to use the Data Tracker, the stress of being a full time data coordinator and a CRC was overwhelming. The Data Tracker was abandoned due to the lack of time to properly test it. Once the new data coordinator begins working at CCBD, the Data Tracker will be used once again.

CONCLUSION

After months of shuffling around office equipment for better storage, discussions regarding better ways to perform tasks, and a full reorganization of the research department, the team at CCBD is better prepared for future research endeavors. The new systems put into place proceeded to give the team a simple, yet effective way of conducting business.

Over the course of this internship experience, the research department has changed. With the addition of new processes, forms, and databases, the staff at CCBD can increase productivity and patient interaction and decrease the amount of time doing needless tasks. The main goal of the practicum project was to implement a set of tools to increase organization in the research department at CCBD. As these tools were developed, they were implemented. Also during this time, the office space for the research department was being reorganized to decrease clutter and allow storage for studies yet to be opened at CCBD.

The tools created for this internship were the PI Update Form, the Pharmacy Inventory Log, the PI Patient Log, the Comprehensive Research Database (no longer operational), the Data Tracker (temporarily not operational) and the Research Database. This collection of tools was designed to increase productivity by bringing information to the staff in a simpler way. Once these tools were executed, data was collected to determine whether these tools were effective in increasing productivity in the research department.

After the collection and analysis of the data, it was determined that overall there was a slight increase in the productivity and efficiency with the research personnel. With all of the information working together, it decreased the number of tasks, and the time it took to complete some tasks. Specifically, the Research Database replaced six patient logs, plus it added a level of organization to tracking study information. For example, the database calculated the number of patients that physicians had referred to the research department, thereby eliminating that task for the research manager. The time saved by using the Research Database allowed every person in the department to spend more time completing other tasks or spending more time with patients.

With continued effort, the research department will continue to become more effective in performing the difficult tasks of running a clinical research program. The implementation of these tools to increase productivity, the research staff at CCBD will continue to grow and bring clinical research to patients who need it.

CHAPTER 3

INTERNSHIP EXPERIENCE

My internship practicum was conducted at The Center for Cancer and Blood Disorder, located in Fort Worth, Texas. The site is a clinical site with focuses in oncology and hematology. There are a total of nine sites across Tarrant County. It is also a strategic site for the Sarah Cannon Research Institute, giving CCBD access to dozens of clinical trials. The research department currently oversees 46 trials at three of their locations. My specific responsibilities during the internship experience included:

- Filing data and paperwork into patient charts
- Preparing for CRA visits by examining regulatory documents
- Preparing for CRA visits by organizing patient charts
- Creating new databases for use by the research department
- Uploading documents into the EMR
- Consenting patients into clinical trials
- Ordering and sending central scans
- Answering data clarification forms (DCF)

- Entering data into the EDC
- Preparing local labs for physician oversight
- Run errands, such as picking up dry ice for shipments and driving to other sites to pick up paperwork
- Answer queries from central scan organizations, such as Perceptive Informatics and CoreLab
- Organized and cleaned out research office space
- Attended Tumor Board at the Fort Worth location weekly
- Attended the Tumor Board at the Weatherford location monthly
- Shadowed patient navigators, radiology technicians, physicians, and clinical research coordinators
- Attended after hour functions, including SoCRA meetings, discussions regarding new pharmaceutical drugs, and work events.

Since the beginning of the internship, there have been many duties learned. Attendance of various meetings was an integral part of the research process, because it allowed multiple departments to maintain communication about various issues in the clinical setting. For example, the Tumor Board, held weekly at the CCBD and monthly at the Weatherford Regional Medical Center, allowed physicians to discuss difficult patients and ask for colleagues' opinions on the cases. Other meetings held at CCBD include the weekly research team meetings and the research meeting. These meetings occurred once a week to discuss various events within the

research department, and they included open discussions about current research, potential problems, and new research coming into the department. They also provided an opportunity to communicate various concerns within the department.

One of the most over-looked tasks during the time of my internship was data storage. The FDA Code of Federal Regulations states in Title 21 Subpart J states that "documentation data, raw data, and specimens pertaining to a nonclinical laboratory study and required to be made by this part shall be retained in the archive(s) for whichever is shortest: (1) A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the nonclinical laboratory study are submitted, is approved by the FDA, (2) a period of at least 5 years following the date on which the results of the nonclinical laboratory study are submitted to the FDA in support of an application for a research or marketing permit. (3) In other situations (e.g., where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued" (United States Food and Drug Administration, 2012).

However, patient care took precedence over data storage, and thus, data storage-related activities were neglected. A major accomplishment over the first few weeks of the internship was the organization and logging of all closed data from shelving into storage. This large undertaking increased workspace within the office and removed a large "To Do list" off the staff's list. While organizing these regulatory documents and patient charts, a large database was constructed to keep the major information available. The list included the study name, protocol number, various days of importance (i.e., Start Date, Site Initiation Visit (SIV) date, Closed to Accrual Date, Study Close Date, and Date of Destruction for documents). This database kept all

pertinent information together so there was no need to go through each research trial's regulatory information. This saved the research team valuable time during the monitoring process.

An important task for clinical research coordinators and all research staff was the monitor query. "…Good Clinical Practice guidelines specify that the study sponsor must ensure clinical trial data are accurately reported, recorded and verified to ensure patient safety and scientific integrity" (Tolmie, Dinnett, Ronald, Gaw, & The AURORA Clinical Endpoints Committee, 2011). These queries were formal questions asked by the monitor of any clinical trial study. As the monitor combs through the study, he or she may find discrepancies between the patient charts, regulatory documents, and the clinical protocol. Queries were ways to ensure that the study was being conducted properly. Once the coordinators or other research staff answered the queries, the answer was faxed to the monitor or sponsor. It was yet another way to assure that patients and protocol were being respected.

Patient screening was a process that ensured there was adequate enrollment into clinical trials. Without patients enrolled in the clinical trials, there would not be advances in medicine. Whenever a physician speculated that one of their patients might qualify for a clinical trial, it was the responsibility of the research team, typically the clinical research coordinator or the research nurse, to look over the patient history and diagnosis to determine if he or she fits the criteria for the study. In order for a patient to qualify for a clinical trial, he or she must fit within the inclusion and exclusion criteria, meaning they must meet all of the inclusion criteria and meet none of the exclusion criteria. Some studies have extensive inclusion criteria with 30 or more markers that the patient must meet in order to be screened for a trial, and that does not include the exclusion factors. The exclusion list can be just as large or larger than the inclusion criteria list.

Drug inventory was an important aspect of a research clinical trial. Due to the potential dangers of pharmaceuticals in a clinical trial, it was critical that all drugs were accounted for during the course of the study. Any time a drug was moved, whether it was shipment from the sponsor to the investigational site, to the patient, or if it had expired, the drug was to be inventoried.

Observation was also a sizeable portion of the internship experience. Knowing how the facility functions gave understanding to how to integrate clinical research thoroughly into the clinic. This was important because it increased physician awareness of possible trials that were beneficial to their patients. Integrating clinical research into other aspects of the clinic also informed patients of research and increased patient enrollment into clinical trials. Patient registration was the initial site at which the patient communicates. Patients walked into the building and checked-in at the registration desk. Registration staff checked the patient in, discussed their schedule for the day with them and handed them any paperwork that they would need. It is the first place the patient went for assistance.

For new patients, the realization of having cancer was overwhelming, but CCBD had patient navigators to help them begin their treatment journey. Patient navigators discussed the amenities of the facility, including classes, groups, activities, and ancillary services provided to the patient. They provided new patients tours of the building and introduced them to important people throughout the center. They welcomed the patients and encouraged them through a difficult time.

In addition to observing staff outside of the research department, a lot of time was spent observing various tasks within the research department. For example, patient consent forms

were a vital part of the clinical research process; it is illegal to include patients in clinical research without them. According to the ICH Part 6, with respect to informed consent, "A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form" (International Confernece on Harmonization, 2002). Learning the proper way to consent was an important tool in order to ease the patient's mind and ensure good clinical practices.

Halfway through the experience, the departure of the data coordinator allowed for increased responsibility. Additional tasks were added to increase the output of the research department. The task of filing source documents into patient charts was added to the weekly schedule in order to ensure that data was properly stored. In addition to storing the paper copies of patient information, the patient informed consent forms were uploaded into the EMR as a back up. It was unlikely that an informed consent form goes missing, but because of its importance, it was added to the EMR, just in case. After the departure of the data coordinator, other tasks were added to fill the day. Central scans are radiology scans performed locally and then sent to a central service that reads the scans for the sponsor. This increases validity of the study in the event of accidental un-blinding of the patient information. The task of sending those scans to the central imaging service was tedious. After making a request to radiology, the scan must be anonymized, or de-identified, before being sent to the central imaging service. Initially, the central scans processing was behind because they had not been completed in a few months. Once it was caught up, the tasks became less laborious. This position has been offered to me upon the completion of this master's program.

Another ongoing task related to central scans is queries. A query is a question the imaging service has regarding scans received (or yet to receive). Queries act as formal questions to the investigative site from the sponsor or ancillary service. In the case of the central scans, the queries were emailed or faxed regarding a particular scan, and it was the responsibility of the research department to answer the query and rectify the issue (i.e., send in a missing radiology scan).

In between filing in patient charts, processing scans to go to the central imaging service, and uploading documents into the EMR, local lab assessments filled the remainder of the day. This arduous undertaking resulted from a CRA monitor visit. The current EMR system has no definitive physician oversight for lab assessment. For a typical patient, this was not an issue. For research patients, the sponsors want to know that the physicians are looking at every lab test being performed on the research patient. In order to confirm this is happening, each lab test was printed off and all abnormal values were highlighted. Next to the highlighted value, two boxes were stamped next to it, one labeled CS and the other labeled NCS. CS stands for "clinically significant" and NCS stands for "not clinically significant." This task had not been performed prior to October, 2012, so all labs for active patients dating back to the respective screening dates were printed out and assessed by the physician. The preparation of the lab sheets for the physician took several days to complete. Once the physician assessed the labs, it also took several days to file these labs away in the patient chart. Currently, the task is completed on a weekly basis for all physicians. While the task no longer takes as long to complete, it does require 4-6 hours per week to maintain.

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APPENDICES

APPENDIX A

PRINCIPAL INVESETIGATOR UPDATE TEMPLATE

DATE:_____ STUDY STATUS: _____

SPONSOR/CRO: _____ SPONSOR PROTOCOL #: _____

MONITOR: _____ LAST VISIT DATE: _____ NEXT VISIT: _____

Data Lock: __ # of Queries: ___

TOXICITIES: (unexpected and anything ≥ grade 3)

Subject Name	Dates	Toxicity	Grade	SAE Y or N	MD

MONITORING ISSUES:

Date Identified	Issue	Resolution	Date Resolved

REGULATORY ISSUES:

Date Identified	Issue	Actions Taken

RECONSENTS:

Date Identified	Issue	Patient	Actions Taken	Date Resolved

OUTSTANDING TRAINING:

Type – Initial or Amendment	MD	Date Resolved

PI ACTION ITEMS:

Date Identified	Action Item	Date Resolved

Deviation Report Attached: × Yes □ No □ N/A (0 Deviations)

APPENDIX B

PHARMACY INVENTORY LOG

Study	Study Protocol	Drug Name	Batch/Package #	Kit/Lot /PO#	Date Received	Date Expired	Autoship?
study #	Protocol #	Drug Name	480072	480072	11/29/12	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	12/7/12	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	12/21/12	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	12/28/12	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	1/10/13	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	1/11/13	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	1/12/13	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	1/13/13	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	1/14/13	May-15	Yes
study #	Protocol #	Drug Name	487839	487839	1/15/13	May-15	Yes

APPENDIX C

PRINCIPAL INVESTIGATOR PATIENT LOG

Protocol Name

Patient	Patient #	Treating Physician	ICF Signed	Screening Date	Treatment Started	Treatment Status	COMMENTS
Active Patients							
Screening Patients							
Screen Fails/ Withdrew Consent							

APPENDIX D

COMPREHENSIVE RESEARCH DATABASE

	Data Entry Boxbar		Site Metric Start Date	SIV Date	Site Activation Date	First Patient In Date	Accrual Close Date	Closure Date	Closed but still being monitored	Process Date	Storage Date	Destroy Date
Study Name	F00021869	F00021870	2/4/04	2/4/04	2/10/04	7/8/04	9/21/06	9/2/09	N	8/31/12	8/31/12	9/2/14

APPENDIX E

RESEARCH DATABASE

Study Name	Status	Number of Patients	NCI CTCAE Version	Recist Version	Drugs Used in Study			Site Metric Start Date	SIV Date	Site Activation Date
*ABI CA002-0 (Pharm Binder)	Closed									
ABI 007 (CA046)	Closed									
ABI CA009-0	Closed									
ABI CA012	Closed									
ABI CA031	Closed									
Amgen 138	Closed									
Amgen 412	Closed									
Amgen Breast	Closed									
Amgen Lung	Closed									
Amgen/NESP	Closed									

First Patient In Date	Accrual Close Date	Closure Date	Storage Date	Destroy Date	Data Entry Boxbar			
			5/1/06		D060014			
		6/15/10	6/15/15		F00021885			
					Box 4	Box 5		
			5/1/06		D060012	D060014		
			5/1/06		D060012	D060014		
			5/25/01		C466478	C466479	C466479	C466480

Status	CRC	Patient Number	Patient Name	Study	Site	Referring Physician	Treatment Start Month	Treatment Start Year	Consent Date	Screening Number	Date of Randomization
Active											
Active											
Active											
Active											
Active											
Active											
Active											
Active											

Randomization Number	ARM	Treatment Start Date	Treatment End Date	ECU Date	Screen Fail Date	Tumor order Date	Pathology Location	Tumor Send Off Date	Tumor Return Date	Comments	Accrual Status

Accruals by Month and Year

Month	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Totals
January			4	6	3	3	7	2	6	1	4	2	5	4	4	51
February			5	3	3	2	1	3	10	5	3	2	1	1	0	39
March			1	7	7	10	4	3	8	3	4	0	0	4	0	51
April			1	0	7	3	2	0	3	5	4	3	3	4	0	35
May			6	5	63	4	3	4	7	3	1	3	1	6	0	106
June			4	8	8	5	7	0	3	5	5	3	1	4	0	53
July			3	6	5	4	4	1	3	2	7	4	0	2	0	41
August			4	6	3	6	11	1	11	2	2	5	2	9	0	62
September			4	5	11	2	2	2	6	4	3	8	1	9	0	57
October			5	9	6	4	5	2	3	2	1	4	1	6	0	48
November			5	10	5	4	2	0	7	4	1	2	3	14	0	57
December			6	2	2	3	0	2	4	6	4	1	3	7	0	40
Year Total	0	0	48	67	123	50	48	20	71	42	39	37	21	70	4	640

Physician Referrals

Physican	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Totals
Page															0	0
Ross															2	2
Mandell															0	0
Young															2	2
Ochs															2	2
Xiong															1	1
Ganesa															1	1
Potluri															0	0
Mansoor															0	0
Reddy															0	0
Skiba															0	0
Gonzalez															0	0
Lynch															1	1
Year Total															9	9

Physican Accruals

Physican	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Totals
Page			16	21	42	23	25	7	26	11	8	4	4	12	0	199
Ross			16	16	26	12	6	4	5	2	4	5	0	1	0	97
Mandell			0	10	1	0	0	1	11	0	0	0	0	0	0	23
Young			0	0	0	1	1	0	1	8	6	11	5	21	2	56
Ochs			0	0	0	0	0	1	4	2	2	1	1	0	2	13
Xiong			0	0	0	0	0	0	6	4	4	1	1	15	0	31
Ganesa			0	0	0	0	0	0	0	2	7	6	3	6	0	24
Potluri			0	0	0	0	0	0	3	5	4	2	2	0	0	16
Mansoor			0	0	0	0	0	0	11	4	0	2	3	2	0	22
Reddy			0	0	0	0	0	0	0	0	1	5	2	14	0	22
Skiba			0	0	0	0	0	0	1	0	0	0	0	0	0	1
Gonzalez			0	0	0	0	0	0	0	1	3	0	0	0	0	4
Lynch			0	0	0	0	0	0	0	0	0	0	0	0	0	0
Freiss			7	8	27	5	9	4	0	0	0	0	0	0	0	60
Jordan			6	7	14	3	4	0	0	3	0	0	0	0	0	37
Barve			0	0	1	1	0	0	0	0	0	0	0	0	0	2
Clibon			2	5	12	5	3	0	0	0	0	0	0	0	0	27
Jordan, C			0	0	0	0	0	3	3	0	0	0	0	0	0	6
Prow			1	0	0	5	0	0	0	0	0	0	0	0	0	6
Year Total	0	0	48	67	123	55	48	20	71	42	39	37	21	71	4	646

Data Entry Boxbar

D197106	**EGF105485** IND Reports (2) Reg Binder (1)
D197107	**GSK SCLC SK&F 104864/903** Reg Binder (1) Inv. Site File Imaging Manual **GSK Met. Breast EGF104383** Reg Binder (1) IND Binder Pharmatech CFR: #06/FEH; 33402/RLB; 33403/JFT; 33401/AMM
D197108	**EGF105485-TEACH** IND Safety Reports (3)
D197109	**Pharmatech NSCLC POI-01-003-050** CFR: #007/DLK; #004/SMF Shadow Chart: 33407/DLK; 33405/DRB; 33410/A-K; 33402/R-B; 33403/T-J; 33404/SMF; 3340 Lilly NSCSC: #0060
D197110	**EGF105485** Study Reference Manual IND Reports (1) IB-Drug Info & Pharmacy Binder

APPENDIX F

PATIENT SCREENING LOG

Patient Name		Physcian	Study	Consent Signed	Reason Not on Study/Tx Initiation	CRC

APPENDIX G

FOLLOW-UP SPREADSHEET

	CRA			PT			REGIST.	DATE		
PATIENT		DIAGNOSIS	STUDY	STUDY#	CLINIC	PHYS	DATE	COMPLETE	F/U	COMMENTS
1001		colorectal ca	Procrit 018		Klabzuba	Page	02/18/99	06/10/99	complete	
1002		SCLC	SKB SCLC		Klabzuba	Page			complete	
1003		SCLC	SKB SCLC		Weathf'd	Page			complete	expired

APPENDIX H

DATA TRACKER

Subject	Status	Screen Fail	Screening	Cycle 1		Cycle 2		Cycle 3		
Subject Number	Active or Follow-Up		Baseline	Day 1	Day 8	Day 1	Day 8	Day 1	Day 8	Day 21
1440		12/23/10								
1441		5/11/11								
1442		12/5/11								
1443		1/20/12								
1444			6/13/12	6/25/12	7/2/12	7/26/12	8/2/12	8/16/12		
1445			7/13/12	8/3/12	8/10/12					
1446			10/3/12	10/18/12	10/25/12					
TOTAL AMOUNT OWED		$4,500	$1,256	$1,256	$1,256	$418.67	$418.67	$418.67		

APPENDIX I

NOTES - RESEARCH ASSISTANT JOB DUTIES

Regulatory/Research Assistant Job Duties

- Tumor Board
    - Schedule breakfast
    - Attend tumor board
    - Type of tumor board minutes
    - Tumor board grant submission
- Monitors
    - Scheduling visits
    - Prepping for monitor visit
    - Answering questions during the visit
    - Addressing follow-up issues
- Finance
    - Bill scan
    - Tissue
    - Contracts
    - Reconcile payments- quarterly
    - Invoiceable charges-reconsents, scans not covered, follow-ups, close-outs
        - Roughly once a week
- Lab Kits
- IRB
    - Continuing review
    - Submissions

        - Increased in amount because of the increased frequency and quantity of studies

- IND Reports (only some studies)
    - Decreased from 75 to 40 because per month because less studies are requiring these
- Filing
    - In the last 2-3 months, there has been a decrease in the amount of time it takes to file because of the more organized system that was put into place.
- Study Start-Up
    - 1572
    - Delegation of authority logs
    - Signatures
    - Financial disclosures
    - Curriculum vitae
    - Lab and physician licensing
- Study Close-Out
    - Original documents to sponsor
- Changes in regulatory documents
    - Amendment Signatures pages
    - New Investigational Brochure Signature Pages
    - Changes in the ICF
- Patient Data
    - Screen Fail ICFs
    - ICFs signed, but patient not enrolled

- Meeting Minutes
    - Typing previous minutes
    - Preparation of current agenda
    - Updating patient information
- Protocol Training
    - Every study, every amendment
    - Every sub-I, research personnel, pharmacy personnel, chemo personnel
- Other
    - Deliveries
    - Supply orders
    - Tumor tissue requests

APPENDIX J

INTERNSHIP JOURNAL

Monday, August 20, 2012 (Day 1)

On the first day of my internship, I shadowed two research nurses and read protocols of active projects within the institution to get an understanding of the research being conducted at TCCBD.

During shadowing, we saw two patients. Patient 1 was a female patient with colorectal cancer. The main task was to document exam with the physician and determine if any labs or procedures needed to be done. Patient 2 was a female with breast cancer that metastasized to the bone. The main task was to have her resign the consent form and to determine which labs needed to be done.

Throughout the day, I also reviewed patient charts to determine possible recruitment into trials. My goal for the day was to assist in any way I could and to learn as much as possible.

Tuesday, August 21, 2012 (Day 2)

Today's main task was to continue learning and becoming acclimated with the facility. The topic of my thesis was discussed.

The first major task of the day was to learn about drug inventory. I worked with the research manager to update, check, and log in drugs for various trials. I learned about drug storage, drug logs, and the process for inventory.

The other major task for the day was monitor queries. I worked on researching and answering queries from monitors. This required looking through patient files and charts. I assisted the research nurse in this task.

Wednesday, August 22, 2012 (Day 3)

At the start of the day, I spent 2 hours sitting with registration desk. During this time, I observed how a patient checks in and what steps an average patient goes through during a visit. After that, I followed a new patient through the first visit. We were given information about the clinic and its facilities and amenities. Then the patient and I went into her exam in which the physician did a physical exam and discussed the test results of the biopsy, the cancer type, and option to the patient.

After lunch, the research staff attended the weekly research meeting. We discussed prescreen and screening patient and possible topics fro my thesis.

For the rest of the day, I assisted one of the research coordinators with queries from monitors. Throughout the rest of the day, I worked on researching and answering queries from monitors. This required looking through patient files and charts. I assisted the research coordinator in this task.

After the end of business day, the research staff attended the Annual Research Dinner/Meeting. During the meeting, the lead investigators summarized their ongoing research and discussed inclusion and exclusion criteria so that fellow physicians could potentially enroll their patients into those trials.

Thursday, August 23, 2012 (Day 4)

Today's major task for the morning was finishing previous day's afternoon task of answering monitor queries. Once this was completed, I double-checked that all of them were completed and then put all of the patient files away.

After lunch, the main task for me was to input IND's. This consisted of looking over severe adverse events (SAEs) and logging them. The log had to include each of the adverse events and whether to not the SAE was attributed to the study drug or trial. This is to ensure that safety and efficacy of the drug.

Once the business day ended, I attended the North Texas Chapter meeting to discuss certification requirements. The meeting lasted approximately one hour.

Friday, August 24, 2012 (Day 5)

Thus far today, my main task as been to organize data for storage and consolidate boxes for more convenient shipping and storage in the warehouse. This includes removing data from binders, consolidating boxes of data, logging which box contains which data and patient information, and keeping track of which type of data is in each box.

Another task in which I was trained was to prepare lab kits for patients' appointments. Working with the research assistant, we determined which patients needed lab kits for the upcoming week, and then pulled the kits and prepared the paperwork for easy handling once the patient arrives next week. Following this, we then prepared tumors for shipment to the central pathology lab off site.

We then sat down for a Site Initiation Visit (SIV) for a new trail that was being initiated. During the SIV, the protocol of a new study was discussed as well as the inclusion/exclusion criteria.

After the conclusion of the SIV, I assisted the research assistant in consolidating data and logging it from completed studies and prepared it for storage for the rest of the afternoon.

Monday, August 27, 2012 (Day 8)

Today I drove out to the Weatherford site of The Center for Cancer and Blood Disorders. I spent the majority of the day shadowing Dr. Page and the nurse practitioner during patient appointments. Some of the patient diagnoses were: melanoma (stage 2 and stage 3), breast cancer follow-ups, colorectal cancer and colorectal cancer follow-ups, and other cancer follow-ups. We also had 3 new patient visits, one for colorectal cancer, one for breast cancer follow-up, and one for melanoma.

After patient visits, I spent the 30 minutes combing through drug lists for one of our studies to determine is any drugs were recalled.

Once that task was completed, I read protocols for the rest of the day.

Tuesday, August 28, 2012 (Day 9)

The day started out with Tumor Board. I sat and listened to case presentations of current patients. Possible treatments were discussed and debated.

Following Tumor Board, I met with the research manager to discuss possible thesis topics. I then spent the rest of the morning performing literature reviews and formulating some cohesive ideas for my thesis project.

After lunch, the research manager and I met with Dr. Page to discuss the direction in which I wanted to go in terms of my thesis. He approved and I prepared for my first committee meeting.

During my first committee meeting, we discussed the site in which I am doing my internship as well as the research topic in which I am going to write. Everyone agreed and the topic was chosen. My major professor and I also discussed attending an IRB meeting at UNTHSC to learn about the IRB process.

Following my committee meeting, I assisted the research assistant for the rest of the day.

Wednesday, August 29, 2012 (Day 10)

The majority of the day consisted of building a new spreadsheet to record all of the research documents. The plan is to have a master sheet that has all of the information relative to each study conducted, both active and closed. I consolidated data and entered the information into the sheet I created.

In the afternoon, I also assisted in my first consent. I consented a patient into the VIEW study: a study in which I am running. We met with the patient, discussed the trial, got her to sign the necessary forms, and walked her to the lab for blood work.

Thursday, August 30, 2012 (Day 11)

Today, I continued cleaning and consolidating data from closed trials and entered the information into the spreadsheet that I created.

Following this task, I entered data for the VIEW study into an online database. I then retrieved the lab kit from LabCorp for process and shipment to the VIEW central lab.

After this task was completed, I met with the research manager and assistant to discuss more about what it takes to start up a research clinical trial. We discussed budgeting, SIVs, IRBs, contracts, protocol, and the order in which they occur.

After lunch, I worked on this journal.

Friday, August 31, 2012 (Day 12)

Today was a major cleanup day. The research assistant and I spent the entire day consolidating and cleaning out the conference room for storage and organization purposes. Once the consolidation and cleanup is finished. The conference room will be repurposed for a monitor room. The large tables will be moved out and smaller cubicle style tables will be put in.

Monday, September 3, 2012 (LABOR DAY, No Internship)

Due to the holiday, The Center for Cancer and Blood Disorders was closed.

Tuesday, September 4, 2012 (Day 16)

The major task of the day was to finish clearing out the conference room. I cleaned 2 bookshelves worth of binders and boxed them up to put into storage. As of right now, there are 27 boxes have been stored. This task has helped me to determine how best to organize study materials for both current and closed studies.

Wednesday, September 5, 2012 (Day 17)

Wednesday morning began with Tumor Board in Weatherford Regional Medical Center. Three cases were presented. See Notes.

I spent the morning observing radiation therapy in Weatherford clinic. The radiation team showed me the process of prepping patients and taught me how radiation therapy works.

Following lunch, I attended 2 conference calls: our weekly research team meeting and the weekly research meeting with Dr. Page.

After the conclusion of the research meetings, I left Weatherford and headed to UNTHSC Library to continue my research on my thesis proposal.

Thursday, September 6, 2012 (Day 18)

For most of the day, I created a master drug list for the research department. I logged every drug in our inventory into a database and noted the lot number, dose, and expiration date. I then pulled all expired drug for proper disposal.

Upon completion of the master drug list, I worked on the organization of the conference room. I cleaned up the binders from off the floor and moved everything into boxes or onto shelves. We moved some shelves out of the conference room and into the main cubicle area and prepared the conference room for the final organizational day on Monday.

Friday, September 8, 2012 (Day 19)

On Friday, I spent the morning attending the monthly research committee meeting. During this meeting, we discussed multiple issues arising during the research process throughout the clinic. We talked about the patient referral process, the lab approval process, the pharmacy and the HVAC system, the education checklist for the chemo nurses, the treatment templates, and the study start-up. We then talked about billing, invoicing, and finance history.

After the research meeting, I read some new protocols that we are considering for our site. I also researched some information form the FDA and emailed the FDA with questions, as well as USMD for questions pertaining to the protocols I read (*still awaiting reply).

After reading the protocols, I filed correspondence into the study binders, and organized the study folders.

Finally, I worked on drug inventory for the remainder of the day. I entered data into the master inventory logs within each study pharmacy binder, logged expired drugs into pharmacy log and put away used/expired drug into the used drug cabinet for proper disposal.

Monday, September 10, 2012 (Day 22)

Today was a busy day. In the morning, I worked on an outline of the GU 92 study. The outline consisted of the major points of the protocol as it pertains to certain people in the research department and pharmacy/chemotherapy. This took most of the day, though I took a break for a few hours to work on finishing organizing the conference room.

The other task that filled up the day was the completion of the storage organization. We finally finished organizing the documents and moving the shelving in the conference room. We then rearranged furniture and moved filing cabinets to make room to add a workspace for me. This task took around 3 hours today, but is not completed.

Tuesday, September 11, 2012 (Day 23)

The day started off with tumor board in the morning. Today we discussed multiple cases, including a patient with a 2 primary cancers (rectal and lung), and another with lung and liver metastasizes.

After tumor board, I began working on the outline of the BRE 193 study. This outline consisted of the same components as the GU 92: scans/labs scheduling data, chemotherapy regime, pharmacy information, etc. However, this was not completed because other tasks came up.

The major task of the day included consenting a patient into the VIEW study. I discussed the procedure and observed while the consent forms were signed. I then waited around the office until the physician signed the lab orders. While I waited for the lab to complete the lab work, I enrolled the patient into the database and organized the records.

After lunch, I began working on the BRE 193 outline again, before switching to regulatory documents. I looked over all of the regulatory documents to confirm everything was filled out and up-to-date.

Once the regulatory documents were in order, I wrote in this journal and continued working on the BRE 193 outline.

Wednesday, September 12, 2012 (Day 24)

To start the day, I updated Dr. Young's clinical trials protocol binder. I updated any outdated protocols and added current informed consent to the binder.

Once I finished updating the binder, I worked on my thesis proposal for a while. I added citations and edited paragraphs.

Right before lunch, I noticed we were running low on Veristrat lab kits for one of our studies. I was then given the task of calling the sponsor and ordering more.

After lunch, I was looking for things to do, so I accessed some literature for my thesis, and reviewed its content for addition into my proposal.

I then completed the protocol outline and summary of the protocol I had been working on the day before.

Once the protocol summary was finished, I began to work on updating screening logs. I updated a screening log for every study. Each log contained different information, including one for the sponsor, and one that was kept as in-house records only.

For the remainder of the day, I assisted the research assistant by typing up tumor board minutes. We also discussed tumor board accreditation and requirements.

Thursday, September 13, 2012 (Day 25)

For the majority of the day, I worked on my thesis. This included typing, researching, editing, and polishing.

Today I also consented my first VIEW patient solo. Once I was informed there was a potential patient, I gathered the test kit, informed consent, and other information and headed down to the patient room. I then reviewed the study with them, walked them through the informed consent, and ushered the patient and his/her family to the lab for blood collection. Once I left the patient, I then finished the necessary paperwork and filed the informed consent.

Throughout the day, I also pulled information from patient charts for our research nurse in Weatherford. As she needed information, I pulled it and emailed her the records.

Friday, September 14, 2012 (Day 26)

For the morning, I spent the first few hours finishing the VIEW study data and putting away VIEW kits that had arrived. I also picked up signed forms from various physicians around the building so that I could finish adding data to the inline database.

I spent the rest of the morning working on my thesis and doing literature reviews for the introduction to my thesis proposal.

In the afternoon, I helped the research assistant with various tasks, including locating documents, invoicing, and itemizing chemotherapy for SCRI.

Monday, September 17, 2012 (Day 29)

This morning, I finished working on the financial invoicing and itemization for last quarter's payment from SCRI. Once I added the figures to excel, I moved on to a new task.

After I finished the invoicing task, I researched preparation requirements for an FDA audit. I looked up inspection protocols and researched proper handling of FDA staff during an FDA inspection.

Once I finished that task, I started by looking over the patient charts for a study that is being audited. I made sure that all of the informed consents are up to date and properly signed. I then went over an internal audit letter and made sure that all of the previous errors from the internal audit were corrected and properly documented.

Tuesday, September 18, 2012 (Day 30)

Tuesday morning, I started the day by working on PI update forms. These forms are used as a summary sheet for the PIs, so they know what is going on in each trial.

After completing 4 of them to the best of my ability, I attended a meeting to discuss potential studies being added. I then read the protocols for 3 studies and typed out questions for the current investigative site. I also added general questions regarding their site.

After lunch, I began working on each PI's master list of all of their studies and patients. This datasheet gives the PI another way to look at the information for each study at a glance. It has more information than the PI update form though. The PI update form is a simple form discussing pertinent information, while the Master PI list shows all patients screened, active, or in follow up since the beginning of the trial.

Wednesday, September 19, 2012 (Day 31)

The majority of the day was spent working on PI update lists. I updated all of the breast cancer trials and the gastrointestinal trials. Once these were completed, I began working on other tasks.

I then began working on updating the VIEW study data. I picked up all outstanding test results from physicians and entered the information into the VIEW database.

I finalized the email to USMD and sent that information for their review.

I assisted the research assistant by completing IND reports for the remainder of the morning.

In the afternoon, we had our weekly research meeting and I continued to work on the PI update forms.

Thursday, September 20, 2012 (Day 32)

For the majority of the day, I created PI Update forms for the principle investigator meetings. These forms give the PI an overview of the study as a whole, including monitoring issues, toxicities, regulatory issues, data issues, and patient reports. Attached is an updated patient report showing all patients on the study, all patients ever screened, and all screen fail patients. The deviation report is also attached for the PI to go over.

Friday, September 21, 2012 (Day 33)

Friday, I continued working on the PI sheets that I began on Wednesday; I created PI Update forms for the principle investigator meetings. These forms give the PI an overview of the study as a whole, including monitoring issues, toxicities, regulatory issues, data issues, and patient reports. Attached is an updated patient report showing all patients on the study, all patients ever screened, and all screen fail patients. The deviation report is also attached for the PI to go over.

The PI update forms and PI trial lists take up most of the day, however, as I was creating each of the data sheets, I also logged any follow up patients into a follow up calendar for the research department to see.

I also pulled drug for a patient, but it wasn't needed so I put it back.

Monday, September 24, 2012 (Day 36)

The majority of Monday was spent preparing for an internal audit. I worked with the research manager and looked at every aspect of the clinical trial. We looked at the regulatory documents, screening logs, patient files, laboratory tests, pharmacy accountability logs, the pharmacy binder, and any other document that supported the study. We corrected any errors and added missing data.

For a portion of the day, the research manager and I drove to Arlington to visit a potential site. We looked at regulatory documents to see if it was a feasibility to take over the studies. We looked over protocols, budgets, and patient charts. This helped us to get a clearer understanding of the undertaking it would be to take over this site.

After lunch, we continued preparing for the internal audit by looking over the documents previously discussed.

Tuesday, September 25, 2012 (Day 37)

This morning, I woke up early to attend Tumor Board. Today's board had many interesting cases, including a patient who underwent an appendectomy while having a stroke.

Today, I continued working on regulatory binders and monitor notes. Once I began working on a study to make sure it was ready to be monitored this week. I spent the entire day looking through regulatory binders, pharmacy binders, drug inventory, and patient charts to ensure all of the data was correct.

Once I finished working on that study, I began the very same process for a different study. Though I didn't finish reviewing the study by the end of the day, I plan on looking at protocol deviations tomorrow in preparation for the monitor visit Thursday.

Wednesday, September 26, 2012 (Day 38)

During Wednesday, I spent the day preparing for the S130 monitor visit. This included going through old monitor letters and ensuring the tasks were completed. I went through each patient's chart and made sure everything was in order. I also checked to make sure that protocol deviations had been sent to the IRB.

I also consented a VIEW patient and completed enrollment for them into the study.

Finally, I made a fact sheet for one of our physicians that explained the process of an FDA audit. It also talked about FDA 482 and FDA 483. I also talked about consequences of audits and attached examples of a 482, 483, and a warning letter.

Thursday, September 27, 2012 (Day 39)

Today, I worked on my thesis for most of the morning. I finalized everything and sent it to my committee for review.

After lunch, I sat in on a webinar called, "The Ins and Out of Regulatory Affairs." The webinar discussed important issues in regulatory affairs, such as study start up, study maintenance, and FDA audits.

After the webinar, I worked on a new flow chart to decrease confusion during the informed consent and screening process.

Friday, September 28, 2012 (Day 40)

Friday, I only worked half of the day. I spent the morning finalizing an invoice of hours for a potential merger between The Center and another site. I calculated hours for regulatory tasks, coordinating tasks, patient visits, training hours, and data entry hours. These figures were then sent to the board for further deliberation.

Monday, October 1, 2012 (Day 43)

Today I spent the day working on incidence reports. These are internal reports for The Center to help discuss protocol deviations to non-research personnel and help to integrate the importance of research protocol into other areas of the clinic.

Tuesday, October 2, 2012 (Day 44)

Tuesday, I worked all day on my thesis. I had a meeting with Dr. Dory and Dr. Gwirtz in the morning to discuss revisions.

After leaving campus, I returned to CCBD to start the revisions on my thesis. The remainder of the afternoon I edited and rewrote my proposal.

The last 2 hours of the day, I attended the weekly staff meeting. We discussed various topics, including deviations, organization and storage issues, and the recent internal audit.

Wednesday, October 3, 2012 (Day 45)

Today, I spent my day working with the research manager. I attended all of her meetings with her. We attended a meeting with a sponsor to discuss enrollment.

I also attended the weekly research staff meeting with Dr. Page. We talked about the current trials and the upcoming opening of GU 92.

After the research meetings, we sat down with the regulatory coordinator to discuss the storage situation and violations of confidentiality. We brainstormed ways to increase confidentiality without overhauling the research department.

At the end of the day, I gathered all keys with unknown locks and through trial and error, paired keys and locks around the office.

Thursday, October 4, 2012 (Day 46)

Today, I started the day off by sending emails regarding the events of the previous day. These included the various meetings attended and discussions about the data storage situation.

After that, I attended a meeting with the billing department to discuss ways of integrating research into billing. We talked about the use of payment tracking sheet, so the billing department will know what is and is not supposed to be billed to the insurance.

Friday, October 5, 2012 (Day 47)

This morning, I started the day by attending the monthly Research Committee Meeting. We discussed a variety of issues including pharmacy, billing and finance, PI issues, and nursing issues. We also discussed the reorganization of the department and asked for input and suggestions from others.

After the meeting, I worked on reorganizing the regulatory coordinators office. We focused on increasing time management and decreasing filing and other errors. We also cleaned out old documents that were ready to be destroyed.

Finally, I spent a few minutes starting to clean the medical assistant/data coordinator's cubicle so to increase time management and decrease errors on her end as well.

Monday, October 8, 2012 (Day 50)

Today, I started the week by having an informal meeting with the research manager to discuss tasks for the week. Some of the tasks include annotating the Standard Operating Procedures (SOPs) to determine if we are abiding by them. We also talked about the Corrective Action Plans (CAPs) from the recent audit, and we discussed a checklist to be completed prior to every monitor visit.

After the meeting, the research manager and I cleaned the desk and office space of the data coordinator to produce a more productive environment for her. This took all day to complete.

Tuesday, October 9, 2012 (Day 51)

I spent the majority of the day working on a procedure for the central scans process. I went through all of the protocols, and made a concise process for each central company. This lasted all day.

Wednesday, October 10, 2012 (Day 52)

Today, I finished organizing the central lab binders and guides and worked with the data coordinator on getting all central scans sent to the proper company.

I continued to perform small tasks and update the central lab system. Toward the end of the day, I worked on transitioning from mailing the central scans to uploading them electronically.

Thursday, October 11, 2012 (Day 53)

This morning, I started out by attending a meeting with the research manager to prepare for a meeting with the LabCorp representative. We discussed questions to bring up and other issues the research team had.

Immediately following that the LabCorp's representative, Jenny Jones, arrived. During the meeting, we discussed issues from recent monitoring visits including the CLIA certification for our multiple sites and the Dallas CAP. We also talked about the lab director's CV and discussed the possibility of a CV/certification expiration calendar.

After the LabCorp meeting, I worked on PI updates and screening log updates.

Friday, October 12, 2012 (Day 54)

Friday, I prepared for the study start up meeting for the new study about to be opened at our site.

The meeting consisted of billing, research, and pharmacy. We talked about the drug, we talked about how to properly receive compensation (whether from insurance, the sponsor, or the patient) and we talked about the study overall.

After the study start up meeting, I performed various tasks from my tasks list.

Monday, October 15, 2012 (Day 57)

I spent the majority of the day preparing for the upcoming monitor visit for the START study. I organized the data and looked over regulatory to ensure the IMV would go smoothly.

Tuesday, October 16, 2012 (Day 58)

Tuesday morning started with tumor board. We discussed patients with various diseases and also talked about social concerns of certain patients.

Then, I worked on PI updates, screening logs, and data trackers for two different studies. This took up the majority of the day.

After lunch, I attended the Site Initiation Visit (SIV) for the new study opening in our clinic. We discussed the overview of the study protocol, drug, schedule of events, and treatments.

After the SIV, I worked on organizing myself for the next week because the research manager will be out of town.

Wednesday, October 17, 2012 (Day 59)

Today, I worked on many tasks. I started the day by pulling drug for two patients at a satellite clinic. I then verified it with the research nurse to ensure that I pulled the correct drug.

I then sat down with a principle investigator (PI) to discuss one of her trials with the PI Update form. She then assessed clinical significance on patient data.

After the PI meeting, I worked on additional PI Updates for other studies. This included updating the screening log for each trial, the active patients status, and look over monitor follow up letters.

I then worked on data tracker for two studies. These data trackers will help to map patients' progress, as well as, the progress of data entry.

After these data trackers were completed, I annotated the SOP and WPG for the site. I looked specifically at informed consent and adverse event logs, and how to maintain them. I also looked at the process for a delegation log.

Finally, to wind down the day, I shopped for office furniture and supplies for the research department.

Thursday, October 18, 2012 (Day 60)

Thursday started off with the completion of PI update forms for the next week's PI meetings. I audited data for 3 studies to ensure everything was ready for the upcoming IMVs.

I then went to the Huguley site to meet with a patient. I discussed a quick error with her and had her initial and date her error. We also got signatures from the physicians at that site.

Finally, I worked on five data trackers for the rest of the day. I went through the protocols and added in budgets and prepared them for use.

Friday, October 19, 2012 (Day 61)

Today, I created the data tracker for the MM 23 clinical trial.

After completion of the data tracker, I spent the rest of the day working on the BRE 193 internal audit to prepare for the upcoming sponsor visit. I worked with the data coordinator and regulatory assistant in completing those tasks.

Monday, October 22, 2012 (Day 64)

I spent Monday working on PI updates for 3 different studies to ensure these studies were up to date in the regulatory binders, and patient information. I updated the screening logs and brought any major issues to the regulatory coordinator's attention.

I also worked on creating data trackers for multiple studies. I created templates for each study based on the protocol, and embedded the budget. This is so we can track the data completed and, it ensures that we are getting paid for each patient visit.

Tuesday, October 23, 2012 (Day 65)

Tuesday was very similar to Monday. I spent the day incorporating budgets into data trackers. I also created an invoice tracker to make sure things are being invoiced in a timely manner.

Additionally, I audited a few studies and brought any discrepancies to the attention of the regulatory coordinator, research nurse, or data coordinator.

Wednesday, October 24, 2012 (Day 66)

Wednesday, I worked half of the day. I spent the morning working with the data coordinator and research nurse to discuss ways to ensure patient follow-ups are not being missed, therefore avoiding unnecessary deviations.

We also worked on updating and entering data.

After lunch, I worked on my IRB application for my thesis project.

Thursday, October 25, 2012 (Day 67)

Today, I worked on finalizing the data for the sponsor audit at the end of the month. We checked on data and updated the data tracker.

I also checked the deviation list against the monitor list and discussed the discrepancies with the research manager.

I then completed data clarification forms (DCFs) for a study (START). Once these DCFs were completed, I sent them out for signature and then faxed them to the sponsor.

Friday, October 26, 2012 (Day 68)

Friday, I spent the day updating and cleaning out the screening logs on the main server. The purpose of this was to ensure that patients were only one the list one time. Once all of the patients were accounted for and put under the correct month, I began to work on the physician referral tracker. I updated this and cleaned it up and made sure that the logs corresponded with each other.

After the logs were cleaned and updated, I worked on a PowerPoint presentation for the research manager, which utilized the data I had just organized.

Monday, October 29, 2012 (Day 71)

Monday, I spent the majority of the day going through study regulatory binders and completing PI update forms. I also made three data trackers.

In the afternoon, we had our weekly research meeting.

Tuesday, October 30, 2012 (Day 72)

For the entire day on Tuesday, I worked with the research manager and the pharmacist on the quarterly board meeting presentations. We also discussed screening log organization and other databases that can be made.

Wednesday, October 31, 2012 (day 73)

Today, I worked on ensuring we are ready for our sponsor audit. I reviewed the regulatory binder again, and ensured everyone was caught up on training.

Thursday, November 1, 2012 (Day 74)

I spent all day today reorganizing the conference room and research office. I moved all of the data storage boxes, binders, shelves, filing cabinets, and tables so the conference room becomes an appropriate monitoring room.

After I finished cleaning the conference room, I reorganized the research department so that all of the things I took out of the conference room would fit into the main area.

Friday, November 2, 2012 (Day 75)

I began the morning at the monthly research committee meeting. We discussed various topics regarding research integration and communication with other departments.

I continued to clean the research department and put away any items that were to be out of view for patient confidentiality.

I worked on my internship journal and my IRB application as well.

I also created two data trackers.

Monday, November 5, 2012 (Day 78)

Today, I worked on data clarification forms from a study that has closed. I thumbed through paper Case Report Forms to answer the queries and ensure the data is being represented correctly. These took up over half of the day.

I then worked on a cheat sheet for a physician to prepare her for the audit that is to begin tomorrow. I answered potential questions for her to ensure she knew her role and the role of everyone in the research department.

I also worked on my internship journal, and my IRB application.

Tuesday, November 6, 2012 (Day 79)

I spent the morning in tumor board taking notes and listening to the physicians discussing patients.

After tumor board, I worked on my IRB application and the internship journal.

I then worked on PI updates and looked over regulatory binders and follow-up letters for monitor visits.

I then left early to get my IRB application signed, my intent to graduate form signed, and to vote.

Wednesday, November 7, 2012 (Day 80)

I started out the morning in Weatherford at the monthly tumor board meeting. I took notes and listened to the four cases that were presented.

I then drove back to Fort Worth, where I spent the day organizing and filing my new workspace. I rearranged furniture and cleaned out filing systems. I also filed a month's worth of patient data into the patient charts.

Thursday, November 8, 2012 (Day 81)

I spent Thursday filing patient data into the patient charts.

After I completed filing, I worked on START DCFs and other queries.

Friday, November 9, 2012 (Day 82)

In the morning, I worked on consenting a patient into the VIEW study.

I worked on central scans for the majority of the morning, getting them ready to be sent to central scans. I then answered multiple queries regarding central scans.

Once I completed those, I worked on DCFs for the START study. After completing these, I reviewed and corrected them with the research manager.

After the START DCFs were sent off, I finished the day by entering data and setting up a follow-up calendar for the VIEW study.

Monday, November 12, 2012 (Day 85)

Today, I spent the day working on the new Google patient follow-up calendar. I updated the PI patient logs and used that information to create a calendar that alerts the research team of a patient needed a follow-up visit.

Around 2pm, I left to work on my IRB application. I received an email stating clarifications, so I worked on those.

Tuesday, November 13, 2012 (Day 86)

I started off today at Tumor Board in Fort Worth. I took notes and listened to cases.

I then worked on START DCFs with the research manager. Once these were answered, I organized them and sent them off for signature.

I then worked on the follow-up calendar more. I updated the PI patient logs and again used that to determine which patients needed a follow-up visit.

I also collected data for the research coordinator who enters data. Whenever she needs information, I find it for her in the patient charts and scan the information to her.

I also filed data into the patient charts.

After lunch, I worked on queries for central scans and ordered scans from the radiology office.

I then sat in on a meeting discussing IND reports and the new policies about them.

Wednesday, November 14, 2012 (Day 87)

Wednesday, I spent the morning filing in patient charts and organizing and filing.

Then I spent the majority of the day on a follow-up database and calendar for one of the closed studies named, BETH. This includes looking up patient information and determining when the patient is due for their next visit based on the protocol. With so many patients, this took up most of my time.

Once the filing was up to date, I worked on data clarification forms for the START study. I then reviewed them with the research manager. Once they were complete, I faxed them to the sponsor and then mailed the originals as well.

After lunch, I sat through a Site Initiation Visit for an upcoming tissue trial that CCBD is opening. We discussed the protocol, procedures, and delegations. We also discussed other possible trials for CCBD. This lasted the rest of the afternoon.

I also collected data for the data coordinator to input into the electronic database (EDC).

Thursday, November 15, 2012 (Day 88)

Today, I again worked on data clarification forms for the START study. I then reviewed them with the research manager. Once they were complete, I faxed them to the sponsor and then mailed the originals as well.

I also collected data for the data coordinator to input into the electronic database (EDC).

Then I spent the majority of the day on a follow-up database and calendar for one of the closed studies named, BETH. This includes looking up patient information and determining when the patient is due for their next visit based on the protocol. With so many patients, this took up most of my time.

Friday, November 16, 2012 (Day 89)

Wednesday, I spent the morning filing in patient charts and organizing and filing.

Once the filing was up to date, I worked on data clarification forms for the START study. I then reviewed them with the research manager. Once they were complete, I faxed them to the sponsor and then mailed the originals as well.

I also collected data for the data coordinator to input into the electronic database (EDC).

For the remainder of the morning, I addressed the clarifications from the IRB regarding my thesis proposal. These were then sent to the PI for review.

Finally, after lunch, I attended a UNTHSC thesis defense to learn about the process.

Monday, November 19, 2012 (Day 92)

Today, I worked on PI updates for the upcoming monitor visits. This includes, ensuring patient data is up to date, looking at regulatory material, and making sure screening logs are up to date. I then add all of this information to a form for the PI to sign for the PI oversight.

I then went to campus to have my major professor sign some forms.

I came back to the internship site, worked on two more PI updates, and then answered START queries, and edited writing for a colleague.

I finally, prepared for the monitor visit for tomorrow, by gathering all of the patient charts needed and the regulatory documents needed.

Tuesday, November 20, 2012 (Day 93)

Today, I attended two UNTHSC thesis defenses. The topics were relevant to my thesis, and I wanted to learn about the defense process.

Wednesday, November 21, 2012 (Day 94)

Vacation

Thursday, November 22, 2012 (Day 95)

Vacation – Thanksgiving Day

Friday, November 23, 2012 (Day 96)

Vacation

Monday, November 26, 2012 (Day 99)

Vacation

Tuesday, November 27, 2012 (Day 100)

Vacation

Wednesday, November 28, 2012 (Day 101)

Vacation

Thursday, November 29, 2012 (Day 102)

Vacation

Friday, November 30, 2012 (Day 103)

Vacation

Monday, December 3, 2012 (Day 106)

I came back from vacation with a ton of paperwork to file. I spent the entire morning catching up on filing in the charts.

I then left at midday because I had meetings on campus with members of my committee.

I discussed my thesis and accompanying paperwork with Dr. Gwirtz, and then talked with the UNTHSC Office of Protection of Human Services (UNTHSC-OPHS) regarding my IRB submission.

Tuesday, December 4, 2012 (Day 107)

In the morning, I worked on my IRB application all morning. I rewrote the entire application, because I had made major changes to my protocol and the UNTHSC-OPHS advised on a new application.

After I completed the IRB application, I worked on queries for the START study. I then sat down with the research manager to look over them and get them ready for submission to the sponsor.

During the remainder of the day, I finished the BETH follow-up calendar. This calendar helps the research department to know when BETH trial patients are due for various tests including a mammogram, an echocardiogram, and their physical exam.

Wednesday, December 5, 2012 (Day 108)

I started the day by researching and preparing a presentation on FDA audit regulations and protocols. This was for a companywide staff meeting that I presented at.

I spent the rest of the day working on patient follow-ups for the VIEW study. I looked up data and entered it into the EDC for patients' 3 month follow-up.

Thursday, December 6, 2012 (Day 109)

On Thursday, I spent the entire day organizing patient charts. With the growing number of patients that the research department sees, we are running out of room, and we needed more filing space for active and follow-up patients. I boxed up all charts for patients that are deceased and were on studies that are no longer active. I then went through the entire collection of follow-up patients and determined if the patient had passed away. I then moved those charts to the ECU (expired care unit) filing cabinets.

At the end of the day, the entire research team decorated the office for the holidays.

Friday, December 7, 2012 (Day 110)

At the beginning of Friday, I spent the morning continuing the task of organizing patient charts. With the growing number of patients that the research department sees, we are running out of room, and we needed more filing space for active and follow-up patients. I boxed up all charts for patients that are deceased and were on studies that are no longer active. I then went through the entire collection of follow-up patients and determined if the patient had passed away. I then moved those charts to the ECU (expired care unit) filing cabinets.

At 2:00pm, the companywide meeting took place and I spoke to the company regarding FDA guidelines for FDA research audits. This meeting lasted three hours.

Monday, December 10, 2012 (Day 113)

This morning, I helped the coordinators with an issue regarding randomization of a patient and a discrepancy in the amount of drug in house.

I then filed paperwork into the charts for the rest of the afternoon.

Tuesday, December 11, 2012 (Day 114)

Today there was no tumor board, so I came in at the usual time.

I began the day by filing records into the charts.

I started the day by helping the data coordinator find and enter data into the EDC. This took up almost the entire morning.

After lunch, I continued to enter data into the EDC and update patient records.

I then scanned consent forms into the T: drive for uploading into the EMR.

Wednesday, December 12, 2012 (Day 115)

This morning, I began the day by cleaning up patient charts for the monitor visit. After finding records in the wrong chart yesterday, I wanted to make sure that the charts being monitored today were accurate and correct.

I then sent out for scans to be sent to research so that I can then send them to Perceptives. These are called "central scans" in the research department.

I then worked on the pharmacy drug inventory log. I wrote macros and edited the log to prepare it for the pharmacy tech that is joining research at the beginning of the year.

During this time, I also volunteered preparing for the Christmas vigil and luncheon for our patients by setting up the event.

After lunch, I cleaned out charts for the two studies in the upcoming SCRI internal audit.

At 2:00pm, we had our weekly research meeting with Dr. Page. We discussed upcoming trials, and current active patients.

The last 30 minutes, I wrote in my internship journal.

Thursday, December 13, 2012 (Day 116)

Today, I spent the entire day cleaning out charts and organizing them. I also checked for local LabCorp labs. If there were no lab results filed in the chart, I printed them off of MedOnc, highlighted the abnormal findings, and prepared them for physician assessment and signature. I completed about 10 patients between yesterday afternoon and today.

The last 15 minutes of the day, I wrote in my internship journal.

Friday, December 14, 2012 (Day 117)

Today, I spent the entire day cleaning out charts and organizing them. I also checked for local LabCorp labs. If there were no lab results filed in the chart, I printed them off of MedOnc, highlighted the abnormal findings, and prepared them for physician assessment and signature. I completed about 10 patients during that time.

Monday, December 17, 2012 (Day 120)

Monday, I spent the day typing up minutes from tumor board. Notes are taken every week and then transcribed for submittal to The University of North Texas Health Science Center.

Tuesday, December 18, 2012 (Day 121)

Tuesday started out early. I retrieved dry ice from the dry ice store on my way to the clinic.

I then out the dry ice away and attended tumor board. We discussed multiple cases.

After tumor board, I began working on adding the new pharmacy technician to all of the delegation of authority logs for each study.

I then left around lunch time.

Wednesday, December 19, 2012 (Day 122)

I began the day by adding the new pharmacy technician to all of the delegation of authority logs for each study.

I then spent the day typing up minutes from tumor board. Notes are taken every week and then transcribed for submittal to The University of North Texas Health Science Center.

Thursday, December 20, 2012 (Day 123)

Today, I finished prepping for the arrival of our new pharmacy technician by adding her to the delegation of authority logs.

I then finished the drug inventory database by going through each study's regulatory and pharmacy binders and determining which studies autoship the drug, and which studies need to have the drug ordered. I added that to the database so the pharmacy technician would know how to order drug. I also created a binder with all of the order forms needed to order Investigational Product (IP).

Finally, I worked on tumor board minutes for the year and gave those to the regulatory coordinator for submission.

Friday, December 21, 2012 (Day 124)

Today, I spent the morning working on tumor board minutes and finally finished the year. I then gave those to the regulatory coordinator for submission.

Next, I answered queries from Perceptive Informatics regarding central scans. I also filed acceptance letters from Perceptive Informatics regarding other central scans.

Once I completed these, I spent over 2 hours filing into the charts. This is a long process because there is so much to file and there are so many patients.

After lunch, we had a research staff gift exchange for Christmas.

I assisted the research coordinator with data input for several studies.

I then worked on my thesis outline and internship journal.

Monday, December 24, 2012 (Day 127)

Christmas Eve – CCBD Closed for the holidays.

Tuesday, December 25, 2012 (Day 128)

Christmas Day – CCBD Closed for the holidays.

Wednesday, December 26, 2012 (Day 129)

Today is the first day that I begin half days here at CCBD. I will work 4 hours at The Center and 4 hours at school or at home working on writing my thesis.

This morning, I began the day by doing various small tasks. I filed patient CRF binders, and prepped for the monitor visit. I also prepped drug for shipment to a satellite site. I packaged the drug, put it on ice, and sent it to the pharmacy for the courier to pick up.

I then cleaned the T: drive. This is a task in which source documents are scanned to the T: drive of the CCBD server. I then label the document, and upload it into the electronic medical record (EMR), MedOnc.

After I completed cleaning the T: drive, I uploaded consent forms onto the T: drive that needed to be uploaded to the EMR. Once these consent forms were scanned into the T: drive, I also uploaded them to the EMR.

Thursday, December 27, 2012 (Day 130)

I was out sick.

Friday, December 28, 2012 (Day 131)

Today, I began the day by filing documents into the charts. This took around one and a half hours.

I then printed off local lab results for all of the research patients that were seen from December 18, 2012 through December 27, 2012. I then prepped them for the physicians by tabbing them with instructions on how to fill them out for clinical significance.

After I finished the local labs, I updated the VIEW follow-ups in the EDC and wrote in my internship journal.

Monday, December 31, 2012 (Day 132)

I started out the day, by collected data for my thesis. I reviewed a regulatory binder for one study to look at protocol deviation numbers and monitor follow-ups.

I also cleaned out filing cabinets. I moved the filing cabinet from the pharmacist's office to the monitor's suite and then moved all of the shadow charts into it. The reason for this is because, the filing cabinets that had previously housed those charts was not a locking cabinet and therefore was a FDA CFR violation of confidentiality as the filing cabinets were moved to the monitor suite to make room for additional staff.

I then cleaned up, had a meeting with HR, and assisted one of the coordinators in data.

Tuesday, January 1, 2013 (Day 133)

New Year's Day – CCBD closed

Wednesday, January 2, 2013 (Day 134)

Today I spent most of the morning working on the follow-up calendar for one of our studies. With 26 patients in follow-up, this will take a lot of time. I finished 2 patients today, so plan on having the calendar completed in 2 weeks.

I also sent out multiple radiology scans to CoreLab. Three patients' scans were waiting for me at the radiology department. I filled out the appropriate paperwork and sent those off through UPS.

I also signed an offer letter to show my intent to stay and work at CCBD after the conclusion of my internship.

Finally, I scanned labs to the Weatherford coordinator for her to use in data management.

Thursday, January 3, 2013 (Day 135)

Today I spent most of the morning working on the follow-up calendar for one of our studies. With 26 patients in follow-up, this will take a lot of time. I finished 3 patients today, so plan on having the calendar completed in 2 weeks.

Friday, January 4, 2013 (Day 136)

Today, I spent the day working on the follow-up calendar that I started on Wednesday. With 26 patients in follow-up, this will take a lot of time. I finished 3 patients today, so plan on having the calendar completed in 2 weeks.

I then worked on the close-out for an older study. There are lots of items pending, and I sifted through all of the regulatory documents to locate them. This took the rest of the day.

Monday, January 07, 2013 (Day 139)

I came in today in the afternoon. I organized the lab counter to make room for all of the lab kits for the week. I made color-coded sections for each day.

I worked on the TAILORx follow-up calendar. With 26 patients in follow-up, this will take a lot of time. I finished one and a half patients today, so plan on having the calendar completed in 2 weeks.

I also finished working the on the study close-out. There are lots of items pending, and I sifted through all of the regulatory documents to locate them. This took the rest of the day.

I then showed the new pharmacy technician the database I created for her. We discussed how to use it.

I then attended the weekly staff meeting. We discussed ongoing issues and had open discussion regarding various topics.

Tuesday, January 08, 2013 (Day 140)

Tuesday morning, I attended tumor board in the morning.

I then worked on the TAILORx follow-up calendar. With 26 patients in follow-up, this will take a lot of time. I finished one and a half patients today, so plan on having the calendar completed in 2 weeks.

I then assisted in gathering information and physician's opinions on a patient's treatment options. I spoke with two physicians regarding a patient and discussed the physicians' opinions with the nurses' manager.

The rest of the day, I collected data for my thesis.

Wednesday, January 09, 2013 (Day 141)

Today, I came into my internship in the afternoon. I started the afternoon by submitting central scan query responses, and emailing the radiology department regarding those scans.

Once I had answered the scan queries, I assisted the research assistant in preparing for the weekly research meeting. I typed up a portion of the research meeting minutes for today's meeting.

I then attended the weekly research departmental meeting. We discussed various studies and issues within the department.

After the meeting, I sent multiple pages of data to the research coordinator in Weatherford so she could enter the data into the EDC.

I then collected some data for my thesis, worked on the TAILORx follow-up calendar, and updated my internship journal.

Thursday, January 10, 2013 (Day 142)

I started the day by meeting with the regulatory assistant and research manager to discuss the roles in which I will be responsible once I begin working at CCBD full time.

After the initial meeting, I sat down with the regulatory assistant and she trained me on tasks to be doing while she is out on vacation. We also talked about a project in which I am taking over from her once I begin full time at CCBD.

After these meetings, I worked on the TAILORx follow-up calendar, filed, and pulled data for research coordinators.

Friday, January 11, 2013 (Day 143)

I started out the day by pulling lab kits for the next week so that we would be organized for the upcoming week. I also made a calendar to make sure that all patients were accounted for and all lab kits were prepared.

I also filed in charts, and sent out three central scans.

Monday, January 14, 2013 (Day 144)

I started out the morning by filing in the patient charts.

Once I completed the filing, I requested central scans from radiology.

Finally, I spent the majority of the morning catching up on regulatory affairs because our regulatory assistant is out on vacation.

Tuesday, January 15, 2013 (Day 145)

Tuesday consisted of many tasks. I started the day by prepping for the monitor. This included adding the monitor to our EMR for access to patient information, filing in the patient shadow charts and the regulatory binders, and then positioning all relevant information in the monitor space.

Then, I spent most of the day working on rectifying items found during our last internal audit. This included filing in the regulatory binders and scanning documents to Sarah Cannon Research Institute (SCRI), our CRO.

Wednesday, January 16, 2013 (Day 146)

Today was busy. I started the day by prepping for the weekly research meeting. This included updating the meeting notes and printing them off as well as printing off the screening log.

I then continued the task from yesterday of filing in the regulatory binders. Since we've increased our staff size, all of the delegation logs were out for signature by the PI. They were all completed today, so they all needed to be filed.

I then prepped for the monitor coming on Thursday, so that I could be prepared.

The research meeting then started. It was brief and we discussed only pertinent matters.

After the meeting, I worked on the internal audit report for a different study. This required getting signatures from PIs, and emailing the regulatory department at SCRI for clarification and to scan things to them that they needed.

I also completed an event notification form for a closed trial that has a monitor visiting next week. I looked at all of the patients in follow up and determined what events are coming up next in their follow up schedule.

I then scanned data to the research nurse in Weatherford, and filed in the patient charts.

Thursday, January 17, 2013 (Day 147)

Thursday, I worked on multiple tasks. I started out the day making a central scan calendar. This calendar alerts me when a patient is due for scans. Now, that the calendar is available, I can easily know which scans to order to be shipped to the central scan company.

In the morning, I set up for the monitor in the beginning of the day, and attended a meeting regarding how to use reminders.

Finally, once the calendar was completed, I filed in the charts for the rest of the day.

Friday, January 18, 2013 (Day 148)

Today, I spent the majority of the day filing in the charts and preparing for the next week.

Monday, January 21, 2013 (Day 151)

Monday, I began the day by checking emails and sending data to the research nurse/interim data coordinator.

I then began printing off labs for the physicians to assess. This task entails, printing off every research patient's labs every day, followed by highlighting the abnormal labs and then stamping and flagging the abnormal labs for the physician's signature.

At 10:00, I attended a conference call with SCRI regarding delegation logs, and the new process for those.

After the call, I continued printing off labs.

Tuesday, January 22, 2013 (Day 152)

The day started with the continuation of printing off, stamping, and flagging labs for the physicians' signatures.

This took the entire working day.

Wednesday, January 23, 2013 (Day 153)

Today, I filed for most of the morning, because I received all of the labs back that had been assessed by the physicians.

I also attended the weekly meeting of the research staff to discuss new protocols.

For the rest of the day, I worked on a new database for the rest of the day.

Thursday, January 24, 2013 (Day 154)

Today, I spent the entire day working on updating the research database. I added sections, such as "CTCAE version," "RECIST version," "drug used per study", and linked all of the sheets together to make them more user friendly.

In the evening, I attended the January meeting for SoCRA. The topics were multigenerational work types, FDA audits, and the national convention.

Friday, January 25, 2013 (Day 155)

Friday, I started the morning by organizing my workspace. As my duties have changed, so have my organizational needs.

I then filed CTNeT files in my new filing cabinet, and organized the regulatory information.

I then filed source documents into patient charts.

Lastly, I had a short meeting with the research manager to discuss ideas for regulatory organization.

Monday, January 28, 2013 (Day 158)

I started the day working on the new research database; this took most of the day.

At the end of the day, I also completed central scans for 2 patients.

Tuesday, January 29, 2013 (Day 159)

Today, I spent the morning completing central scans for two patients. I also answered a central scan query.

Then, I filed in the patient charts.

Finally, I printed off the local lab analyses for all of the patients who we saw last week. I then highlighted any values that were out of range, and gave them to the physicians for clinical significance assessments.

For the last hour of the day, I worked on the Follow Up calendar for the TAILORx study.

Wednesday, January 30, 2013 (Day 160)

Today, I worked on the research database for the majority of the morning. I finished the formulation of the spreadsheet, so I began filling the sheet with data.

Secondly, I sat down with the research assistant and regulatory coordinator to discuss her tasks and job description for my thesis.

Finally, I attended a talk over dinner on the drug Abraxane given by Dr. Page.

Thursday, January 31, 2013 (Day 161)

I spent almost the entire morning working on filling the research database with patient information.

I also had a meeting with the pharmacist to discuss a project that I am helping him with.

Finally, I filed some papers organized patient charts.

For the rest of the internship experience, I will be working 100% on my thesis.