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Although clinical trials are essential for the development of cancer treatments, only approximately 3% of cancer patients in the U.S. participate in them. While 55% of these patients are enrolled in cancer clinical trials through community-based practices and around 80% of all cancer patients are seen at this type of practice, there is a lack of knowledge about the enrollment barriers at these sites. This study evaluates enrollment barriers at a community-based cancer clinic at the levels of the investigative site, healthcare provider, and patient. Barriers to enrollment and strategies to increase enrollment are evaluated through historical data analyses and results from a survey assessing the opinions of healthcare providers on enrollment and research practices.

IDENTIFYING BARRIERS TO ENROLLMENT AND STRATEGIES TO

INCREASE ENROLLMENT AT A COMMUNITY-BASED

CANCER TREATMENT CENTER

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INTERNSHIP PRACTICUM REPORT

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CHAPTER I

INTRODUCTION

Enrolling patients in cancer clinical trials (CCT) is essential for the advancement of cancer treatments, yet only 3% of adult cancer patients in the U.S. are enrolled in CCT (Colon-Otero et al., 2008; Comis, Miller, Colaizzi, & Kimmel, 2009). Many investigative sites and clinical trials fail to meet their enrollment goals, which can make it difficult to assess new cancer treatments (Schroen et al., 2012). This slows down the advancement of treatment options and prevents patients from receiving the best of care (Cheng, Dietrich, & Dilts, 2010; Schroen et al., 2010). Therefore, it is important to identify the barriers to enrollment and strategies to improve enrollment in CCT in order to keep improving cancer therapies.

Approximately 55% of patients participating in CCT are enrolled in these studies through community-based practices (Dobson et al., 2006). However, barriers to enrollment at community-based cancer clinics are not studied as often as barriers at academic centers, and many of the studies that have been conducted have focused on patient perspectives and not the opinions of the healthcare providers that offer trials to patients as a treatment option (Somkin et al., 2005). This study was designed to identify barriers to enrollment and evaluate strategies that may overcome those barriers at The Center for Cancer and Blood Disorders (CCBD), which is a community-based oncology practice that participates in clinical research. Some of the challenges

that CCBD faces may apply to all cancer research centers, may be unique to community-based practices, or may be specific to the research practices at CCBD.

Two types of data were collected and analyzed in this study. First, this study utilizes historical data on CCBD research practices, such as the date CCBD became associated with a site management organization and the number of patients referred, screened, and enrolled each month. In this study, the definitions of these terms are based on their use at CCBD. Referred patients are patients that have been referred to the research department for trial participation. Screened patients are patients that have gone through screening procedures or a screening visit to determine trial eligibility, which requires informed consent. The number of screened patients includes screen fails, or patients that were screened but did not meet trial eligibility. Enrollment is defined by the number of patients that have started study treatment.

The second part of this study focuses on current barriers to enrollment and research practices at CCBD through the survey responses of the CCBD healthcare providers. The survey contained several opinion items that each provider was asked to evaluate, which addressed enrollment barriers that have been identified by members of the CCBD staff or that have been evaluated in previous studies. The results of this study may be useful to CCBD, other community-based oncology clinics, and even academic cancer centers in determining what the barriers to enrollment are at those sites or what strategies may be useful in improving research practices and increasing enrollment to CCT in the future.

CHAPTER II

BACKGROUND AND LITERATURE REVIEW

In 2013 there were an estimated 580,000 deaths from cancer, 1.7 million new cancer diagnoses, and 12.6 million people living with cancer in the United States (American Cancer Society, 2013; Howlader et al., 2012). In the U.S., cancer is the second leading cause of death and costs approximately \$201.5 billion per year through direct and indirect costs (American Cancer Society, 2013; Murphy, Xu, & Kochanek, 2013). Therefore, it is important to develop and advance cancer therapies and treatments in order to reduce the burden of this disease.

Cancer treatments are advanced through CCT, which evaluate cancer therapies for safety and effectiveness in human subjects. CCT benefit patients and the public by providing a way to offer cancer patients the newest treatment options, close monitoring of their disease and progress, and eventually improved standard of care treatment options (National Cancer Institute, 2013). CCT also benefit study sponsors and research sites by allowing physicians to offer patients state-of-the-art treatments, by recruiting physicians to research institutions, by increasing revenue from conducting CCT, and by increasing distinction for the sponsor, site, or physicians (National Cancer Institute, 2013).

The development of new cancer therapies is delayed by poor CCT enrollment. Approximately one third of end-phase CCT close with insufficient enrollment to address the primary endpoints of the study (Schroen et al., 2012). Increasing CCT enrollment can help avoid

this problem while creating solutions for current and future cancer patients. In order to increase enrollment, the causes of low patient enrollment must be identified, and effective solutions must be implemented to address these issues.

Past studies on low CCT enrollment have identified barriers to enrollment at different levels of the clinical trial and recruitment process that can prevent cancer patients from enrolling in CCT (ENACCT, 2012). These barriers can be due to an organization, such as the sponsor or investigative site, or an individual, such as the healthcare provider or the patient.

Barriers at the level of the sponsor can include a need for improved reimbursement of trial participants or investigative sites, the development of protocols with strict eligibility criteria, blinding and randomization requirements, non-standard procedures that are not covered by insurance, or protocols that do not allow for certain therapies to be given in addition to the study treatment that the physician feels are necessary (Frank, 2004; Weiss et al., 2013). Barriers at the level of the investigative site or institution typically include a lack of organization and efficiency, a lack of designated research staff, not having a method to efficiently screen patients for eligibility, insufficient advertisement of CCT, and choosing to open trials that are not appropriate for the patient population seen at that site (Dilts & Sandler, 2006; Ulrich et al., 2010).

Barriers at the level of the provider include a lack of awareness of clinical trials, fear of losing a patient through referral to a trial, the additional time investment or administrative burden involved in offering CCT, a lack of communication to patients about CCT, and a lack of confidence in the treatments offered in research studies or the belief that standard of care treatment is better (Albrecht et al., 2008; Frank, 2004). Barriers at the level of the patient include a fear of being a "guinea pig," discomfort with randomization, fear of receiving placebo in place of actual treatment, distrust of research or medical professionals, noncompliance with study

protocols, lack of insurance coverage, and lack of awareness that clinical trials are available (Mills et al., 2006; Simon et al., 2004).

The barriers faced by a group or individual are highly dependent on several factors. For example, patient perspectives have been studied extensively and previous research has found that sex, race, age, primary language, place of residence, education, income, and even type of cancer can play a factor in whether or not the patient can or will participate in a clinical study (Kanarek et al., 2010; Murthy, Krumholz, & Gross, 2004). Barriers to enrollment faced at research sites may also depend on several factors, such as whether or not the site is a community-based clinic or a large academic center, or whether or not the site has additional administrative support through a contract research organization (CRO) or site management organization (SMO). However, many of the studies evaluating provider perspectives and institutional barriers have only focused on large, academic research institutions or physicians that are out in the community but unaffiliated with the investigative site (Crosson, Eisner, Brown, & Ter Maat, 2001; Simon et al., 2004).

Due to the various factors that influence enrollment, no single study on barriers to enrollment or set of recommendations to increase enrollment is applicable to all patient populations, healthcare providers, or research institutions. However, while 80% of cancer patients are treated at community-based practices, this type of oncology practice is not often evaluated in studies on the causes of low enrollment (Mulvey, 2008). In addition, provider perspectives should be taken into account more often as healthcare providers are the primary source of information for patients about CCT. Healthcare providers at community-based practices have the potential to be major contributors to the identification of barriers to

enrollment, overcoming these barriers, and the development of recommendations for improving CCT enrollment at their own site and other community-based practices (Yates, 2003).

The Center for Cancer and Blood Disorders is a community-based cancer treatment center that conducts CCT as an investigative site. CCBD includes nine different clinics that are located in North Texas in the United States. While CCBD's research department is centralized in the main campus, four of the nine clinics offer CCT to patients and physicians at the other five clinics can easily refer patients for clinical trials. There are currently a total of 19 physicians at CCBD specializing in medical oncology, gynecologic oncology, hematology, and radiation oncology. In addition, there also are five physician assistants and nurse practitioners at CCBD that work with these physicians.

The research department staff includes a clinical research manager, three additional clinical research coordinators, a regulatory coordinator, data manager, and investigational product coordinator. The research staff is responsible for the majority of the patient enrollment process at CCBD. The study coordinators are responsible for pre-screening and screening patients for trial eligibility and consenting patients. Pre-screening patients involves determining whether or not patients that have been referred to the research department meet initial eligibility requirements, which often include the patient's age, sex, type of cancer, and stage of disease. Screening patients involves having the patient go through screening procedures, which typically involve questionnaires, laboratory tests, and radiology scans to further determine eligibility. Patients must be consented and sign the informed consent form before going through any screening procedures. Patients that meet the eligibility criteria are randomized to a treatment arm in order to begin study treatment (Schroedter, 2013).

An additional aspect of research at CCBD is the use of Via Oncology Pathways, which is a web-based oncology decision support software that assists physicians in choosing a treatment for their patients based on the patients disease profile (Via Oncology Pathways, 2012). The treatments are constantly updated to reflect current standards of care, with the best treatment for a patient being the first treatment option on Pathways. If a provider chooses to treat the patient "off-Pathway," they must bypass the first treatment option. If a provider treats patients "off-Pathway" too often, it can reflect poorly on the provider because it shows that the provider is choosing treatments other than the current standard of care. At CCBD, trial treatments are added to Pathways and are set as the first treatment option because they provide the most current standard of care and are considered to be the best treatment option for patients. Therefore, when using Pathways CCBD providers see that there is a CCT available for their patient, and the provider must choose to bypass the CCT if they want to treat the patient using a different therapy. Technically this means that all patients are pre-screened for trial eligibility to some degree by the use of the Pathways software, although there are some issues with its usefulness in pre-screening patients.

Finally, while CCBD has been conducting CCT since 1999, significant changes in research practices at CCBD have taken place in recent years. For example, CCBD has doubled its research staff since 2010 and improved upon its research policies (Schroedter, 2013). In addition, CCBD has become a strategic site of a SMO, the Sarah Cannon Research Institute (SCRI). SCRI conducts community-based trials through affiliations with oncology practices in the United States and United Kingdom. Similar to a CRO, SCRI provides management, regulatory and other support services to both sponsors and sites, such as assisting in opening

studies. SCRI also sets monthly and yearly enrollment goals for CCBD based on their current contract.

SPECIFIC AIMS

The specific aims of the retrospective portion of this study are to identify how certain variables were related to enrollment and if changes in the past have significantly affected enrollment at CCBD. The following hypotheses are tested: 1) Enrollment increased as the number of research referrals increased; 2) Enrollment increased as more patients were screened for trial eligibility; 3) Enrollment increased as the number of staff involved in research increased; and 4) There was a difference in enrollment in the months before and after CCBD became a SCRI strategic site. An additional aim of this part of the study is to identify the main reasons referred patients did not enroll in CCT.

The specific aims of the survey portion of this study are: 1) To assess the opinions of CCBD healthcare providers on specific barriers to enrollment and strategies to increase enrollment, and 2) To determine if differences in responses between providers are related to the amount of experience that the providers have in research and oncology or hematology. The overall aim of this study is to be able to provide suggestions for CCBD and other community-based cancer clinics to overcome enrollment barriers. The results of this study may also be useful for academic cancer research centers or clinics conducting clinical trials for pathologies other than cancer.

SIGNIFICANCE

As previously stated, only 3% of adult cancer patients choose to enroll in CCT, and 55% of those patients are enrolled through community-based practices (Colon-Otero et al., 2008; Dobson et al., 2006). While the literature on the subject of barriers to enrollment in clinical trials is extensive, enrollment barriers cannot be generalized to all practice types. The research conducted on barriers to enrollment at non-academic investigative sites is limited, and there may be factors that are unique to individual practices that affect enrollment (Somkin et al., 2005). Identifying these factors through assessing barriers to enrollment and strategies to increase enrollment at CCBD should add to the current literature and allow recommendations to be made for similar practices to increase enrollment in the future.

In this aim, it is important to utilize the knowledge and opinions of the CCBD healthcare providers that typically enroll and interact with the research patients for several reasons. First, these healthcare providers directly discuss CCT participation with patients, and through this communication have knowledge about why patients typically decline participation or are ineligible. Second, providers have insight into their own reservations towards clinical trials and may have useful and valid opinions to share about why they choose not to enroll to particular studies or CCT in general. Third, healthcare providers currently employed at a community-based clinic such as CCBD can evaluate the research practices that are implemented by the site, such as

methods of pre-screening or screening patients for trial eligibility. In addition, many of these providers have completed training or have been employed at other cancer research clinics and large academic centers, and they may be able to make suggestions from their past experiences on ways to improve research practices at CCBD.

MATERIALS AND METHODS

Historical Data

In order to determine whether or not past changes at CCBD have made a significant impact on enrollment, data on research practices from the beginning of 2010 to the end of 2013 were collected and analyzed. These data include: the number of patients referred, screened, and enrolled each month; the number of clinicians involved in research; and the number of research staff employed. These historical data were collected from existing records and electronic databases kept by the CCBD research department. Statistical analyses were conducted in order to identify significant relationships between the variables listed previously. In addition, Mann-Whitney U tests were performed to compare patient enrollment before and after CCBD became one of SCRI's strategic sites. All data were entered and analyzed in SPSS Statistics 22.

Provider Survey

In order to identify and evaluate current barriers to enrollment and potential strategies to increase enrollment in the future at CCBD, a self-administered survey was designed to be answered by the CCBD healthcare providers involved in research. The items on the survey were divided into the categories of patient and community, physician or provider, and investigative site. The survey also included items inquiring about the participant's experience in research and oncology or hematology, and included a space for any additional comments (see Appendix A).

The items on the survey were chosen based on suggestions from CCBD healthcare providers, discussions with research staff, observations of CCBD research practices, and information from previous literature (Somkin et al., 2013; Denicoff et al., 2013).

A cover letter clearly explaining the purpose of the study and the rights of the subjects, should they choose to participate, was included with each survey and served as the informed consent for this study. The cover letter and four-page survey were mailed to each potential participant through the CCBD mail courier system, and each envelope contained a pre-labeled return envelope through which participants were asked to anonymously mail their responses back through the same courier system. If a survey was returned in the pre-labeled return envelope, then the participant was considered to have agreed to participate in the survey study. The surveys were assigned unique identification numbers and the answers were coded and entered into SPSS Statistics for analysis.

The four page survey included a total of 66 items grouped into four categories of interest with 21 items in the patient and community category, 23 items in the physician or provider category, 19 items in the investigative site category, and 3 items in the experience in research and oncology section. The survey items were primarily opinion statements that either addressed a barrier to enrollment or a strategy to improve enrollment and research practices at CCBD. Participants were asked to respond to each item as it applies to their practice and the CCBD clinic they primarily practice in. Participants were asked to respond to each statement by circling SD for strongly disagree, D for disagree, N for neutral or no opinion, A for agree, or SA for strongly agree.

In order to be considered for this study, potential participants had to meet several requirements. They had to be physicians, physician assistants (PA), nurse practitioners (NP), or

clinical research coordinators (CRC) that worked at one of the CCBD clinics at the time of this study. The healthcare providers can pre-screen patients and refer them for CCT, and most providers have the opportunity to treat patients enrolled in CCT. Information about the potential study participants and the clinic they primarily practiced in was obtained from the clinical research manager and the CCBD website (The Center for Cancer and Blood Disorders, 2013). Physicians were considered if they were listed as medical oncologists, hematologists, or gynecologic oncologists. The PAs and NPs associated with these physicians were also considered because they see the same patients, including research patients. Physicians were not considered if they were radiation oncologists, as these doctors do not offer patients the opportunity to enroll in CCT and may not always know if they are treating a research patient. All clinical research coordinators were considered for this study.

RESULTS AND DISCUSSION

Historical Data

In order to determine what factors have led to an increase or decrease in enrollment at CCBD in the past, enrollment data were collected and analyzed with respect to changes that have been made at CCBD from the beginning of 2010 to the end of 2013. These changes include the number of staff in the research department, the number of clinicians participating in research, and the association of CCBD with SCRI. If possible, associations between these variables and enrollment by month were analyzed by conducting statistical tests.

Why Patients Were Not Enrolled in CCT

First, it may be useful to look at the reasons why patients did not go on trial in the past in order to assess barriers to enrollment and areas that may be improved. That information is presented in Table 1, and represents the year of 2012 only due to the lack of available data for reasons patients were not enrolled in other years. For the year of 2012, electronic screening logs were used with each referral listing the reason the patient declined to enroll or was not eligible. These data include all referred patients that did not go on trial that year, whether they were only pre-screened or if they were screened for trial eligibility. In addition, most referrals were internal; that is, they came from CCBD physicians and not from physicians outside of the clinic. However, not all referrals came from physicians at CCBD research clinics.

Table 1

Reason Cited	Percentage
Prior cancer treatment excludes patient	23
Disease profile excludes patient	19
Other eligibility criteria exclude patient	16
Patient declined participation	16
Patient was non-English speaking	7
No reason given by patient or coordinator	5
Non-compliance with protocol timing	4
Study closed to enrollment	4
Insurance or financial issues	2
Patient did not want cancer treated	2
Patient was at nursing home	1
Study was not at patient's preferred site	1
Physician decided to treat off study	<1

Reasons Referred Patients Were Not Enrolled

Note: Percentage is out of the number of patients that were referred but did not enroll in 2012.

The main reasons cited for why patients were not enrolled were that the patient's prior cancer treatment (23%), disease profile (19%), and other eligibility criteria (16%) excluded the patient from trial eligibility. A patient's prior treatment history is a major part of the eligibility criteria in CCT. For example, some studies do not allow patients to enroll if they have received a certain chemotherapy drug in the past, or the study may actually require that a patient has previously received a specific cancer treatment to be considered eligible for that study. A patient's disease profile is also a major part of CCT eligibility criteria, and sometimes the full disease profile may not be clear until further tests have been performed during screening. For example, a tumor biopsy as part of the screening procedures may reveal more about the type of cancer a patient has and the therapy that the patient needs. However, known aspects of a patients disease profile may also simply be overlooked at the time of referral. Other eligibility criteria, outside of prior cancer treatment or the disease profile, may include the patient's age, general well-being, comorbidities, or factors such as the patient taking medications for comorbidities that would interfere with the study treatment.

The next two most often cited reasons for why patients were not enrolled were that the patient declined participation (16%) and that the patient was non-English speaking (7%). The reasons patients may decline CCT participation have been discussed previously. Non-English speaking patients cannot be enrolled in CCT at CCBD due to a lack of informed consent forms in languages other than English, study coordinators being unable to properly consent the patient, and physicians being unable to answer questions from the patient, especially in emergency situations.

These data may exemplify how strict inclusion and exclusion criteria in CCT can be major barriers to enrollment, although many are necessary for the sake of the patient's safety and the integrity of the study's results. In addition, this information may indicate that patients declining participation is possibly an enrollment barrier at CCBD, and that designing a way for non-English speaking patients to have access to CCT could increase enrollment.

Factors Related to Enrollment

Data were collected for the following factors related to research and enrollment at CCBD from 2012 through 2013 by month: the number of patients referred, screened, and enrolled; the number of research clinicians and research staff employed; the number of research sites; and the number of open studies. However, data on the number of CCBD research sites and the number of open studies were not analyzed. The only change to the number of research sites since 2010 happened very recently, and therefore there was not enough information to conduct any meaningful analyses. The only information available about many of the studies at CCBD is the site activation date, which is the date the study became open to enrollment at CCBD, and the date of the last enrollment from CCBD. However, counting the number of open studies using this

information excluded studies that were open but did not enroll patients. In addition, the date of the last enrollment is not always representative of the date the study closed at CCBD.

For the number of patients referred, patients screened, research clinicians, and research staff, linear regression analyses could not be conducted due to the high correlation between variables that predict enrollment. In addition, Pearson's correlation could not be calculated because the number of clinicians, research staff, screened patients, and enrolled patients by month were not normally distributed as assessed by Shapiro-Wilk's tests (p < .05). Therefore, Spearman's rank-order correlations were calculated instead of Pearson's product-moment correlations. The calculated Spearman's rho coefficients are shown in the correlation matrix in Table 2. Only data from 2012 through 2013 were analyzed because these are the most recent data available, reliable information about the number of patients referred and screened by month is not available before 2012, and this helps avoid the confounding factor of the association of CCBD and SCRI which began in 2011.

Table 2

	Enrolled	Screened	Referred	<u>Clinicians</u>	Research Staff
Enrolled					
Screened	.694**				
Referred	.469*	.666**			
Clinicians	.023	163	182		
Research Staff	287	373	382	.596**	

Note: * Correlation is significant at the 0.05 level (2-tailed). ** Correlation is significant at the 0.01 level (2-tailed).

Patients must be referred for research studies and then screened for eligibility before they can be enrolled in CCT. Therefore, it is not surprising that there was a significant, positive correlation between the number of patients screened for eligibility per month and the number of patients enrolled per month from the beginning of 2012 through 2013, r_s (22) = .694, p < .01. There was also a significant positive correlation between the number of patients referred for research studies and the number of patients enrolled, r_s (22) = .469, p < .05. The number of patients referred and the number of patients screened were also positively related, r_s (22) = .666, p < .01.

However, the number of staff involved in research was not significantly correlated with monthly enrollment, screening, or referrals. The number of clinicians involved in research included physicians, physician assistants, and nurse practitioners that were principal investigators or sub-investigators. This number was only significantly correlated with the number of staff in the research department, which included study coordinators, regulatory coordinators, and data managers, r_s (22) = .596, p < .01. These results, in addition to the weak, negative trends between the number of staff and enrollment, screening, and referrals, may have been due to a rise in the number of staff at CCBD with a slight decrease in factors associated with enrollment. This may especially be the case for the increase in the number of research department staff due to an increase in CCT complexity, number of procedures, and visits required in past years (Good, Lubejko, Humphriese & Medders, 2013). These additional regulatory burdens increase the amount of work per patient, which may have resulted in the need to hire additional staff to handle the workload and a reduction in the number of research patients the department can handle at one time (Good et al., 2013).

SCRI and Enrollment

In order to determine whether or not there was a significant difference in enrollment between the months before and the months after CCBD became one of SCRI's strategic sites, monthly enrollment data were collected from the beginning of 2010 through 2013 and analyzed. There were two dates of interest examined in these analyses: the date of the first contract between CCBD and SCRI, which occurred in July 2011, and the date the first patient was enrolled onto a study opened by SCRI and CCBD, which occurred in January 2012.

When using the date of the first contract as the cutoff for the time periods determined to be pre-SCRI and post-SCRI, there was homogeneity of variances for enrollment in these two groups as assessed by Levene's test for equality of variances (p = .193). However, there were three outliers in the data that were confirmed to not be data entry errors, as seen in the boxplot in Figure 1, and monthly enrollment was not found to be normally distributed as assessed by Shapiro-Wilk's test (p < .05). Due to the violation of these parametric assumptions, a Mann-Whitney U test was conducted instead of a t-test because it is less sensitive to outliers and does not require normally distributed data. The test found that the median enrollment was not significantly different between the months before the first SCRI contract (median = 3.00, mean rank = 20.56, n = 18) and the months after (median = 4.00, mean rank = 26.87, n = 30), U =341.0, z = 1.528, p = .126.

When using the date of the first enrollment to a study opened by SCRI as the cutoff between the pre-SCRI and post-SCRI groups, there was again homogeneity of variances for enrollment as assessed by Levene's test for equality of variances (p = .275). There were again three outliers in the data that can be seen in Figure 1, and monthly enrollment was not found to be normally distributed as assessed by Shapiro-Wilk's test (p < .05). Due to the violation of these parametric assumptions, a Mann-Whitney U test was conducted. The Mann-Whitney U test showed that distributions of monthly enrollment were similar for the pre-SCRI and post-SCRI months. In addition, the test found median enrollment to be significantly different between the pre-SCRI months (median = 2.50, mean rank = 18.77, n = 24, n = 24) and post-SCRI months (median = 4.00, mean rank = 30.23), U = 425.5, z = 2.866, p = .004. Therefore, the median monthly enrollment was higher after CCBD began enrolling patients on SCRI studies, but not after the first contract with SCRI.



Figure 1. Boxplot of monthly enrollment for pre-SCRI and post-SCRI months. The outliers are the same whether the designation of pre-SCRI and post-SCRI months is determined by the date of the first contract or first enrollment. Data points that are more than 1.5 box-lengths from the edge of their box are indicated by the circular dots. The numbers next to these dots indicate which data entry they refer to.

The discrepancy in results may be due to delays in the effects of the contract actually taking place. The first study opened by SCRI at CCBD was not activated until late in 2011, and the first patient was not enrolled until early 2012. In addition, it may have taken several months for some regulatory tasks to be taken over by SCRI, only later allowing the CCBD research staff

to focus on other tasks such as enrolling patients. For a community-based oncology practice that is not affiliated with a larger institution, a contract research organization (CRO) or SMO like SCRI may be able to help improve enrollment. This could be through assisting the site with patient recruitment, increasing the number of studies available at the site, or providing a way for the site to increase enrollment without significantly increasing the regulatory burdens that may otherwise limit enrollment.

Provider Survey

Of the 23 surveys that were mailed to CCBD healthcare providers, 17 were received back resulting in a response rate of 74%. The responses to the survey items are shown in Tables 1-10. Due to the small sample size of this study, the responses of Strongly Disagree and Disagree were combined into a single Disagree category with the reasoning that participants that chose either of these responses disagreed with the survey item to some extent. Similarly, the responses of Strongly Agree and Agree were combined into a single Agree category. The responses in Tables 4-12 are presented under columns D, N, and A, for Disagree, Neutral or No opinion, and Agree, respectively. If a participant did not answer a survey item, then the number of total responses for that specific item is identified in the table note. In addition, if there are fewer than 17 responses for a survey item, then the percent reported is out of the total responses to that individual item.

The results of the survey are presented below by category. The larger categories of *Patient and Community, Physician or Provider*, and *Investigative Site* in the survey can be further separated by nine areas of interest, with three areas in each category. The areas of interest in the *Patient and Community* category are (1) patient knowledge and fear of clinical trials, (2) patient awareness of the availability of clinical trials, and (3) community outreach. The three

areas of interest in the *Physician or Provider* category are (4) clinical trials as a treatment option, (5) motivation to enroll patients, and (6) provider knowledge and awareness of open trials. The final three areas of interest in the category of *Investigative Site* are (7) methods of identifying potential research patients, (8) the use of Pathways to pre-screen patients, and (9) clinic staff and attitude towards research.

Additionally, in order to determine whether or not survey responses were associated with the participants' years of experience at CCBD or in research and oncology, tests of statistical significance were conducted between responses to the survey items in the *Experience in Research and Oncology* category and the participants' responses to items in the other three categories. Fisher's exact test was chosen for these analyses because of the small sample size in this study and because all data can be considered categorical. However, no significant relationships were found.

Experience in Research and Oncology

The responses to the three survey items addressing the participant's experience in research and oncology or hematology can be seen in Table 3. Most participants reported having several years of experience in clinical research, with 65% of participants having 6 or more years of experience and 35% reporting 5 or fewer years of experience. Participants varied in their number of years of oncology or hematology experience, with 41% having 5 or less years of experience and 59% of participants having 6 or more years of experience. Finally, the majority of participants reported having a lower number of years of research involvement at CCBD, with 65% of participants having 5 or fewer years of experience and only 35% having 6 or greater years of involvement.

Table 3

Experience in Research and Oncology or Hematology

Survey Item	<u>0-5</u>	<u>6-10</u>	<u>11-15</u>	<u>15+</u>	
How many years have you been involved in clinical	6	3	6	2	
research?	(35)	(18)	(35)	(12)	
How many years of oncology or hematology	7	1	5	4	
experience do you have?	(41)	(6)	(29)	(24)	
How many years have you been actively involved in	11	4	1	1	
research at CCBD?	(65)	(24)	(6)	(6)	

Note: The response choices of 0-5, 6-10, 11-15, and 15+ are in years. The frequency of responses are shown with the percentage of responses in parentheses. Due to rounding the responses for some items total more than 100%.

Patient and Community

Patient knowledge and fear of clinical trials. The responses to the items related to patient knowledge and fear of clinical trials can be seen in Table 4. This area of interest contains 12 items, with 5 items related to potential barriers to enrollment at CCBD and 7 items addressing strategies to increase enrollment.

The results of this survey show that only 47% of participating CCBD healthcare providers felt that their patients understand the importance of cancer research and participating in clinical trials. In addition, 88% of participants agreed that healthcare providers should take the time to explain to patients why clinical trials are worth enrolling in, and 77% felt that education materials about research and participating in clinical trials should be included in the patient notebooks that new patients receive at CCBD. Previous studies on participation in CCT have shown that the leading factors that positively influence a patient's decision to enroll are the desire to improve cancer care and the advice of their physician (Byrne et al., 2013; Jenkins & Fallowfield, 2000). Therefore, it may be helpful to provide more information to patients at CCBD through conversations with their healthcare provider and written information in their new patient notebooks about the various benefits of enrolling in CCT, including the potential benefit to future cancer patients.

Only 13% of participants agreed that eligible patients usually decline to participate in studies that they are offered. Eighty-two percent of CCBD healthcare providers felt that providers should record why a patient declined participation in a trial or why that patient was not eligible. If the reasons patients refused CCT were recorded accurately, this would allow the major barriers to enrollment in terms of patient refusal to be documented for future improvements, as well as information about the appropriateness of trial eligibility criteria for CCBD's patient population.

Fifty-nine percent of survey participants felt that patients do not understand the concept of placebos or control arms in a clinical trial setting, while only 12% disagreed. In addition, 88% of participants agreed that providers should take the time to carefully explain what the placebo or control arm is in a study and how it compares to standard of care. Previous studies have shown that many patients have a dislike or fear of being given a placebo in a clinical trial, and that misconceptions about placebos in CCT are often a reason patients choose not to participate (Mills et al., 2006; Comis, Miller, Aldige, Krebs & Stoval, 2003; Comis et al., 2000). Improved communication between providers and their patients and an effort to educate patients may be an effective way to overcome fears and misconceptions about the use of placebos in clinical trials. For example, providers may need to overcome the misconception that receiving placebo means that a patient is not receiving any treatment, and should explain to patients that most studies provide standard of care treatment regardless of which study arm the patient is randomized to.

Table 4

Patient Knowledge and Fear of Participating in Clinical Trials			
Survey Item	\underline{D}	N	$\underline{\underline{A}}$
My patients understand the importance of cancer research and	$\begin{pmatrix} 0 \\ (0) \end{pmatrix}$	9 (52)	8
participating in chinical utais.	(0)	(33)	(47)
Healthcare providers should take the time to explain to patients why	0	2	15
clinical trials are worth enrolling in.	(0)	(12)	(88)
	0	4	10
should be included in the patient notebooks that new patients receive at	$\begin{pmatrix} 0 \\ (0) \end{pmatrix}$	(24)	(77)
CCBD.	(0)	(24)	(n)
Eligible patients usually decline to participate in studies that I offer	9	5	2
them.*	(56)	(31)	(13)
Providers should record why a patient has declined participation in a	2	1	14
clinical trial or why the patient was not eligible.	(12)	(6)	(82)
	~ /		~ /
Patients do not understand the concept of placebos or control arms in a	2	5	10
clinical trial setting.	(12)	(29)	(59)
Healthcare providers should take the time to carefully explain what the	0	2	15
placebo or control arm is in a study and how it compares to standard of	(0)	(12)	(88)
care.			
Mana a farma di anta farma ha anni a sa "anni ana ais" and da ant tarat	4	2	0
Many of my patients fear becoming a guinea pig and do not trust clinical trials *	(25)	(19)	9 (56)
chinear thats.	(23)	(1))	(50)
Healthcare providers, patient navigators, and patient coordinators	0	2	15
should spend more time discussing clinical trials with patients in order	(0)	(12)	(88)
to alleviate their fears of participating.			
Current or previous research patients should be allowed to volunteer as	4	3	10
peer mentors for patients going on trial and offer additional support.	(24)	(18)	(59)
	~ /		
My patients often have concerns about the financial requirements of	3	6	8
participating in a study.	(18)	(35)	(47)
Financial counselors should better explain to patients what is and is not	0	2	15
covered on a research trial and what reimbursements may be available.	(0)	(12)	(88)
<i>Note</i> . The frequency of responses are shown with the percentage of respo	nses in r	arenthes	ses

Patient Knowledge and Fear of Participating in Clinical Trials

Note: The frequency of responses are shown with the percentage of responses in parentheses. Items with asterisks were only answered by 16 participants, while all other items had 17 total responses. Due to rounding the responses for some items total more than 100%. Fifty-six percent of participating CCBD healthcare providers agreed with the statement that many of their patients fear becoming a "guinea pig" and do not trust clinical trials. A previous study found that 59% of physicians perceived fear of being treated like a "guinea pig" to be a major reason patients decline CCT participation, while only 22% of patients actually cited fear as a major reason for refusing to enroll (Comis et al., 2000). There may also be a similar disparity at CCBD between the beliefs of physicians and patients, where physicians believe that fear of becoming a "guinea pig" is a greater barrier to enrollment than it actually is. However, efforts should still be made in order to reduce patient fear of CCT. Eighty-eight percent of CCBD healthcare providers agreed that healthcare providers, patient navigators, and patient coordinators should spend more time discussing clinical trials with their patients in order to alleviate their fears of participating. Fifty-nine percent agreed that current or previous research patients should be allowed to volunteer as peer mentors for patients going on trial and offer additional support.

Finally, 47% of participating CCBD healthcare providers agreed that their patients often have concerns about the financial requirements of participating in a study, and 88% agreed that financial counselors should better explain to patients what is and is not covered on a research trial and what reimbursements may be available. In a previous study examining barriers to enrollment from the perspective of cancer patients, it was found that 85% of patients had the concern that insurance would not cover the cost associated with additional tests or treatments that might arise from participation (Byrne et al., 2013). However, 79% of patients who enroll in CCT get insurance coverage for cancer treatment, and starting in 2014 new health insurance plans in the U.S. cover the routine care costs of people taking part in clinical trials (Comis et al., 2000; American Cancer Society, 2014). Better explanations of the insurance coverage for specific

research trials to patients may help alleviate some unnecessary fears of enrolling in CCT and subsequently increase enrollment.

Patient awareness of the availability of clinical trials. The responses to the items

related to patient awareness of the availability of clinical trials can be seen in Table 5. This area

of interest contains 4 items, with 1 item being a potential barrier to enrollment at CCBD and 3

items being potential strategies to increase enrollment and improve research practices.

Table 5

Patient Awareness of the Availability of Clinical Trials				
Survey Item	D	N	A	
Most of my patients know that clinical trials are available at CCBD.	2	8	7	
	(12)	(47)	(41)	
Research patient testimonials should be included on the CCBD website	1	4	12	
to increase patient interest in research.	(6)	(24)	(71)	
The CCBD website should have an easy to locate and understand page	0	1	16	
of the clinical trials currently available for patients to view.	(0)	(6)	(94)	
A search engine on the CCBD website that would allow patients to	3	3	11	
input their disease profile and identify a clinical trial they might be eligible for would spark more interest in research from patients	(18)	(18)	(65)	

Note: The frequency of responses are shown with the percentage of responses in parentheses. Due to rounding the responses for some items total more than 100%.

Only 41% of participating CCBD healthcare providers agreed that most of their patients know that clinical trials are available at CCBD, while 47% of participants felt neutral or had no opinion on the statement and 12% disagreed. Seventy-one percent of participants agreed that research patient testimonials should be included on the CCBD website to increase patient interest in research, and 94% felt that the website should have an easy to locate and understand page of the clinical trials currently available for patients to view. In addition, 65% said that a search engine on the CCBD website that would allow patients to input their disease profile and identify a clinical trial they might be eligible for would spark more interest in research from patients.

If implemented at CCBD, these media techniques may be effective in increasing patient awareness, interest, and enrollment. Low CCT enrollment rates are partly due to a lack of knowledge about what clinical trials are or awareness that clinical trials are available (American Society of Clinical Oncology, 2009). Online information about clinical trials such as text or videos can improve patient knowledge and attitude towards CCT, and in today's world of technology, media techniques such as utilizing clinical trial websites can be effective in recruiting patients (Meropol et al., 2013; Korde et al., 2009).

Community outreach. The responses to the items related to community outreach can be seen in Table 6. This area of interest contains 5 items, with 2 items addressing barriers to enrollment at CCBD and 3 items related to potential strategies to increase enrollment.

Table 6

Community	Outreach
Community	Ouneuch

Community Our each			
Survey Item	D	N	A
There is a lack of community outreach about the availability of clinical	0	4	13
trials at CCBD.	(0)	(24)	(77)
CCBD should advertise clinical trials to the general public in order to	3	5	9
increase enrollment.	(18)	(29)	(53)
Physicians out in the community often refer patients to CCBD for	12	5	0
clinical trials.	(71)	(29)	(0)
The research department or study PI should send a letter to surgeons	0	2	15
and referring physicians about the trials available at CCBD.	(0)	(12)	(88)
Physicians should present research patient cases at tumor boards to	0	5	12
increase community knowledge of clinical trials.	(0)	(29)	(71)

Note: The frequency of responses are shown with the percentage of responses in parentheses. Due to rounding the responses for some items total more than 100%.

Seventy-seven percent of survey participants agreed that there is a lack of community outreach about the availability of clinical trials at CCBD. Fifty-three percent felt that CCBD should advertise clinical trials to the general public in order to increase enrollment, while 29%
had no opinion and 18% disagreed. Successful, low-cost methods of reaching out to the public may include news articles, written advertisements, and recruitment mailings, which can yield enrollment rates of 56%, 23%, and 10%, respectively, out of people who inquire about the study (Korde et al., 2009). Implementing similar advertising strategies may also prove effective at CCBD, although recruitment materials will have to be approved by the central institutional review board (IRB) used by CCBD and SCRI. Advertising through social networking sites in order to increase awareness and enrollment may also be effective, especially in clinical trials studying rare diseases (Tweet, Gulati, Aase, & Hayes, 2011).

Seventy-one percent of CCBD healthcare providers did not feel that physicians out in the community often refer patients to CCBD for clinical trials. This is a barrier to enrollment, as 98% of primary care physicians refer patients to oncologists without bringing up the topic of CCT, 41% of physicians cite preferring to leave the discussion of CCT to the oncologist, and 37% are unaware of any CCT that may be available for their patients (Crosson et al., 2001).

In terms of reaching out to physicians in the community, 88% of CCBD healthcare providers felt that the research department or study PI should send a letter to surgeons and referring physicians about the trials available at CCBD. In addition, 71% agreed that physicians should present research patient cases at tumor boards to increase community knowledge of clinical trials. Improving communication with referring primary care physicians through these methods could increase their knowledge of CCT and their comfort with discussing trial participation with their patients, subsequently increasing patient knowledge and awareness and potentially increasing enrollment (Crosson et al., 2001).

Physician or Provider

Clinical trials as a treatment option. The responses to the items related to clinical trials as a treatment option can be seen in Table 7. This area of interest contains 8 items, with 5 items addressing barriers to enrollment at CCBD and 3 items addressing potential strategies to increase enrollment.

Table 7

Clinical 2	Trials	as a	a Treat	tment (Option
------------	--------	------	---------	---------	--------

1			
Survey Item	D	Ν	А
Sometimes I do not enroll patients on a study if I believe it offers	2	3	11
substandard care.	(13)	(19)	(69)
When evaluating a study protocol, the PI should ensure that the study	0	1	15
treatments are up to date with current treatment practices.	(0)	(6)	(94)
I consider clinical trials to be the best treatment option for my patients.	2	8	6
	(13)	(50)	(38)
Clinical trials should be the first treatment option on Pathways.	4	2	10
	(25)	(13)	(63)
Patients should only be on clinical trials if there is no other treatment	14	1	1
option.	(88)	(6)	(6)
	_		-
I generally do not offer trials to patients who will do well on standard	1	4	5
therapy.	(44)	(25)	(31)
	7	(2
I do not discuss clinical trials with patients that I believe would not	(17)	6 (10)	2
enroll.*	(47)	(40)	(13)
All notantially aligible nations should be approached about the artist	2	2	10
An potentiary engible patients should be approached about the option	3 (10)	3 (10)	10
of participating in a trial.	(19)	(19)	(63)
<i>Note:</i> The frequency of responses are shown with the percentage of responses	onses in p	barenthes	ses.

Note: The frequency of responses are shown with the percentage of responses in parentheses Items with asterisks were answered by 15 participants, while all other items had 16 total responses. Due to rounding the responses for some items total more than 100%.

Sixty-nine percent of survey participants stated that they sometimes do not enroll patients

on a study if they believe it offers substandard care, and 94% believe that the principal

investigator should ensure that the study treatments are up to date with current treatment

practices when evaluating a study protocol. Only 38% of participants considered clinical trials to be the best treatment option for their patients, while 50% had no opinion. However, in most CCT the treatments being tested are at least as effective as the current standard of care and may be better than the current standard (National Cancer Institute, 2013). If the study drug was not effective at all then it does not make it to human clinical trial testing. If a standard therapy exists, both the study drug and placebo are given in addition to standard therapy (National Cancer Institute, 2013). This is done for ethical reasons so that patients that enroll in clinical trials do not receive substandard treatment or no treatment. This is also done in order to demonstrate that the study drug improves or is more effective than the current standard treatment alone (Mesothelioma Research Foundation of America, 2014).

While only 6% of survey participants agreed with the statement that patients should only be on clinical trials if there is no other treatment option, 31% of CCBD providers said they generally do not offer trials to patients who will do well on standard therapy. Unsurprisingly, a previous study found that physicians who do not offer CCT to patients who would do well on standard therapy have lower enrollment rates than physicians who do offer CCT to those patients (Somkin et al., 2013). In addition, 13% of CCBD providers stated that they do not discuss clinical trials with patients they believe would not enroll. Only 63% of survey participants agreed that all potentially eligible patients should be approached about the option of participating in a trial, and only 63% of participants agreed that clinical trials should be the first treatment option on Pathways.

Previous studies have found that most people would consider enrolling in CCT if given the option; approximately 32% of adults in the general public would be very willing to participant in CCT if given the option, and 38% would consider participating but would have

some reservations (Comis et al., 2003). While only 3% of cancer survivors have participated in CCT, only 9% were even aware that trials were a treatment option at the time of their most recent diagnosis. In addition, 65% of the cancer survivors who did not know about CCT state that they would have been receptive to enrollment if they had known it was a possibility (Comis et al., 2009). Participation in CCT by cancer patients is directly related to the level of physician encouragement to enroll and effort to educate the patient about CCT (Comis et al., 2009).

The results from the current study and past studies may indicate that a major barrier to enrollment at CCBD and other cancer clinics is a lack of encouragement and communication between physicians and patients. If CCBD healthcare providers begin encouraging and educating all potentially eligible patients about the opportunity to participate in a clinical trial, regardless of whether they would do well on standard therapy or if the provider believes they will not enroll, enrollment rates may improve.

Motivation to enroll patients. The responses to the items related motivation to enroll patients can be seen in Table 8. This area of interest contains 8 items, with 4 items addressing barriers to enrollment at CCBD and 4 items related to potential strategies to improve enrollment and research practices.

Sixty-nine percent of survey participants disagreed with the statement that the amount of time and effort involved with having a patient on a research study deters them from enrolling. Fifty-six percent agreed that electronic methods of signing documents and assessing lab values would save them time, while 38% had no opinion and 6% disagreed. Although only 6% of participants felt deterred from enrolling patients due to potential protocol deviations that are out of their control, 69% agreed that CCBD needs to implement standard operating procedures and working practice guidelines that hold staff responsible for their delegated research tasks. CCBD

healthcare providers do not seem deterred by the amount of time and effort involved in having a patient on a CCT or potential protocol deviations that may be outside of their control. However, further utilizing computer technology and implementing procedures and guidelines at CCBD may be useful in saving time for providers involved in research and improving research practices.

Table 8

Motivation i	to Enroll	Patients
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Survey Item	D	N	A
The amount of time and effort involved with having a patient on a	11	4	1
research study deters me from enrolling.	(69)	(25)	(6)
			_
Electronic methods of signing documents and assessing lab values as	1	6	9
clinically significant or not clinically significant would save me time.	(6)	(38)	(56)
	2	1	12
am motivated to enroll patients in clinical trials.	(12)		(01)
	(13)	(6)	(81)
Healthy competition between providers through acknowledgement or	5	4	7
incentives for enrolling providers would motivate me to increase	(31)	(25)	(AA)
enrollment	(51)	(23)	(++)
enforment.			
I feel deterred from enrolling patients due to potential protocol	7	8	1
deviations that are out of my control.	(44)	(50)	(6)
CCBD needs to implement standard operating procedures and working	2	3	11
practice guidelines that hold staff responsible for their delegated	(13)	(19)	(69)
research tasks.			
I do not enroll patients in studies if they need to start treatment as soon	4	6	6
as possible.	(25)	(38)	(38)
CCBD and SCRI should develop a more streamlined process to get	0	5	11
nation patients enrolled and treatment started right away	(0)	(31)	(69)
putients enforced and deatment started right urray.	(-)	. ,	
<i>Note:</i> The frequency of responses are shown with the percentage of respo	onses in p	parenthes	ses. All

survey items had a total of 16 responses. Due to rounding the responses for some items total more than 100%.

In order to motivate providers to enroll patients in CCT, a recent cancer trial symposium

recommended providing incentives for providers that participate in research, such as protected

time, administrative support, training, or participation in professional meetings in order to increase enrollment (Denicoff et al., 2013). However, CCBD healthcare providers are divided on whether or not providing incentives for enrolling clinicians would be a good practice at CCBD. Only 13% of CCBD healthcare providers said they are not motivated to enroll patients in clinical trials. While 44% agreed that healthy competition between providers through acknowledgement or incentives for enrolling providers would motivate them to increase enrollment, 31% disagreed and 25% had no opinion. These results may be due to several factors. Some CCBD healthcare providers may not be motivated by acknowledgement or incentives, or some providers may feel that it is unfair that they do not have the opportunity to heavily participate in research. Not all of CCBD's campuses have access to clinical trials, and CCBD tends to have many studies available for some types of cancer but few if any for others. This may cause a disparity in how many potentially eligible patients a provider sees and is able to enroll.

Finally, while only 38% of participating CCBD providers agreed that they do not enroll patients in studies if they need to start treatment as soon as possible, 69% of participants agreed that CCBD and SCRI should develop a more streamlined process to get patients enrolled and treatment started right away. Studies have shown that for both academic and community-based cancer research sites, sites that accrue more patients tend to have more CCT open and have faster turnaround times for IRB approval and study opening (Zaren et al., 2012; Wang-Gillam et al., 2010). Developing a way to open studies, enroll patients, and have treatment started quickly may be a way to increase enrollment at CCBD.

Provider knowledge and awareness of open trials. The responses to the items relating to provider knowledge and awareness of open trials can be seen in Table 9. This area of interest

contains 7 items, with 3 items addressing barriers to enrollment at CCBD and 4 items related to potential strategies to improve enrollment and research practices.

While 56% of participants stated that they are aware how most study treatments are an improvement on current medical practices, 75% agreed that SCRI and the CCBD research department should emphasize how a study treatment may be better than standard of care to enrolling physicians and potential research patients. Establishing the legitimacy and importance of studies to healthcare providers can increase enthusiasm for trials, and this may be an area of improvement that could increase both provider and patient interest in CCT (Roll et al., 2013).

Table 9

Trovider Knowledge and Awareness of Open Trials			
Survey Item	D	N	A
I am aware how most study treatments are an improvement on current	2	5	9
medical practices.	(13)	(31)	(56)
SCRI and the CCBD research department should emphasize how a	0	4	12
study treatment may be better than standard of care to enrolling physicians and potential research patients.	(0)	(25)	(75)
I am kept adequately up to date about open clinical trials at CCBD	5	4	7
	(31)	(25)	(44)
Monthly email reminders from the research department listing what	1	2	13
trials are open would be useful to me.	(6)	(13)	(81)
Having a frequently updated list of open studies in my office and	1	1	14
each exam room to reference is or would be useful to me.	(6)	(6)	(88)
I am aware of the inclusion and exclusion criteria of the studies that	5	5	6
are most relevant to my practice.	(31)	(31)	(38)
I would like to have index cards for each study that I can keep in my	5	3	8
office or take into exam rooms that list the study name, mechanism of	(31)	(19)	(50)
action of the study drug, and inclusion/exclusion criteria.			

Provider Knowledge and Awareness of Open Trials

Note: The frequency of responses are shown with the percentage of responses in parentheses. All survey items had a total of 16 responses.

Only 44% of survey participants agreed with the statement that they are kept adequately up to date about open clinical trials at CCBD, and 81% agreed that monthly email reminders from the research department listing what trials are open would be useful to them. In addition, 88% stated that having a frequently updated list of open studies in their office and each exam room to reference would be useful to them. Even though several CCBD healthcare providers may feel adequately aware and up to date about open trials, sending email reminders or providing updated lists of open trials to all providers may be an effective strategy to increase enrollment, as oncologists' level of awareness of open trials is positively associated with the number of patients those physicians enroll (Somkin et al., 2013).

Finally, only 38% of participants stated that they are aware of the inclusion and exclusion criteria of the studies that are most relevant to their practice, while 31% disagreed and 31% had no opinion. Fifty percent agreed that they would like to have index cards for each study that they can keep in their office or take into exam rooms that list the study name, mechanism of action of the study drug, and inclusion/exclusion criteria, and 31% disagreed. Pocket-sized protocols and flash cards listing inclusion and exclusion criteria for studies provided by the study sponsor can help oncologists prescreen and enroll patients for these studies (Mills, 2008). If the CCBD research department creates and provides similar materials for their healthcare providers, provider awareness of study criteria may increase and assist providers in identifying eligible patients. However, not all CCBD providers may find this useful, and creating these materials may be time consuming for the research staff.

Investigative Site

Methods of identifying potential research patients. The responses to the items related

to methods of identifying potential research patients can be seen in Table 10. This area of interest contains 7 items, with 3 items addressing barriers to enrollment at CCBD and 4 items related to potential strategies to increase enrollment.

Table 10

Methods of	Identifying	Potential	Research	Patients
------------	-------------	-----------	----------	----------

Survey Item	D	N	Α
Patients are often screened or enrolled in studies that they are actually	8	$\frac{1}{4}$	$\frac{II}{A}$
inaligible for	(50)	(25)	(25)
lifeligible for.	(30)	(23)	(23)
To prevent supposed and according to a condition of the	n	5	0
To prevent unnecessary screening, research coordinators and	(12)	$\mathbf{\tilde{c}}$	9
physicians should work to perform a double review of patient	(13)	(31)	(56)
eligibility.			
Comment mostly de fan mer commine motion to at CCDD and in efficient an	2	7	ſ
Current methods for pre-screening patients at CCBD are inefficient or	3		6
inadequate.	(19)	(44)	(38)
Patient accordinators and nations newspaters should play a rale in	2	C	11
i loutificine metantial management metionte	(10)	(12)	(0)
identifying potential research patients.	(19)	(13)	(69)
Patient registries or electronic databases should be kent to keen track of	0	6	10
CCDD patients and pre-screen them for studies	(0)	(28)	(62)
CCBD patients and pre-screen them for studies.	(0)	(38)	(03)
Most of the time the eligibility criteria of studies at CCBD are	2	6	8
wost of the time the englotinty effective of studies at CCDD are	(12)	(20)	(50)
appropriate for the patient population.	(12)	(38)	(30)
CCBD should utilize available site data and screening logs to verify	0	3	13
that nations populations are available for trials before opening them	(0)	(10)	(91)
that patient populations are available for trials before opening them.	(0)	(19)	(01)

Note: The frequency of responses are shown with the percentage of responses in parentheses. All survey items had a total of 16 responses. Due to rounding the responses for some items total more than 100%.

Only 25% of participants felt that patients are often screened or enrolled in studies that

they are actually ineligible for, while 50% disagreed. Fifty-six percent felt that research

coordinators and physicians should work to perform a double review of patient eligibility to

prevent unnecessary screening. Performing a double review of patient eligibility may help reduce

the amount of time spent on consenting, screening, and enrolling patients by clinicians and study coordinators at CCBD. However, performing double review of patients would be time-consuming in itself and may not increase enrollment significantly.

Thirty-eight percent of participants agreed that current methods for pre-screening patients at CCBD are inefficient or inadequate. Sixty-nine percent believed that new patient coordinators and patient navigators should play a role in identifying potential research patients. Having other members of the staff pre-screen patients may help increase enrollment through the identification of eligible patients that the clinician may have missed (Chen, Grant, Cheung, & Kennecke, 2013). In addition, 63% of survey participants felt that patient registries or electronic databases should be kept to keep track of CCBD patients and pre-screen them for studies.

Fifty percent of participants agreed that most of the time the eligibility criteria of studies at CCBD are appropriate for the patient population, and only 12% disagreed. However, 81% said that CCBD should utilize available site data and screening logs to verify that patient populations are available for trials before opening them. Gathering information on patient population seen at CCBD and the most common reasons patients are not eligible for CCT may help the site avoid opening trials that are not the best fit. These strategies can also help in identifying types of patients or cancers that are typically seen at the site, but that the site does not have trials available for (Denicoff et al., 2013).

The use of Pathways to pre-screen patients. The responses to the items related to the use of Pathways can be seen in Table 11. This area of interest contains 4 items, with 2 items addressing barriers to enrollment and 2 items related to potential strategies to increase enrollment and improve research practices at CCBD.

Table 11

The	Use	of F	Pathwavs	to P	re-Scr	een F	<i>atients</i>
1110	000	<i>v</i> , <i>i</i>	<i>cutturi cuy c</i>			00111	000000000

Survey Item	D	N	A	
The use of Pathways is an effective method for pre-screening patients	3	4	9	
for eligibility.	(19)	(25)	(56)	
Study treatments need to be uploaded on Pathways as soon as	0	1	15	
possible and placed appropriately in the system.	(0)	(6)	(94)	
Pathways does not contain all the inclusion and exclusion criteria	0	6	10	
necessary to recommend a trial to a patient.	(0)	(38)	(63)	
Additional information should be included for study treatments	0	4	12	
placed in Pathways to make Pathways an effective way to pre-screen patients	(0)	(25)	(75)	

Note: The frequency of responses are shown with the percentage of responses in parentheses. All survey items had a total of 16 responses. Due to rounding the responses for some items total more than 100%.

Fifty-six percent of survey participants agreed that the use of Pathways is an effective method for pre-screening patients for eligibility, and 19% disagreed. However, 94% of participants agreed that study treatments need to be uploaded on Pathways as soon as possible and placed appropriately in the system. Sixty-three percent of participants agreed with the statement that Pathways does not contain all the inclusion and exclusion criteria necessary to recommend a trial to a patient, and 75% believe that additional information should be included for study treatments placed in Pathways to make Pathways an effective way to pre-screen patients.

While the majority of participants agreed that Pathways is an effective method for prescreening patients, the most participants also felt that the use of Pathways for research purposes could be improved. Providers may not be aware that a trial is available for their patients if it is not in Pathways, and it may be difficult to suggest a CCT to a patient during a visit if not all inclusion and exclusion criteria or additional information is included in Pathways. This is an area of improvement that could potentially increase enrollment at CCBD through increasing provider awareness and opportunities to offer CCT participant to patients.

Clinic staff and attitude towards research. The responses to the items related to clinic staff and attitude towards research can be seen in Table 12. This area of interest contains 8 items, with 4 items addressing barriers to enrollment and 4 items related to potential strategies to

improve research practices at CCBD.

Table 12

Clinic Staff and Attitude Towards Research			
Survey Item	D	N	A
More research staff is needed at the different CCBD campuses.*	1	6	8
	(7)	(40)	(53)
CCBD should hire additional research staff in order to cover	1	6	9
additional campuses.	(6)	(38)	(56)
There is a lack of research knowledge and training for staff that are	1	4	11
not directly involved in research.	(6)	(25)	(69)
All staff at CCBD should receive some level of research training or	3	1	12
education.	(19)	(6)	(75)
There is a lack of communication and support between CCBD staff	2	7	7
participating in research and staff that is not directly involved.	(13)	(44)	(44)
Events should be held by CCBD to improve inter-departmental	0	4	11
relationships.*	(0)	(27)	(73)
CCBD is seen as a research clinic and there is a culture of research	8	5	3
among the staff.	(50)	(31)	(19)
The leaders of the clinic should support the image of CCBD as a	0	5	11
research clinic.	(0)	(31)	(69)
<i>Note:</i> The frequency of responses are shown with the percentage of responses.	ponses in	parenthe	ses.

Note: The frequency of responses are shown with the percentage of responses in parentheses Items with asterisks were answered by 15 participants, while all other items had 16 total responses. Due to rounding the responses for some items total more than 100%.

Fifty-three percent of survey participants agreed that more research staff is needed at the different CCBD campuses, while 40% had no opinion and only 7% disagree. Fifty-six percent of participants believed that CCBD should hire additional research staff in order to cover additional campuses. A lack of support staff to assist in enrolling patients negatively impacts enrollment (Somkin et al., 2005). This may be the case at CCBD, where only four of the nine campuses have access to research support staff. Giving healthcare providers greater access to clinical trials and research resources may increase enrollment, although the hiring of additional staff can be a significant financial decision and one of the more expensive components of conducting CCT (Baer, Zon, Devine, & Lyss, 2011).

Sixty-nine percent of survey participants agreed with the statement that there is a lack of research knowledge and training for staff that are not directly involved in research, and 75% of providers agreed that all staff at CCBD should receive some level of research training or education. Forty-four percent of participants agreed that there is a lack of communication and support between CCBD staff participating in research and staff that is not directly involved, and 73% felt that events should be held by CCBD to improve inter-departmental relationships.

Staff that are considered extended members of the research team, such as infusion nurses and pharmacists, already receive training regarding study protocols and investigational product at CCBD. However, even staff members that are considered outside of the research team, such as patient navigators or those involved in billing, also play critical roles at research sites and may need research education and training (Baer et al., 2011). In addition, the benefit of conducting CCT may not be apparent to members outside of the research department, and efforts to promote support and awareness among the rest of the staff are essential. Activities with the research team can be used to promote this awareness (Baer et al., 2011).

Finally, 50% of survey participants disagreed that CCBD is seen as a research clinic and that there is a culture of research among the staff, and only 19% agreed with this statement. Sixty-nine percent of participants felt that the leaders of the clinic should support the image of CCBD as a research clinic. In addition to the ability to provide patients access to quality care through participating in CCT, supporting a practice-wide culture of commitment to research can lead to better care and outcomes for patients who are not enrolled (du Bois, Rochon, Lamparter, & Pfisterer, 2005; Rochon and du Bois, 2011; Selby and Autier, 2011). Physicians and other leaders at the investigative site are critical in setting the tone of a culture of research, and can accomplish this by emphasizing to nurses and support staff that conducting CCT is important for the practice and the benefit of its patients (Jameson, 2006; Denicoff et al., 2013).

SUMMARY AND CONCLUSIONS

Historical Data

The historical data indicate that 58% of the time referred patients are not enrolled in CCT because they do not meet eligibility criteria, which include the patient's disease profile, previous cancer treatments, and other aspects of their health. While investigative sites have little control over this aspect of clinical research, there may be other ways for sites to increase enrollment. Enrollment would increase if the number of eligible patients that decline participation decreased from 16%, so it would be helpful to find out why patients are hesitant about participating in CCT and how to address their concerns. Some of these reasons were addressed in the healthcare provider survey, although a more direct and accurate way to find out why patients' declined participation would be to ask them about their concerns while discussing CCT with them and to address and record those reasons.

In addition, the results indicate that enrollment would increase if non-English speaking patients could be enrolled in CCT at CCBD, which is cited as the reason patients were not enrolled in 7% of the time. This may also be an enrollment barrier at other sites depending on the patient population seen at those sites. However, study materials in the patient's primary language would need to be approved by the IRB, and multilingual research staff and clinicians would need to be hired in order to consent and treat non-English speaking patients. While enrollment may

increase if non-English speaking patients could be enrolled in CCT, it may not be a practical or cost-effective method for sites to increase enrollment.

The historical data analyses also showed that the number of patients referred and screened is significantly, positively correlated with the number of patients enrolled. These results are not surprising, as referred patients must be screened for trial eligibility in order to be considered for enrollment. For example, if 100 patients were referred in a year, and 50 of those patients agreed to sign the ICF and go through screening procedures, then 30 of the patients might be enrolled as long as they meet the eligibility criteria. Therefore, all enrolled patients have been both screened and referred, and all screened patients have been referred. Implementing strategies to increase referrals and screening may lead to an increase in enrollment in the future, and some of these strategies are further addressed in the provider survey.

Although it was hypothesized that enrollment would increase as the number of research staff and research clinicians increased, a positive relationship with enrollment was not found. It was believed that an increase in research staff would increase the total number of research patients that CCBD could manage at one time, and that having more research clinicians would lead to more referrals and therefore more enrollment. However, there was no correlation between the number of patients enrolled and the number of research clinicians. Furthermore, there was a slight, non-significant negative trend between the number of research clinicians and the number of patients referred and screened. Additionally, there was a weak, non-significant negative trend between the number of patients referred, screened, and enrolled.

While these trends were not significant, the general direction is unexpected. Some of the relationships may be explained by the fact that not all clinicians refer or enroll equal numbers of

patients, with the majority of referrals coming from only three or four physicians at CCBD. In fact, the majority of referrals come from the principal investigators of the studies, and subinvestigators may not be engaged or feel motivated to participate in research. One way to increase referrals may be to award enrolling clinicians, or to have more physicians act as principal investigators of trials instead of just a small percentage. This may help physicians feel more interested in research and more responsible for the success of CCT at their site.

An explanation for the small, non-significant negative trends with the number of research staff is that there may have been an increase in the workload associated with each research patient during recent years. For example, the complexity of CCT, number of procedures, and number of visits required has increased (Good et al., 2013). An increase in any of these would cause more work for the research staff since they are responsible for related tasks such as setting up visits, seeing patients, collecting data, and preparing for procedures. If the workload per patient increased, then more research staff would be needed to handle the higher workload even if the number of patients stayed the same. If this were true at CCBD, then that would explain the slight negative correlations between enrollment and the number of research staff, where enrollment is not increasing with the number of staff and may even be decreasing as the workload per patient increases. However, it could also be the case that the research staff at CCBD is not being utilized effectively and more staff is currently employed than is necessary based on the number of research patients.

Finally, historical data analyses showed that enrollment significantly increased after CCBD became one of SCRI's strategic sites when comparing the months before and months after the first enrollment in a study opened through SCRI. However, the same increase was not seen when comparing the months before and months after the first contract between CCBD and

SCRI. A possible explanation is that it may have taken several months for management tasks and regulatory processes to be taken over by SCRI. If SCRI took on some of the regulatory workload associated with conducting CCT, then the research staff could have been able to focus more on enrollment or handle having more research patients enrolled at one time. Another possible explanation is that studies opened through SCRI were not activated until months after the contract. Increasing the number of open studies at CCBD may have increased enrollment because CCBD does not open multiple studies that would compete for the same patients due to eligibility criteria. This means that if the total number of studies was increased, then the total percentage of patients that are potentially eligible for CCT would also likely increase because the studies do not compete for participants. However, due to a lack of data on the number of open studies is positively correlated with enrollment or if the number of open studies increased after CCBD and SCRI became affiliated.

Community-based practices may not have a large research staff to handle research patients and regulatory tasks, which would be a difference between community-based practices and most large academic research centers. These results indicate that community-based research practices may benefit from partnering with a CRO or SMO that can assist in opening studies, managing regulatory processes, and increasing enrollment. As trials become more complex, the workload associated with individual research patients will continue to increase. In addition, as trial eligibility criteria become more strict, fewer patients will be eligible for individual studies. A CRO or SMO may be able to help increase or maintain overall enrollment numbers at a site by assisting in opening and managing additional studies.

Provider Survey

The results from the survey provided several insights into the barriers to enrollment at different levels at CCBD. Only a few survey participants agreed that eligible patients usually decline to participate in studies that they are offered, which was expected to be a barrier to enrollment based on the reasons referred patients were not enrolled. However, the majority of participants still felt that the reason a patient declined participation or was not eligible should be recorded. This information would be useful in further determining barriers to enrollment or what studies are appropriate for the patient population seen at CCBD.

According to the survey participants, patients at CCBD may believe the common misconceptions that they will be treated like a "guinea pig" or that they may not be treated if they are receiving placebo. Providers agreed that healthcare providers, new patient navigators, and patient coordinators to spend more time discussing CCT with their patients, and that current or previous research patients to be allowed to volunteer as peer mentors for new research patients. Some patients at CCBD may also have concerns about financial requirements and insurance coverage, which most providers agreed should be addressed by financial counselors.

In addition, patients at CCBD may not be aware that trials are available. The site's website should be utilized in order to increase patient and public awareness by including research patient testimonials, a list of open CCT, and a search engine to allow patients to match themselves to a CCT. Survey participants also agreed that there is a lack of community outreach about the availability of CCT at CCBD, which is a barrier to enrollment as this limits the amount of referrals to CCT that come from outside the clinic. Solutions that may help overcome this barrier are that physician letters could be mailed to providers in the community, and that research patient cases could be presented at tumor boards. Patients also sometimes self-refer themselves

to CCT at CCBD. A way to increase this self-referral, in addition to utilizing the site's website, is to advertise CCT to the general public. However, advertising to the general public in the past has not increased enrollment at CCBD.

The majority of survey participants said they sometimes do not enroll patients on a study if they believe it offers substandard care. This is not surprising, as most providers would not want their patients receiving less than the standard care. However, very few providers stated that they consider clinical trials to be the best treatment option for their patients. This is an unexpected barrier to enrollment, as CCT typically offer standard of care with additional monitoring of a patient's progress. Close monitoring and one-on-one care that patients receive from their physician and clinical research coordinator are typically seen as positive aspects of enrolling in CCT that increase the quality of care (Cancer101, 2013). A third of providers also stated that they generally do not offer trials to patients who would do well on standard therapy, which is another unexpected barrier to enrollment due to the potential benefits that research patients receive from participating.

Most providers agreed that clinical trials should be the first treatment option on Pathways, which was expected to be a barrier to enrollment based on discussions with the providers about the issues with using Pathways for pre-screening. Also, if providers do not feel CCT are the best treatment option then it would be expected that many providers would also not want CCT as the first Pathway option. This discrepancy may be due to the wording of the statements. Providers may not feel that CCT are always the best treatment option for all their patients, but still feel that CCT should usually be the first treatment option offered to patients.

Another anticipated barrier to enrollment based on discussions with the CCBD physicians and research staff was that providers might feel that patients should only be on trial if there is no

other treatment option. However, this does not seem to be a problem at CCBD based on the survey results. It was also expected that a barrier to enrollment may be that providers do not discuss CCT with patients they do not believe would enroll, but the results do not support this, as most providers actually agreed that all potentially eligible patients should be approached about the option of participating in a trial.

Since most referrals at CCBD only come from a few physicians, it was interesting that 81% of providers said they are motivated to enroll patients in CCT. This result indicates that a lack of motivation may not be the reason for low referrals from most physicians. However, half of providers agreed that incentives for enrolling providers would motivate them to increase enrollment, which may indicate that providers already want to enroll patients but could be further motivated. In addition, most providers did not feel deterred from enrolling patients by the time and effort involved with having a patient on trial, although providers still felt that processes to save time should be in place. As expected, providers do not enroll patients in studies if they need to start treatment quickly, and feel that there should be a way to get patients enrolled and starting treatment faster.

The survey results did not indicate many barriers to enrollment due to a lack of provider knowledge and awareness of trial treatments and eligibility criteria. This result is a little unexpected, as most patients that are referred by providers at CCBD are not actually eligible for CCT and this may indicate a lack of knowledge and awareness on the part of the referring physician. However, some of eligibility information may not be known before the patient is screened, and many referred patients ultimately screen fail. The results did show that providers' awareness may be improved through monthly email reminders and easy to reference lists of open studies and eligibility criteria. These methods to increase provider awareness and knowledge

would be easy and cost-effective to implement, and may increase referrals and enrollment at CCBD.

Based on the survey results, there are also several ways in which research practices can be improved at the level of the investigative site. While providers did not feel that patients are often screened or enrolled in CCT they are actually ineligible for, most providers agreed that a double review of patient eligibility should be performed by study coordinators and physicians in order to prevent unnecessary screening. However, if patients are not usually screened for studies they are ineligible for, then a double review process would be time-consuming and unnecessary.

Many providers agreed that current methods for pre-screening patients at CCBD are inadequate, and agreed that new patient navigators and coordinators should assist in identifying potential research patients and that electronic databases or patient registries should be kept to track patients. However, providers also agreed that using Pathways for pre-screening patients is effective, which contradicts the statement about current pre-screening methods being inadequate at CCBD. Providers may have responded this way because they believe that Pathways would be an effective way to pre-screen patients if certain improvements were made. The use of Pathways for pre-screening patients could be improved by placing treatments in the system quickly and appropriately, and by adding more information to Pathways about the trial treatment and eligibility criteria. Non-research staff may not need to pre-screen patients if the Pathways software is made to be more effective for this purpose.

Finally, the results of the provider survey indicate that there are ways to create and improve the culture of research at CCBD. Providers agreed that additional research staff is needed to cover the other CCBD clinics, that all CCBD staff should receive some research training or education, and that events should be held by CCBD to improve inter-departmental

relationships. However, a barrier to enrollment that was not completely anticipated is that CCBD is not seen as a research clinic, which may reduce awareness that CCT are offered at CCBD. The leaders of the clinic, which may include physicians, administrators, and department managers, should support the image of CCBD as a research clinic in order to change the clinic culture.

Limitations

A limitation of the historical data analysis is that certain data were not available for some years. The reasons that every referred patient was not enrolled in CCT were only available for one year, and the numbers of patients referred and screened were only available for two years. In addition, it is difficult to control for confounding variables in any historical data analysis, such as in determining a significant difference in enrollment before and after CCBD became affiliated with a SMO. Finally, there was very little data available on the number of studies open every month at CCBD. It may have been useful to see whether or not the number of open studies correlated with enrollment, and if the number of open studies changed significantly before and after affiliation with a SMO.

The limitations of the prospective data collection through the provider survey are that the data are subjective and may not accurately represent the most significant barriers to enrollment or effective strategies to increase enrollment, especially at the level of the patient or site. In addition, the sample size for the survey study is small. Out of the 23 surveys that were mailed, 17 were received back resulting in a response rate of 74%. This means that the survey results were not representative of the opinions of all the providers at CCBD and may include a response bias where providers with certain characteristics, such as not being interested in research or not offering trials to patients, did not reply.

Finally, the results of this study are most applicable to CCBD, although they likely apply to other community-based cancer treatment centers as well. The results and recommendations for increasing enrollment and improving research practices at the level of the investigative site may not be useful for large academic research centers that are already seen as research institutions by patients, have motivated research physicians, and have a large research department that handles all regulatory requirements.

Future Research

In order to increase the participation rate in CCT from a mere 3% of cancer patients, much more research is needed to find out why that figure is so low and how to increase it. Due to the large number of patients treated at community-based cancer centers, further studies on barriers to enrollment at these practices may help increase that number. In addition, as the challenges faced by investigative sites change over time, research practices should be re-assessed to keep up with changing enrollment barriers and additional studies should be conducted in order to evaluate strategies to increase enrollment.

If the strategies to increase enrollment and improve research practices from this study are implemented at CCBD, then changes in referrals, screening, and enrollment should be monitored to assess whether or not these suggestions made a significant impact. This information would be useful in identifying strategies that were the most effective based on quantitative data and in supporting their implementation at other investigative sites.

CHAPTER III

INTERNSHIP SITE

My research internship practicum was completed at The Center for Cancer and Blood Disorders under the supervision of the director of research, Dr. Ray Page, DO, PhD, and the clinical research manager, Melissa Sottosanti, BSN, RN. I also worked closely with the study coordinators and the research staff in charge of data management, regulatory affairs, and investigational product.

CCBD is a community-based cancer treatment center that has been conducting clinical research trials in oncology and hematology since 1999, and has been one of Sarah Cannon Research Institute's strategic sites since 2011. The nine CCBD clinics are located in north central Texas, and four of these clinics participate in research. Most of my internship practicum was spent at the main campus in Fort Worth, which is where the centralized research department is located. Some of my time was also dedicated to two of the satellite sites that offer clinical trials.

JOURNAL SUMMARY

One of my main tasks at the beginning of the internship was to interact and communicate with the research physicians and staff at the CCBD clinics that offer clinical trials. Through discussions, interactions, and observations I was able to identify some of the barriers to enrollment at CCBD, how these barriers may be specific to a community-based practice, and how these barriers may be overcome in order to increase enrollment. The knowledge I gained was utilized in creating the provider survey used in my research project.

Throughout my internship practicum I have been heavily involved with the CCBD research department and have learned about many of the aspects involved in managing clinical research trials. I have sat in on meetings with SCRI representatives and learned about the role of SCRI as a site management organization and its relationship with CCBD, and have attended the CCBD research committee meetings, research department meetings, and tumor board. In addition, I sat in on pre-study and site initiation visits, attended the quarterly research dinners, learned about CCBDs standard operating procedures and working practice guidelines, and attended the research strategic planning retreat to discuss to goals for the research department.

In addition to participating as a member of the CCBD research department, I interacted one-on-one with all of the members of the research staff. I assisted the data coordinator in several of her duties, such as answering data queries, data entry into the electronic data capture (EDC) systems or onto paper case report forms (CRF), marking data for PIs to review and sign

off on, ordering study supplies, interacting with study monitors, and keeping track of patient enrollment. I assisted the regulatory coordinator with updating the regulatory binders with protocol amendments and revised informed consent forms, writing note-to-files, keeping track of correspondence, reviewing the PI's curriculum vitae, storing study materials after studies have closed in short term on-site storage and long term off-site storage, and the handling and destruction of lab kits. I assisted the IP coordinator with the relabeling of study drug, recording IP accountability, and writing administration instructions for the chemotherapy nurses. I also assisted the study coordinators by performing internal adverse event audits in order to capture and clarify aspects of adverse events that needed to be recorded or changed for accuracy, and helped create lists of open studies to place in the exam rooms and physician offices.

APPENDIX A

COVER LETTER AND SURVEY

IDENTIFYING BARRIERS TO ENROLLMENT AND STRATEGIES TO INCREASE ACCRUAL AT A COMMUNITY-BASED CANCER TREATMENT CENTER

Principal Investigator: Dr. Patricia Gwirtz, Ph.D., FACC

Student Investigator: Sheila Gokul, BS

Institution: University of North Texas Health Science Center

Introduction:

We are conducting a study to identify the barriers to patient enrollment at The Center for Cancer and Blood Disorders and to identify the best strategies to overcome these barriers. The results of this study may be used in the future to implement new practices to improve research and increase accrual at The Center for Cancer and Blood Disorders or other community-based cancer centers.

You are invited to participate in this research study survey because you are a healthcare provider involved in research at one of The Center for Cancer and Blood Disorders sites. This survey will gauge your opinions and ideas on clinical research and current research practices at your site. The survey contains four parts, each of which will take no more than 5 minutes to complete.

Risk/Benefit:

There are no foreseeable risks associated with participating in this survey. You may receive no direct benefit from participating in this study. The potential benefits of participating in this study are that it will allow you to confidentially give your opinions on many issues directly affecting your practice, and that it will allow us to identify the most significant barriers to enrollment and most useful strategies to improve practices at The Center for Cancer and Blood Disorders based on those opinions.

Agreement to Participate:

Participation in the study is completely voluntary. If you decide to participate, please complete and return the survey in the attached pre-addressed return envelope through The Center for Cancer and Blood Disorders interdepartmental mail system by **January 17, 2014**.

Confidentiality:

You will not be asked for your name or any other identifying information on the survey.

Leaving the Study:

Since the survey is not identifiable, there will be no way to withdraw from the study once you complete and return the survey in the mail.

Questions/Concerns:

If you have any questions regarding this research project, please feel free to contact:

- · Principal Investigator: Dr. Patricia Gwirtz, Ph.D. FACC, at Patricia.Gwirtz@unthsc.edu
- Student Investigator: Sheila Gokul, at srg0180@live.unthsc.edu or (254) 592-5082

If you have any questions about your rights as a research subject, please contact the UNT Health Science Center Institutional Review Board at (817) 735-0409.

Thank you for participating in the study.



Category: Patient and Community

Please circle your response to each of the following items. SD = strongly disagree, D = disagree, N = neutral or no opinion, A = agree, SA = strongly agree.

1	Eligible patients usually decline to participate in studies that I offer them.	SD	D	Ν	Α	SA
2	Providers should record why a patient has declined participation in a clinical	SD	D	Ν	Α	SA
	trial or why the patient was not eligible.					
3	My patients understand the importance of cancer research and participating in	SD	D	Ν	Α	SA
	clinical trials.					
4	Healthcare providers should take the time to explain to patients why clinical	SD	D	Ν	Α	SA
	trials are worth enrolling in.					
5	Education materials about research and participating in clinical trials should be	SD	D	Ν	Α	SA
	included in the patient notebooks that new patients receive at CCBD.					
6	Patients do not understand the concept of placebos or control arms in a clinical	SD	D	Ν	А	SA
	trial setting.					
7	Healthcare providers should take the time to carefully explain what the	SD	D	Ν	Α	SA
	placebo or control arm is in a study and how it compares to standard of care.					
8	Many of my patients fear becoming a "guinea pig" and do not trust clinical	SD	D	Ν	А	SA
	trials.					
9	Healthcare providers, patient navigators, and patient coordinators should	SD	D	Ν	Α	SA
	spend more time discussing clinical trials with patients in order to alleviate					
	their fears of participating.					~ .
0	Current or previous research patients should be allowed to volunteer as peer	SD	D	Ν	A	SA
-	mentors for patients going on trial and offer additional support.	GD	-			C 4
1	Most of my patients know that clinical trials are available at CCBD.	SD	<u>D</u>	N	<u>A</u>	SA
2	Research patient testimonials should be included on the CCBD website to	SD	D	Ν	A	SA
-	increase patient interest in research.	CD.	D	N	٨	C A
3	The CCBD website should have an easy to locate and understand page of the	SD	D	N	А	ЪA
4	clinical trials currently available for patients to view.	SD.	D	N	٨	C A
4	A search engine on the CCBD website that would allow patients to input their	SD	D	14	А	ЪA
	disease prome and identify a chinical that they highly be engible for would					
5	Spark more interest in research noin patients.	SD	D	N	Δ	S.A.
5	my patients often have concerns about the infancial requirements of	50	D	14	n	104.1
6	Financial counselors should better explain to natients what is and is not	SD	D	N	A	SA
×	covered on a research trial and what reimbursements may be available.	00	2	11		
7	Physicians out in the community often refer patients to CCBD for clinical	SD	D	Ν	Α	SA
	trials.		-			
8	The research department or study PI should send a letter to surgeons and	SD	D	Ν	Α	SA
-	referring physicians about the trials available at CCBD.					
9	There is a lack of community outreach about the availability of clinical trials	SD	D	N	Α	SA
	at CCBD.					
0	CCBD should advertise clinical trials to the general public in order to increase	SD	D	Ν	Α	SA
-	enrollment.					
1	Physicians should present research patient cases at tumor boards to increase	SD	D	Ν	А	SA
	community knowledge of clinical trials.	D/AS	5 AT	ope	ov	ED
	EXEMP	Ť	-	E)	EM	IPT
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	Page 1 of 4 JAN 07 2	2013		JAI	07	2014

Category: Physician or Provider

Please circle your response to each of the following items. $SD = strongly \ disagree, D = disagree, N = neutral or no opinion, A = agree, SA = strongly agree.$

 Sometimes I do not enroll patients on a study if I believe it offers substandard care. 	SD	D	Ν	Α	SA
2 When evaluating a study protocol, the PI should ensure that the study	SD	D	Ν	Α	SA
I consider aligieal trials to be the best treatment practices.	SD.	D	N		S A
Clinical trials should be the first treatment option on Bathware	SD		N	A .	SA SA
Climical thats should be the first treatment option on Pathways. Detients about dealty be an aligned trials if there is no other treatment option	SD SD	- <u>D</u>	N	A .	SA SA
5 Fatients should only be on clinical triais if there is no other treatment option.	SD SD	- <u>D</u>	N	<u>A</u>	SA SA
6 I generally do not orier trials to patients who will do well on standard unerapy. 7 I do not discuss clinical trials with patients that I halians mould not enroll	SD SD		N		CA CA
7 I do not discuss clinical triais with patients that I believe would not enroll. 8 All notentially aligible nations should be appressed about the antion of	SD	- <u>D</u>	N	A .	SA SA
8 All potentially engible patients should be approached about the option of participating in a trial.	SD		N	A	- SA
9 The amount of time and effort involved with having a patient on a research study deters me from enrolling.	SD	D	Ν	A	SA
10 Electronic methods of signing documents and assessing lab values as clinically significant or not clinically significant would save me time.	SD	D	Ν	A	SA
11 I am motivated to enroll patients in clinical trials.	SD	D	Ν	Α	SA
12 Healthy competition between providers through acknowledgement or	SD	D	N	Α	SA
incentives for enrolling providers would motivate me to increase enrollment.					
13 I am aware how most study treatments are an improvement on current medical practices.	SD	D	Ν	A	SA
14 SCRI and the CCBD research department should emphasize how a study treatment may be better than standard of care to enrolling physicians and potential research patients.	SD	D	Ν	А	SA
15 I feel deterred from enrolling patients due to potential protocol deviations that are out of my control.	SD	D	Ν	Α	SA
16 CCBD needs to implement standard operating procedures and working practice guidelines that hold staff responsible for their delegated research tasks.	SD	D	Ν	Α	SA
17 I do not enroll patients in studies if they need to start treatment as soon as possible.	SD	D	N	Α	SA
18 CCBD and SCRI should develop a more streamlined process to get patients enrolled and treatment started right away.	SD	D	Ν	Α	SA
19 I am kept adequately up-to-date about open clinical trials at CCBD.	SD	D	Ν	A	SA
20 Monthly email reminders from the research department listing what trials are open would be useful to me.	SD	D	N	Α	SA
21 Having a frequently updated list of open studies in my office and each exam room to reference is or would be useful to me	SD	D	N	Α	SA
122 I am aware of the inclusion and exclusion criteria of the studies that are most	SD	D	N	А	SA
relevant to my practice	1	2	.,		
23 L would like to have index cards for each study that I can keep in my office or	SD	D	N	А	SA
take into exam rooms that list the study name mechanism of action of the	⁵⁰ .	D	1.4	~	
study drug and inclusion/exclusion criteria	VPD	لھي	PPR	201	ED /
study drug, and mendsion/exclusion eriteria.	MDT	AS	= E)	KEN	IPT
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Category: Site

Please circle your response to each of the following items. SD = strongly disagree, D = disagree, N = neutral or no opinion, A = agree, SA = strongly agree.

1	More research staff is needed at the different CCBD campuses.	SD	D	Ν	Α	SA
2	CCBD should hire additional research staff in order to cover additional	SD	D	Ν	Α	SA
	campuses.					
3	The use of Pathways is an effective method for pre-screening patients for	SD	D	Ν	Α	SA
	eligibility.					
4	Study treatments need to be uploaded on Pathways as soon as possible and	SD	D	Ν	Α	SA
	placed appropriately in the system.					
5	Pathways does not contain all the inclusion and exclusion criteria necessary to	SD	D	Ν	Α	SA
	recommend a trial to a patient.					
6	Additional information should be included for study treatments placed in	SD	D	Ν	Α	SA
	Pathways to make Pathways an effective way to pre-screen patients.					
7	Patients are often screened or enrolled in studies that they are actually	SD	D	Ν	Α	SA
	ineligible for.					
8	To prevent unnecessary screening, research coordinators and physicians	SD	D	Ν	Α	SA
	should work to perform a double review of patient eligibility.					
9	Current methods for pre-screening patients at CCBD are inefficient or	SD	D	Ν	Α	SA
	inadequate.					
10	Patient coordinators and patient navigators should play a role in identifying	SD	D	Ν	Α	SA
	potential research patients.					
11	Patient registries or electronic databases should be kept to track of CCBD	SD	D	Ν	А	SA
	patients and pre-screen them for studies.					
12	Most of the time the eligibility criteria of studies at CCBD are appropriate for	SD	D	Ν	А	SA
	the patient population.			_		
13	CCBD should utilize available site data and screening logs to verify that	SD	D	Ν	А	SA
	patient populations are available for trials before opening them.					
14	There is a lack of communication and support between CCBD staff	SD	D	Ν	А	SA
	participating in research and staff that is not directly involved.					
15	Events should be held by CCBD to improve inter-departmental relationships.	SD	D	Ν	Α	SA
16	There is a lack of research knowledge and training for staff that are not	SD	D	Ν	А	SA
	directly involved in research.					
17	All staff at CCB should receive some level of research training or education.	SD	D	Ν	А	SA
18	CCBD is seen as a research clinic and there is a culture of research among the	SD	D	N	Α	SA
	staff.					
19	The leaders of the clinic should support the image of CCBD as a research	SD	D	Ν	Α	SA
	clinic.					

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Research Compliance Page 3 of 4

UNTHSC Research Compliance

Your experience in research and oncology or hematology.

Please circle your response to each of the following questions.

1	How many years have you been involved in clinical research?	0-5	6-10	11-15	15+
2	How many years of oncology or hematology experience do you have?	0-5	6-10	11-15	15+
3	How many years have you been actively involved in research at CCBD?	0-5	6-10	11-15	15+

Please list any additional comments or suggestions you may have. (Optional)

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APPENDIX B

INTERNSHIP JOURNAL

INTERNSHIP PRACTICUM JOURNAL

Week 1: August 19 – August 23

Monday, August 19, 2013

- Spoke with the clinical research manager about the research department at The Center for Cancer and Blood Disorders (CCBD) and my upcoming project on barriers to enrollment from a physician's perspective.
- Assisted the regulatory coordinator with preparing clinical study records for monitor visits occurring this week.
- Attended a meeting for the research department to discuss the implementation of standard operating procedures (SOPs) and afterwards spent time reviewing the SOPs.
- Helped the data coordinator resolve queries in data clarification forms (DCFs).

Tuesday, August 20, 2013

- Attended tumor board meeting on current difficult cases at the clinic.
- Continued to review SOPs from the previous day.
- Reviewed the document "Increasing Accrual in Cancer Clinical Trials" from The Advisory Board Company, Oncology Roundtable, to identify potential barriers to accrual and sources for my research proposal.
- Sat in on meeting with Sarah Cannon Research Institute (SCRI), which essentially functions as a contract research organization (CRO) for CCBD, about the status of current trials at the clinic.

Wednesday, August 21, 2013

- Spent the morning at the front desk learning about the process patients go through when they come to the clinic for a visit, and how information about patients is entered into the clinic-wide system. Learned about the role patient coordinators and patient navigators.
- Read the Education Network to Advance Cancer Clinical Trials (ENACCT) report, A Quality Improvement Program to Improve Cancer Clinical Trial Recruitment, Accrual, and Retention: Lessons Learned from the National Clinical Trials Pilot Breakthrough Collaborative, November 2012.
- Observed the data coordinator file lab reports and enter data for a trial.
- Organized first CRM committee meeting for August 28, 2013.

Thursday, August 22, 2013

- Assisted data coordinator in answering data queries.
- Reviewed past UNTHSC Clinical Research Management internship practicum reports on patient enrollment through Digital Commons.
- Started categorizing barriers to patient accrual, organizing ideas for proposal, and finding sources that have prospectively studied specific barriers to enrollment.

- Helped locate old correspondence from a study that is closing soon, and learned about writing a note-to-file.
- Met with the clinical research manager about my internship practicum schedule and data collection for my research proposal.

Friday, August 23, 2013

- Reviewed the National Cancer Institute's AccrualNet strategies, tools, and resources to support accrual to clinical trials, specifically on evaluating accrual and reporting lessons learned after a trial has ended.
- Searched CRF binders for information to answer data queries.
- Learned how to enter adverse events and concomitant medications into a study database.
- Attended site initiation visit (SIV) meeting for a randomized, double-blind, placebocontrolled study. We reviewed the protocol, background, inclusion and exclusion criteria, the study drug, adverse events, data management, and safety reporting for the trial.

Week 2: August 26 – August 30

Monday, August 26, 2013

- Visited the Weatherford CCBD clinic in order to identify barriers to enrollment at that site. Spent most of the day shadowing Dr. Page. Observations:
 - The research staff shares an office with other clinic staff and cannot openly discuss trial information with each other or with patients. There are offices in the clinic that are being underutilized; it might be beneficial for the research staff to be able to use one of those offices instead.
 - Like at the Fort Worth site, the clinic staff outside of the research department is not very involved with research and recruitment. However, the Weatherford clinic typically has better communication because it is so much smaller.
 - Difficult to discuss clinical trials with older or confused patients; wouldn't be able to properly obtain consent. Difficult to discuss clinical trials with any patient in lay terms they can clearly understand, like in explaining tumor markers, treatment purpose, what causes side effects, etc.
 - Difficult patients may not be willing to come in for regular visits or take their trial drug regularly, and number of medications or complexity of treatments deters patients from enrolling.
 - No active PR for trials at the clinic. However, PR for clinical trials has not increased enrollment in the past.
 - There is some competition in enrolling patients with other clinics that we coordinate with on patient care.
 - When a patient is newly diagnosed, it's an emotional time and difficult to discuss clinical trials. We also can't properly consent depressed patients.
 - Patient may assume a side effect (i.e., mouth sores) is due to the study drug and want to be taken off trial, while in reality it may be due to the standard of care treatment.
Tuesday, August 27, 2013

- I again spent the day at the Weatherford clinic, this time shadowing Dr. Young. Observations:
 - Training of new staff is a barrier, especially if they have never been involved in research. Not only have to train for their job, but teach them about all the trials that are open and how to discuss trial enrollment with patients. The other staff is also slowed down.
 - Again, the trials we have open do not involve some of our largest patient populations. Patients that are deciding between hormone therapy and chemotherapy don't have a trial that looks at one versus the other. For example, out of the 13 breast cancer patients we saw, 5 were metastatic, 6 were adjuvant, 1 was inflammatory, and 1 was on trial. We don't have trials available for most of our patients.
 - Only 10% of patients actually accept the offer to enroll. Most say they don't want to be a guinea pig. Need to better explain that trial treatments are as good or better than standard of care.
 - Suggestion from physician: give laminated pocket cards of the inclusion/exclusion criteria for clinical trials to physicians. Have them keep them at their desk, in their coat pocket, and in exam rooms. Instead of listing every single trial (around 40 total), list only the ones relevant to that physician's patients. For example, Dr. Young only sees breast cancer patients, so would only need 3 of the current open trials on a card. The research department would have to keep the card updated.

Wednesday, August 28, 2013

- Took my current list of barriers to enrollment at TCCBD and categorized each by type: institutional, provider, or patient. If possible, I listed a potential solution to overcome the barrier if it had shown to be successful in recruiting at other clinics, and gave a source for each solution idea.
- Ordered study supplies.
- Organized ideas for research proposal to discuss at committee meeting next week. Reserved a room for the meeting.
- Reviewed a study protocol to determine the specific criteria for adverse events.
- Helped assemble folders for two newly enrolled patients.
- Filed information into patient charts.

Thursday, August 29, 2013

- Identified barrier: TCCBD has doctors on the 1572 that do not enroll patients. Adding them to studies adds extra work for the research department to add them to studies, but does not increase accrual.
- Searched through electronic medical record (EMR) for information the monitor needed to review. De-identified patient exam results to give to trial monitor.

- Searched through all binders for two trials about to close in order to record last visit and follow up visit dates. Labeled complete and lost to follow up (LTF) patients and began reviewing patient charts to confirm LTF.
- Learned about regular follow up (FU) visits vs. abbreviated follow up visits, which occur after one of the endpoints of the study has been reached for that patient (i.e., recurrence of cancer).
- Potential solution: some of the physicians engage in healthy competition and want to be acknowledged as one of the top research physicians at TCCBD. We could use that as a way to incentivize them to increase their enrollment.

Friday, August 30, 2013

- Assisted in recording data from physician notes and lab results.
- Sat in on meeting with SCRI about the scheduling of monitoring visits and confidentiality concerns with more than one monitor visiting at a time.
- RECIST measurement source documentation with electronic data RECIST measurements.
- Updated adverse events in data sheets.
- Attended research department meeting. Discussed:
 - Inform PIs of any upcoming monitoring meetings.
 - Update forms so everyone is documenting the same way.
 - Address processing issues in order to get data recorded sooner.
 - Avoid deviations by making sure patients are scheduled for a follow up visit within the time frame specified by the protocol.
 - Review and improve serious adverse event (SAE) reporting process.
 - Data update for upcoming monitors.

Week 3: September 2 – September 6

Monday, September 2, 2013

• Labor Day

Tuesday, September 3, 2013

- Reviewed lab values and marked high or low values for physicians to designate as clinically significant (CS) or not clinically significant (NCS).
- Went through source documents to resolve discrepancy between local lab values and values from a sample that was sent to an off-site lab, which resulted in a difference in the grade of severity assigned to abnormal values.
- Searched for information from a specific chemotherapy cycle for a study patient.
- Learned how to put together a new patient chart.
- Addressed list of Outstanding Actions that needed to be completed before the remote Interim Monitoring Visit scheduled for tomorrow.
- Sat in on weekly meeting between SCRI and the CCBD research department. Discussed the opening of new trials, IRB approval and SIV scheduling for pending studies, issues

with study forms and timely feedback from monitors, and current enrollment in open studies.

• Filed information into patient charts for different studies.

Wednesday, September 4, 2013

- Searched through a protocol to identify what data was needed for end of treatment (EOT). I then went through all the patient binders and identified patients that were still on trial vs. patients that have finished the study. For patients that have finished the study, I completed the various data collection forms associated with EOT for that trial with information from the EMR and placed them into the patient binders.
- Sat in on remote monitoring visit via telephone. Discussed determination of major or minor status of deviations by local IRBs vs. the medical monitor's decision. Also discussed updated consent forms and specific subject data that need to be clarified or submitted.
- Reviewed all signed informed consents for the study discussed at the remote monitoring visit to confirm that patients had signed and initialed all areas required.
- Attended quarterly TCCBD Research Committee Meeting with clinical research manager. Discussed initiatives for physicians to enroll, lab approval process, radiology staffing, developing a way for all TCCBD staff to identify research patients, and research-specific chemo treatment sheets and adhering to the protocol for infusion times.
- Attended monthly The Center Research Meeting. Discussed pending protocols, open studies, and closing studies. Also discussed adding mechanism of action (MOA) of drugs to portal where our physicians can look at enrolling studies.
- On-site mentor and committee members met at TCCBD at 3pm to discuss my internship and research/practicum proposal for clinical research management. We discussed that I should have my proposal finished and approved by mid October, and that I needed to submit to the IRB soon after that. We also discussed that my project would be focused on barriers to enrollment and I explained in general the type of data I wanted to collect and the questions I wanted to answer. My committee members signed my designation of advisory committee and master of science degree plan forms, and Dr. Gwirtz took them back to UNTHSC.

Thursday, September 5, 2013

- Searched for articles on why infusion times are sometimes longer or shorter, and looked for specific research ethics examples of when an infusion time was shortened and it negatively affected the patient.
- Visited the Arlington TCCBD clinic with the research manager and new coordinator to get signatures from physicians and meet the staff. I will be going back to Arlington to work with Dr. Lynch on Monday afternoon.
- Resolved queries from a monitor follow up letter.
- Reviewed a study protocol to find out when long term follow up visits had to occur and whether or not there was a window of time you could be flexible in (i.e., +/- 2 weeks).
- Checked the number of study drug we had specific to each visit for two studies. Recorded lot numbers and expiration dates to give to the sponsor for drug accountability.

• Mailed an EKG to the sponsor.

Friday, September 6, 2013

- Sat in on meeting between the data coordinator and research manager. Discussed what to do when the data coordinator is sick or on vacation, and who will cover for what tasks. Also talked about ordering scans for patient visits, upcoming monitor visits and data locks, and issues to bring up at SCRI meeting next week.
- Began working on my research proposal by creating a rough outline of the sections and what I wanted to include in each.
- Counted patient enrollment at TCCBD by month for 1999 and 2000 for Dr. Page. Consolidated the data from other years so it would all be in the same excel sheet.
- Read about the different types and stages of cancers that we have open trials on.
- Observed official relabeling of study drug to extend the expiration date.

Week 4: September 9 – September 13

Monday, September 9, 2013

- Emailed my advisory committee a summary of my research project plans and began working on the outline for my proposal based on the CRM handbook.
- Reviewed The Center for Information & Study on Clinical Research Participation (CISCRP) facts and figures online.
- Went to the Arlington clinic to see how that site operates. This clinic will soon be enrolling patients in CCTs once the new study coordinator is trained. I spent most of my time with Dr. Lynch.
- Barriers: It has been hard getting research to come to Arlington. There's a learning curve for new physicians, and it can be difficult to decide what studies are best because the patient population for any new physician isn't set in the beginning. The non-physician staff at Arlington don't have research experience; however, it is such a small and close-knit facility that the study coordinator should have no problem communicating with the doctors and nurses.
- Solutions: The physicians need the coordinators and navigators to help counsel patients and allay fears about participating in a clinical trial. Patients are suspicious about being a guinea pig, and the research coordinators and nurses can also take more time to explain why the trial is worth enrolling in than the physicians can. We also need to keep doctors up-to-date on what trials are open, what patient population can enroll, and most importantly why the physician should care. What's the background of the drug? Why is it an improvement over the drugs that physicians are already using? Does it have less side effects? Need fewer treatments? Just works better? Tell the doctors why they should want their patients on trials what makes it better care than standard of care.

Tuesday, September 10, 2013

- Attended tumor board to learn about the clinic physicians' difficult cases. Dr. Page presented the case of one of our patients on a clinical trial and advocated enrolling patients.
- Observed SIV for a 2 part phase II trial, and learned about the study drug, inclusion and exclusion criteria, screening, tests and exams during the study, drug storage, preparation, and administration, reporting of adverse events and SAEs, concomitant medications, and dose modifications. I stayed for the separate parts of the SIV involving regulatory, data, coordinators, pharmacy, and the PI.
- Marked lab reports for physicians to sign off on abnormal lab values as clinically significant or not clinically significant.
- Sat in on weekly SCRI meeting.
- Worked on my research proposal.

Wednesday, September 11, 2013

- For a study that is closing, I went through all the patient charts and electronic data capture (EDC) system in order to confirm whether patients were lost to follow-up. I checked each patient's survival status, if the patient transferred to another care provider, or if there was a public record of the patient's survival status. I also noted date and cause of death when appropriate.
- Cleaned out study binders and filed away the contents in order to make more room for new study information.
- Let on-site research mentors about upcoming days where I will not be able to come into the clinic.
- Worked on research proposal. Focused on finding and organizing sources for the significance and background sections.
- Observed a study audit take place that will finish tomorrow.
- Attended in-person meeting between the director of application services at SCRI and the CCBD research staff. We discussed physicians being able to print off consent forms at other sites, using the team site to fill in and download documents at different clinics, and the use of electronic signatures which would reduce the amount of time and effort required from physicians and research staff. We also discussed how SCRI is developing a way to profile patients based on disease and storing their data in a database so that it's possible to easily match up patients with trials that are available in the future. This could be a potential solution for increasing enrollment in place of CCBD staff outside of the physicians and research department trying to identify patients once implemented.

Thursday, September 12, 2013

- Reviewed more of AccrualNet: Strategies, Tools and Resources to Support Accrual to Clinical Trials website, looking over both the staff education materials and patient education materials. May use some material in my surveys.
- Read the paper: Methods to improve recruitment to randomized controlled trials: Cochrane systematic review and meta-analysis, Treweek S, Lockhart P, Pitkethly M, et al. BMJ Open 2013;3:e002360. doi:10.1136/bmjopen-2012-002360. The authors stated that very few studies have looked at ways to improve recruitment to studies that are

aimed at those doing the recruiting, and the few that have didn't find that their strategies worked.

- Sat in on meeting between a SCRI representative and the research manager. Discussed major vs. minor deviations and medical monitor decisions vs. PI decisions. Also discussed that from now on the site won't fill out forms for deviations and will do it online through SCRI from now on.
- Sat in on weekly meeting between the data coordinator and research manager. Discussed that the research department is considering hiring a new data person, monitor follow up letters, upcoming monitor visits, data locks and analysis, and outstanding issues with coordinators and pharmacy.
- Addressed data query for an adverse event and filed treatment sheets.

Friday, September 13, 2013

- Checked EDCs online for data tracking. Noted outstanding items and recorded dates for study visits.
- Looked at the protocol for a study to determine the initial scans that needed to be performed on patients when starting the study.
- Retrieved patient charts.
- Reviewed the websites of other cancer treatment and research centers. Possible solution: include information about clinical trials on the front page of the CCBD website and a search engine to look at the open studies patients may be eligible for.
- Worked on the Research Design and Methodology section of my research proposal.
- Helped organize paper CRFs for new clinical trial patients.

Week 5: September 16 – September 20

Monday, September 16, 2013

- Printed off all research patient labs from the EMR from last week. Marked each abnormal value with CS or NCS and labeled them for the doctors to sign. Placed the labs in the physician folders.
- Worked on research proposal.
- For two studies that closed in July and one study that closed in September, I boxed up all documents and patient charts. I also labeled them according to their contents and kept a record of their bar codes in case we needed to look at the information in the future. The study materials will be kept on-site for two years and then shipped to an off-site storage facility.
- Assisted in entering data and answering queries for two studies using information from patient charts and the EMR.
- De-identified patient documents to be scanned and uploaded online.

Tuesday, September 17, 2013

• Did an internal audit of all the adverse events for one patient that has finished a study in order to clean the data.

- Reviewed all adverse event/concomitant medication logs and compared them to old toxicity assessments to make sure they were all transferred over.
- Looked up each adverse event in the old physician notes, physical exams, nursing notes, and research notes to make sure that adverse events, serious adverse events, grade, start date, end date, action taken, and medication given all matched what was written on the adverse events/concomitant medication log.
- If the details of adverse events did not match up I highlighted them and noted what didn't match, and marked the source document for later review.

Wednesday, September 18, 2013

- I repeated my task from yesterday with a different patient from the same study. I improved how I marked and reviewed adverse events, and noted how I could improve my efficiency and thoroughness in auditing future patient data. I also printed off all the notes and data for the next patient to be audited.
 - Did an internal audit of all the adverse events for one patient that has finished a study in order to clean the data.
 - Reviewed all adverse event/concomitant medication logs, toxicity assessments, individual adverse events in source documentation, and noted AEs that need to be updated.

Thursday, September 19, 2013

- Finished the first draft of my research proposal. I will email it to my on-site mentor and major professor to review.
- Pulled all patient charts for the study the monitor is reviewing today. Filed away patient charts from the monitor earlier in the week.
- Left the clinic early to drive to Lubbock for an interview.

Friday, September 20, 2013

• Did not go into the clinic today. Interview in Lubbock.

Week 6: September 23 – September 27

Monday, September 23, 2013

- Spent most of the day with Dr. Xiong at the main CCBD clinic in Fort Worth, who primarily sees patients with colon, pancreatic, and bile duct cancers.
 - Dr. Xiong stated that the biggest barrier he sees as a physician is that the clinic does not have trials for most of the patients that come in. Today we saw patients with multiple myeloma, colon, pancreatic, lung, liver, anal, and testicular cancers.
 - The two patients with pancreatic cancer may have been eligible for an open clinical trial. However, these patients were healthy and would most benefit from an aggressive treatment, while the standard of care in the clinical trial was a much milder treatment for sicker patients. The standard of care in this trial is not as up

to date as it should be, and as such the clinical trial would not have been the best treatment option.

- Dr. Xiong stated that he did not think that patients turning down trials was an issue. He estimated that about 80% of his patients that he offers trials to opt to go on trial.
- Potential barriers that I observed were that there are some language barriers in communication between physicians and patients and we wouldn't be able to recruit Spanish-only speaking patients. Patient compliance and comprehension may also be an issue; patients may not understand when or why they need to take certain medications or come in for visits.
- Assisted in marking data as CS or NCS for assessment by the nurse practitioner.

Tuesday, September 24, 2013

• Did not go into the clinic today. Interview in Fort Worth.

Wednesday, September 25, 2013

- Spent the morning with Dr. Reddy at the main CCBD clinic in Fort Worth, who sees many lung and GI cancer patients
 - Dr. Reddy stated that physicians need to have easier access to inclusion and exclusion criteria and what trials are currently open. Suggested updating the webpage that contains this information and including it on the desktop for physicians so it is easy to see, or printing out a single sheet and keeping it updated for physicians. Stated that the Pathways system sometimes doesn't have all the inclusion and exclusion criteria. Sometimes patients or their family members go online, and if they saw clinical trials listed on the CCBD website they may inquire about them.
 - He also felt that trial criteria are becoming too specific, and it's becoming more and more difficult to find patients that are even eligible for a study.
 - We did not see any research patients. We saw HPV+ head and neck, GI stromal, lymphoma, laryngeal, kidney, and lung cancer patients.
 - Stated that it would be nice to have more access to all the trials that SCRI has open.
 - Suggested the research department develop an efficient method to prescreen patients and notify physicians.
 - Physicians themselves can be barriers. They need to think of research as the first treatment option.
 - Patient understanding of clinical trials is sometimes an issue. May want to see why patients decline to participate in trials.
- Helped check which follow-up visits were complete and which were not done for half the patients on one study.
- Attended the weekly research department meeting. Discussed closing trials and patients that have been asked to participate recently. Also discussed recent methods we've used for trying to prescreen patients by diagnosis code, how study coordinators will need to

work more with physicians in order to identify eligible patients, and how patient navigators may be able to help in the near future.

Thursday, September 26, 2013

- I met briefly with Dr. Skiba today.
 - Dr. Skiba stated that she doesn't see a lot of malignancies, and that the patients that do have the right disease don't meet the study criteria.
 - She stated that it would be helpful to get frequent reminders from the research department and monthly emails from Dr. Page about the studies because physicians are often not aware of open studies or forget with everything else going on in their practice.
- Attended the weekly data meeting. The research manager said that we need to do an internal audit of a study, which may be my task for the next week or so.
- Created labels for a new system of filing patient information.
- Filed away new information for follow-up, deceased, and active patients.
- Barrier from a research coordinator: some physicians want patients on a specific drug, and if that drug is not what is used as the standard of care treatment in a study then they won't enroll them even if all criteria match. May be a mismatch between what certain physicians feel is the most appropriate standard of care and what a sponsor decides.
- Checked the temperature wheel on the investigational product freezer, and logged the time and temperature.

Friday, September 27, 2013

- Spent most of the day with Dr. Ganesa, an oncology physician at the Fort Worth clinic.
 - We saw patients with mantle cell lymphoma and cancers of the brain, breast, liver, and ovary and endometrium.
 - Dr. Ganesa stated that some of her patients, like prisoners, match the eligibility criteria for a trial but cannot be enrolled.
 - She also said that sometimes patient understanding and education can be a barrier. If they don't understand the purpose of a clinical trial or why they have to receive treatment even if they feel okay, it complicates things.
 - The amount of paperwork required for patients on a CCT vs. a regular cancer patient is very different.
 - Most patients are adjuvant, but there just aren't that many adjuvant trials out there.
 - As a private practice cancer center it's difficult to have many trials open.
 - Sometimes treatment needs to start immediately, but the process of enrolling a patient in a trial can take a few weeks.
 - There are some trials that physicians just don't believe in or think provide good treatment.
 - She stated that something we could do to help the physicians is to have an updated sheet of the different trials that is kept in the exam rooms. Physicians aren't always on the computer when they're with the patient, and they don't

usually look at Pathways until after already discussing treatment options with the patient.

- I observed that some patients do not speak English or do not speak it well, and as always this is a barrier to enrollment when we don't have Spanish-speaking physicians on the 1572 that are available 24/7 for trial patients.
- Attended the SIV for a new study via teleconference. Reviewed the background, protocol, reporting of AEs and what constitutes a SAE, unblinding patients when necessary, investigator obligations, lab kits and sample processing, data management and EDC system, randomization, and drug information.

Week 7: September 30 – October 4

Monday, September 30, 2013

- Dr. Mandell does not have time to meet with me, so I emailed him asking 1) What he, personally, felt were barriers to enrollment at CCBD, and 2) What the research department could do to help physicians enroll patients.
- Attended a study audit meeting with the data coordinator and research manager. It was decided that I most likely handle the audit with the exception of verifying data, since one of the coordinators has to do it.
- Created an excel spreadsheet for AEs since the study is all paper forms, with a tab for each patient. Recorded the following information about each AE: patient no., AE running log page, event, start date, grade, serious (yes or no), outcome, intermittent (yes or no), action taken, most likely cause, and whether any significant medication was administered to treat the adverse event.

Tuesday, October 1, 2013

- Finished filling in the AE excel spreadsheet that I started yesterday. Emailed to the data coordinator and research manager.
- Attended three research meetings today.
 - Discussed the site management plan, which details the roles and responsibilities
 of the research staff and SCRI and that we follow SOPs. We also discussed
 monitoring guidelines, including the hours available for monitoring and
 scheduling, how we will accommodate having two monitors visit on the same
 day, how monitors will be able to meet with PIs that are not at the Fort Worth
 campus, and that monitors should not be allowed to bring portable scanners or
 move freely in the research department and ask everyone questions.
 - Discussed the research databases, and the need for separate databases for each role in the department. We also need databases specific for each patient and study. We need a way for grade 3 or higher AEs and SAEs to update automatically.
 - Discussed response evaluation criteria in solid tumors (RECIST) calculation, including the baseline calculation that adds up all of the tumors using longest diameter, the new sum of diameters, and the smallest sum of diameters (nadir). We need a new excel form that can do these calculations for the coordinators and monitors when raw data is entered.

- Uploaded source data to the network to be emailed to the monitor as requested and filed correspondence into patient charts.
- Marked labs for CS or NCS designation and filed information into patient charts, including updated informed consents.

Wednesday, October 2, 2013

- Worked on my research proposal in the morning.
- Attended 3 meetings in the afternoon.
 - In a meeting between the manager, data coordinator, and research coordinators, we discussed new toxicity assessment sheets as requested by one of the principal investigators (PI). The new forms will allow the patients to fill out their AEs and address expected side effects for specific drugs. Problems are that other physicians may not want to use the new form, it may be difficult for the coordinators to learn how to transfer information to source documentation, and asking about specific AEs may lead to a response bias.
 - In the weekly research department meeting with Dr. Page, we discussed two studies that are closing at the next interim monitoring visit (IMV), upcoming pre-SIV and SIV meetings, and two prescreens for a new study. We also discussed that patients on one arm of a study are doing very well, and patients on the other arm aren't improving at all, and when it becomes unethical to keep the ones who are not improving on that arm of the study. Also talked about how having staff that are new to oncology can be a barrier by deterring patients who have low confidence in the competence of their provider. Another barrier we talked about was that if a study is not appropriately placed in Pathways, it's a big barrier to enrollment because physicians won't be able to see it as a treatment option.
 - The CCBD research department and SCRI program development (study start up), budget, and contract departments had a teleconference meeting to do an overview of program development and SCRI's role as a bridge between CCBD and the sponsor or CRO. CCBD brought up the issues of blinding requirements, which limits the sites we can open studies at because of limited staff and is an enrollment issue.

Thursday, October 3, 2013

- Helped answer queries about cardiac adverse events (CAE).
- Sat in on the four weekly research meetings with the clinical research manager.
 - Data: Recent follow-up letters, confirmations, monitor notes, study drug administration, billing for standard procedures vs. non-standard study procedures, PI meetings with monitors, and patient drug diaries.
 - Regulatory: Major deviation and the corrective and preventative action (CAPA) plan, physician and physician assistant Collaborative Institutional Training Initiative (CITI) training certificates, the site management plan and editing SOPs, getting EDC access and lab kits before SIVs, tumor board, timers for chemo nurses to use with research infusion times, fee ticket. Barrier: As a private

practice clinic, there may not be processes and regulations to keep people accountable at the level that sponsors expect.

- IP: Dose reduction.
- Coordinator: Patient drug diaries, patient compliance and deviations, site management plan, monitoring guidelines, database forms, uploading documents into the EMR, having a backup person for the pharmacy technician, infusion times, AEs and conmeds, documentation templates.
- Placed scan requests into study binders and checked if a patient had signed a revised informed consent.
- Worked on research proposal.

Friday, October 4, 2013

- Mailed information to a sponsor.
- Added DCFs to 3 patient binders.
- Filed labs and other data into patient charts.
- Assisted in filling out CRFs. Measured responses from a Lung Cancer Symptom Scale (LCSS) subject scale and helped fill out long term follow up sheets.
- Participated in fire drill. The responsibility of the research department is to go to the chemotherapy department and help patients exit the building.
- Learned how to complete an inventory of the remaining lab kits for a closing study and dispose of the lab kits properly.
- Put away a shipment of new lab kits in the proper study area.
- For a new study, created a label for the study area and stored the lab kits.

Week 8: October 7 – October 11

Monday, October 7, 2013

- Prepared for the monitor visit tomorrow by going through the confirmation of IMV letter. Addressed all follow-up items and any actions required, which primarily were concerned with AEs and training log documentation. I used the EMR, patient charts, and study folders to address these items.
- Typed up all paper AEs for the patients on the study being monitored tomorrow into an excel sheet. Recorded term, whether or not the AE is an injection site reaction, AE no., start and stop dates, if the AE occurred before or after that day's administration of study drug, grade/severity, relationship to investigational product, action on study drug, other actions, outcome, and whether or not the AE was an SAE.
- Printed off all the physician, research, and nursing notes for the patients on this study so I can do an internal audit.
- Dr. Mandell emailed me back about barriers to enrollment.
 - Barriers: Traditionally CCBD has had very few studies available for malignant hematology patients. The studies here have often been for exceedingly rare diseases (e.g. T-Cell lymphomas) or have had poor study design so that either almost no patient qualified or the control arm offered substandard care.

 Solutions: It would be helpful to have some form of email reminder maybe every 1-2 weeks to see what current studies actually are, which would only help if there were reasonable studies open to put patients on. There should be an easy way to check current study status.

Tuesday, October 8, 2013

- Started an internal AE audit by going through the notes and the typed AEs from yesterday, which span the 4 years the study has been open at this site. I searched for any discrepancies, marking them in the printed notes. I highlighted mentions of AEs in the printed notes and typed any questions or discrepancies into a Word document for review, which mainly included more recent AEs that had not yet been documented.
- Started monitoring data for three patients on one study by comparing data in the EDC with information in the patient charts to make sure everything matches. I took notes on any discrepancies to give to the data coordinator.
- Attended SCRI meeting via phone.
- Completed the CITI training for graduate students.

Wednesday, October 9, 2013

- Completed the task of monitoring data that I started yesterday. I also used the EMR to monitor items that were not printed and in the patient charts.
- Completed the CITI training for biomedical-clinical research personnel. Thursday, October 10, 2013
 - Continued the task of doing an internal AE audit. Typed up my notes for the research manager to review.
 - Typed up notes from past internal AE audit and printed for the manager because handwritten notes were difficult to read.
 - Completed the CITI training for social-behavioral research personnel.

Friday, October 11, 2013

• Continued the internal AE audit. Added to my notes for the research manager to review.

Week 9: October 14 – October 18

Monday, October 14, 2013

- Continued the internal AE audit I worked on last week. I worked on the same tasks of reading notes and the recorded AEs, searching for any discrepancies between the notes and recorded AEs and marking and highlighting them in the notes, and typing up discrepancies and additional AEs into a Word document for later review.
- I placed the printed notes into binders for each patient to make it easier for the research manager and study coordinators to review.

- Attended the pre-SIV meeting the new study that I organized lab kits for last week. We are not having an SIV because the manager and PI attended the investigator meeting.
 - Phase 2 and phase 3 study looking at 1st line metastatic disease.
 - May try marketing the trial. For example, could send a CCBD physician letter to surgeons and referring physicians.
 - The drugs are provided in Canada because of universal healthcare, but the sponsor does not provide the drugs in the U.S. because they are commercially available. Same situation for another study and Europe.
 - When reporting SAEs, physicians just need to summarize the event and we don't need to send source documents and medical records.
 - Need to see if IRB will allow approval of the phase 2 and 3 together, even though they have separate informed consent forms.
 - Every visit is registered so it's possible to run reports for the physicians, such as a study summary report that will show the number of patients screened and enrolled at all sites.
 - Other sites are contracting with pathologists and radiologists to notify patient's physicians when the patient has a pathology that may make them eligible for a trial. We may try to do the same.
 - This study has travel reimbursement for patients, so we will have to figure out how to address that with patients and the billing office.

Tuesday, October 15, 2013

- Finished the internal AE audit and gave my notes to the clinical research manager.
- Started working on the paperwork for my research project so that when my proposal is approved by my entire committee I can move on to getting IRB approval.
 - Determined that my project falls under the exempt category review of research studies due to the fact that it involves the collection and study of existing data, and a survey.
 - Planned to submit a cover letter in lieu of informed consent, unless instructed otherwise. Started working on the cover letter.
 - Began finding examples of past surveys similar to the one I want to implement to use as templates as my data collection tool. Started designing my survey.
 - Need to find out if I have to apply for a waiver of documentation of informed consent if I'm using a cover letter, and if I need to request a waiver of HIPAA authorization for studies involving protected health information.

Wednesday, October 16, 2013

- Sat in on conference call for one trial's data, addressing queries and an upcoming data freeze.
- Put together the patient chart for a new research participant.
- Assisted one of the research coordinators in reviewing my notes and filling in CRFs for the internal AE audit for two patients.
- Placed documents, such as informed consent forms, AE logs, and fax acceptances into patient charts and study binders.

- Filled out the CRFs using the LCSS and EDQ5, which are measurement tools for patientreported quality of life, that a patient came in and filled today. I measured his responses with a ruler and recorded the responses on the forms, and then placed the forms in the patient's study binder.
- Sent a reminder email to my committee members to review my research proposal.
- Helped the data coordinator in updating AEs in the EDC for three patients on two studies.

Thursday, October 17, 2013

- Assisted in entering data into the EDC for three patients on the same study. I used paper source documents, such as urinalysis results, patient questionnaires, and patient drug diaries, as well as information in the EMR to fill out the forms. I then put the paper sources into the patient's charts.
- Sat in on the data meeting with the research manager. Discussed scheduling monitor meetings with the PIs, the new RECIST and AE assessment forms, the two studies that are closing soon and need to have their data cleaned, the monitoring issues that I identified last week, and ways to get radiologists to focus on target lesions specifically for research purposes.
- Marked printed labs for the physician's to designate at CS or NCS and placed them in their folders to review.
- Edited my research proposal based on the feedback I have received so far. I shortened it by taking out repetitive statements, provided more examples from the literature, expanded on my study question, and included how many subjects I expected to participate. By request, I also added what the appropriate percentage of patients enrolled in CCT should be. I emailed Dr. Page and talked to Melissa Sottosanti about expanding the focus of my paper from just barriers to enrollment from a physician's perspective to increasing enrollment at a community-based cancer clinic.

Friday, October 18, 2013

- Finished editing my research proposal for now. Emailed the revised draft to my research committee to review.
- Boxed up all study materials for a study that has recently closed. Noted the barcode, study, and contents of the storage box for when the box goes into off-site storage.
- Inventoried all the remaining lab kits, totaling 53, for a study that has recently closed.
- Assisted the regulatory coordinator in filling out an annual site progress report to be sent to the sponsor. I learned that it has been difficult to find any patients that are eligible for the study because they have to be first line stage IV lung cancer, whereas most patients with advanced cancer have received previous treatment and the stage IV is due to disease progression or metastatic disease.
- Attended a head shaving fundraiser event being held at CCBD.
- I properly disposed of the lab kits that I inventoried earlier. I also checked all the lab kits in the research department to see if they were expired or near the expiration date. I let the regulatory coordinator know so she could order new ones and I disposed of the expired ones.

Week 10: October 21 – October 25

Monday, October 21, 2013

- Answered monitor queries for two patients on the same study in order to clean the data for an interim data analysis. The queries mainly asked about start and end dates for AEs, the AE relationship to the study drug, and chemotherapy doses given. I had to look in their study binders, patient charts, and research notes in the EMR to find the answers. Afterward I consulted with the data coordinator to send the information to the monitor through an email.
- Attended the Research Strategic Planning Retreat, where the research department met to discuss department goals and individual goals.
 - No clinic support, lack of knowledge and research training, binders not having everything, enrollment is top priority (hiring research nurses increased enrollment), what is needed before or when we get new studies.
 - Developing SOPs and site management plan, working practice guidelines, changing the culture here to that of a research clinic where everyone feels responsible for their part in research, research should be standard of practice, financial counselors and billing department discussing what is covered for patients, utilizing patient coordinators and navigators for prescreening.
 - Barriers to enrollment: patients are ineligible or decline (ex. for timing of study treatments and wanting to take a break for a vacation), patients don't like the word "placebo" and doctors and nurses approach the subject differently, new staff not understanding prescreening vs. enrollment process, physicians not feeling the research department is well staffed or knows what it's doing, SCRI as a potential barrier in getting EDC access and communication between us and the sponsor.

Tuesday, October 22, 2013

- Printed off notes from the EMR for ten patients in order to do an internal audit. I looked in the study protocol to find out how long AEs should be followed after study treatment, which is 18 months after randomization. I then checked the patients' charts to look for their randomization or registration date, and printed off the notes from that date until 18 months after.
- I went to the Weatherford clinic to follow the research coordinators in seeing patients. Discussed the role of coordinators and barriers they face.
 - Coordinator responsibilities are patient enrollment, documenting inclusion/exclusion criteria, making sure everything is verifiable in source, scheduling scans and labs within the protocol window, reviewing scan and lab results, addressing open AEs with the patient, patient follow up, communicating with other staff, being organized and knowing the protocols well.
 - The difference in training for an LVN vs. an RN may cause problems in research because RNs typically have more clinical skills, such as being able to read scans, and may be more detail-oriented.

- At one of the CCBD sites, the physicians feel that patients should only be on studies if they have to be. For example, only if there is no other treatment or patients that couldn't pay for treatment otherwise.
- Technology is a barrier for some staff because almost all research data and patient information has to be entered into the sponsor's EDC.
- Barriers for study coordinators include inadequate staff to handle non-patient tasks, a lack of support from the non-research staff, and inadequate research training and education for nurses in school. Solutions might be hiring staff to handle other tasks, to build relationships with the rest of the clinic, and to teach necessary research skills to all nurses.
- A barrier for a community-based clinic is that everything a sponsor requires to be done might not regularly get done, such as taking respiration rate. This can be fixed through communication with other staff members.

Wednesday, October 23, 2013

- I began the internal AE audit for the study I printed notes off for yesterday. I made copies of the toxicity assessments from the patient's chart and a copy of the AE reporting requirements from the study's protocol. I also typed up all the AEs on the paper CRFs in the patient's study binder and printed them out. I organized everything into a binder and started going through the notes, highlighting AEs and typing them into a Word document for the coordinators to review later.
- I answered three DCFs using paper CRFs for a different study. The PI needs to sign off on the DCFs before they can be sent to the sponsor.
- Attended the weekly research department meeting.
 - We discussed a physician that has stated that our department refuses to enroll his patients; however, he has only referred two patients in recent years and neither could enroll.
 - We want to get more hematology studies open here. We mostly have breast cancer studies, and some GI and lung.
 - There is a lack of support from other clinic departments. The president or CEO of the clinic may need to step in and emphasize the importance of research and what happens when we don't follow study protocols.
 - One of the coordinators has been screening all patients at CCBD, however she has not found any eligible subjects this way.
 - We have had sponsor audits because of enrolling many patients, but is possible that the FDA may audit us one day due to deviations.
 - We no longer have studies that are not through SCRI, our CRO. A problem with this could be that if anything happened to SCRI or they no longer wanted us as one of their strategic sites, research would shut down at CCBD temporarily.
 - We need to get study treatments onto Pathways so physicians can see that they are an option and put patients on that Pathway as their treatment.

Thursday, October 24, 2013

• I continued the internal AE audit with the second patient.

- Attended the weekly data meeting.
 - Discussed contacting the monitor for a new study we just enrolled our first patients to, follow-up letters and monitoring notes, open action items, issues with co-monitors and the monitoring guidelines, the status of ongoing internal audits, drug diaries for a study with three oral drugs and IRB approval of the diary, printing patient calendars, the finished site management plan, database update, access to study EDC systems, SAE reporting to the IRB, and suggestions from SCRI on how to meet with monitors and address issues.
- Filed signed, revised consent forms and other forms into patient charts.
- Assisted in entering data for two patients into the EDC.

Friday, October 25, 2013

• I continued the internal AE audit with the third patient.

Week 11: October 28 – November 1

Monday, October 28, 2013

- Edited my research proposal using the feedback from Dr. Page. Sent a reminder email and revised draft to the committee members I haven't heard from.
- Continued the internal AE audit with the fourth patient.
- Put away patient charts.

Tuesday, October 29, 2013

- Placed source documents, primarily correspondence, into patient charts.
- Verified that the items listed in several monitoring clarification forms have been completed or corrected in the EDC and source documents.
- Verified that AEs have been entered for a patient at the suggestion of a monitor.
- Continued the internal AE audit with the fifth patient. Decided to stop taking notes but will continue highlighting, since the protocol guidelines for reporting AEs for this study are very specific and the coordinators will have to review the source documents themselves.

Wednesday, October 30, 2013

- Read the article Melissa Sottosanti sent me on how doctors at Penn are increasing enrollment by spending more time discussing clinical trials with their patients.
- Read two articles Dr. Page sent me about the effect of medical oncologists' attitudes on accrual to clinical trials in a community setting and the NCI recommendations on increasing accrual. I plan to include some of the recommendations into my survey.
- Continued the internal AE audit with the sixth patient. Started marking AEs of special interest to make it easier for the coordinators to review.
- Sat in on a study close out visit via phone call with the PI, research manager, and regulatory coordinator.

- No patients were enrolled on the study, and other sites only had 1-2 patients.
- Discussed the location of archives for documents, copies of the monitor visit log and site delegation log, confirmation of the destruction of lab kits, notification of closeout to the IRB, submission of IND safety reports, update financial disclosure forms and CVs and medical licenses.
- \circ $\,$ Need to remove the study as a treatment option from Pathways.
- Attended the weekly research department meeting. Discussed having a social with the chemo nurses to discuss research, the upcoming research dinner in December, and strategic planning. Dr. Page and Melissa Sottosanti will have me give a presentation on enrollment at the next research dinner in February in order to educate the CCBD physicians and to let me practice for my defense.

Thursday, October 31, 2013

- Attended the weekly data meeting. Discussed queries, data locks, pending close-outs, upcoming IMVs, follow-up letters, outstanding data, EDC access, and issues with individual monitors.
- Continued internal AE audit with the seventh patient's data.
- Disposed of the lab kits for the study that closed.
- Observed one of the study coordinators and nurse practitioner handle an infusion reaction in the chemo room. Afterwards I reviewed the study protocol with the coordinator to go over the steps involved in handling the AE and whether or not it qualified as an SAE.

Friday, November 1, 2013

- Followed up about the patient yesterday. The PI confirmed that it was an infusion reaction, but the patient was not admitted to the hospital so it was not an SAE.
- Continued the internal AE audit for the 8th patient.

Week 12: November 4 – November 8

Monday, November 4, 2013

- Continued the internal audit with the 9th and 10th patients' source documents.
- My research proposal has finally been approved by my entire committee. I prepared my proposal, research proposal form, and intent to graduate form in order to get them signed and submitted in the graduate school.

Tuesday, November 5, 2013

• Attended a presentation that Dr. Page gave to the pharmaceutical representatives titled "Affordable Care Act and Other Policies: Impact on Cancer Patients." Dr. Page discussed several pressures that have affected oncology, including measurements of quality care, reimbursement, the individual mandate, and changes to the doctor-patient relationship.

- Boxed up a study that recently closed, noting the bar code, contents, and start and end dates for the two year requirement to keep study documents on site.
- Filled out a site progress report with the regulatory coordinator.
- Reviewed AE and SAE reporting in a protocol and the case report form completion guidelines in order to assist the data coordinator in filling out CRFs.
- Sat in on a SCRI meeting via phone, which is now held every other week. We discussed recent screenings and enrollments.

Wednesday, November 6, 2013

- Began the internal AE audit for the 11th patient. The patient's binder is currently off-site so I will complete it at a later time.
- Left the clinic early in order to travel to my interview.

Thursday, November 7, 2013

- Did not go into the clinic today due to an interview out of town.
- Found articles online that Dr. Page requested.

Friday, November 8, 2013

- Went to campus to get Dr. Wordinger to sign my proposal form.
- Sat in on part of a global site training conference call for a newly opened breast cancer study.
- Answered three data queries for two patients using CRFs and LCSS books.
- Completed the internal AE audit for the 12th patient.
- Worked on the provider survey for my research project.

Week 13: November 11 – 15

Monday, November 11, 2013

- Continued preparing my documents to submit to the UNTHSC IRB, primarily working on the provider survey.
- Went to campus to get Dr. Dory to sign my proposal and intent to graduate form.
- Observed a lab kit for a new patient being completed and shipped.
- Sat in on a call with a monitor to discuss follow up items, such as protocol for when a patient is extended on the trial, the systems required on a new patient physical, and timing for submitting SAEs.
- Prepared a patient's chart for a monitor visit tomorrow.
- Prepared the documents for the last two patients I need to do an AE audit for.

Tuesday, November 12, 2013

• Dropped off my intent to graduate form at the front desk at Dr. Gwirtz's office.

- Attended the Fit Worth walk on the lawn outside of the clinic.
- Filed the source documents for recently entered data.
- Completed the internal AE audit for the 13th patient.
- Continued working on my IRB documents, including the IRB application and provider survey.

Wednesday, November 13, 2013

- Completed the internal AE audit for the 14th patient. Went back and completed the audit for the 11th patient now that we have the binder on site, which concludes the internal AE audit for this study.
- Continued working on my IRB documents, including the cover letter (in lieu of informed consent) and the application for a waiver of written informed consent.
- Checked the EMR to make sure the hospital discharge documents were scanned into the system for two patients. Faxed documents that I did not find in the EMR downstairs and requested for them to be scanned into the system.

Thursday, November 14, 2013

- Attended the weekly data meeting with the data coordinator and research manager. We discussed baseline diagnoses, AEs, queries, filing major and minor deviations, old monitoring notes, the AE audits and CRFs that need to be filled out and signed off on, and how the insurance exchanges are affecting CCBD.
- Assisted in finding source documentation of two drugs that were entered into the EDC for the monitor.
- Worked on my healthcare provider survey.
- Turned in my signed and completed research proposal and evaluation form.

Friday, November 15, 2013

• Did not go to the clinic today due to an interview in Dallas.

Week 14: November 18 – November 22

Monday, November 18, 2013

- Set up a monitor in the small conference room and assisted in escorting the monitors in the clinic throughout the day.
- Made two charts for new research patients and filed their current documents.
- Highlighted abnormal lab values and marked them as CS or NCS for the physicians to review.
- Filed a note to file about a patient's new address in that patient's chart.
- Worked on the required documents to submit to the IRB.

Tuesday, November 19, 2013

- Highlighted abnormal lab values and marked them as CS or NCS for the physicians to review.
- Assisted in setting up the monitors for today and escorting them within the clinic throughout the day.
- Located and scanned an EKG straight to email for a study coordinator at a different site.
- Sat in on a SCRI call, where we discussed studies that the PI has accepted, studies that are pending and open, patient screening at our sites, and enrollment updates.
- Helped prepare the patient charts for tomorrow's study monitors.
- Looked up the use of a drug that was entered onto a concomitant medication sheet to answer a query on why it was prescribed.
- Continued preparing my provider survey.

Wednesday, November 20, 2013

- Assisted in escorting the study monitors throughout the day.
- Attended a phone call PSV for a triple negative breast cancer study that is opening soon with the PI, manager/lead coordinator, and regulatory coordinator. Discussed the assigned coordinators, EDC, data manager, ALCOA (attributable, legible, contemporaneous, original, and accurate) principles for source documentation, IP and pharmacy, potential advertising for the study, the main CCBD and three satellite sites that will be participating, monitoring, long term storage, IP shipping, the local STAT lab, our centralized IRB through SCRI, and GCP training. The PI addressed an eligibility issue where patients must have had a adjuvant therapy that is not standard care, which reduces the potential study population.
- Prepared documents and labs that physicians have signed off on for the data manager to enter into the EDC.
- Added source documents to a patient chart for a monitor to review.
- Prepared AE CRFs for a physician to sign off on.
- Scanned several study documents to the data manager's email.
- Learned about how to look up current amendments of study protocols and signing off for drug that has been received at our site.
- Assisted in making drug labels using the protocol that give instructions on infusion time and the order the drugs need to be given.

Thursday, November 21, 2013

- Attended Toke Omiwade's internship practicum report presentation on campus at 1pm. The title of her report is "Efficacy of Alcohol-Impregnated Port Protectors for the Prevention of Central Line-Associated Blood Stream Infections in Intensive Care Units."
- Did not go into the clinic today. Worked on my IRB documents in the library between and after the practicum report presentations.

Friday, November 22, 2013

- Properly disposed of lab kits that I previously inventoried for a study that recently closed.
- Placed source documents into patient charts, and put up patient charts for the data manager.
- Put away the charts and regulatory binders that were monitored yesterday.
- Organized the patient charts in the ECU (eternal care unit) filing cabinet and relabeled the drawers.
- Worked on my IRB documents.

Week 15: November 25 – November 29

Monday, November 25, 2013

- Registered for the internship practicum course for the Spring 2014 semester. Emailed the UNTHSC Office of the Registrar about the number of credit hours.
- Assisted the regulatory coordinator in recording research department finances. I recorded the check number, amount, date, and reason for payment from sponsors. Also recorded reimbursement for required study procedures that were not covered by the patients' insurance. I placed the copies of the checks and any letters that came with them in study-specific folders.
- Made finance folders for recently opened studies.
- Prepared protocol addendum copies for the PI and sub-Is to sign and date, and placed them in their research folders.
- Sat down with the research manager to talk about Medicare, Medigap, and Medicare Advantage coverage of clinical trials. 10 million patients in the U.S. use Medicare Advantage, which does not cover the cost of clinical trial treatment even if it is standard care. If these patients switch to regular Medicare in the middle of the contract year, they cannot get Medigap, which covers most of their 20% copay required with Medicare. Due to the expensive nature of surgery, radiation, and chemotherapy, this means that almost all Medicare Advantage patients choose not to enroll in clinical trials because of this financial barrier.

Tuesday, November 26, 2013

- Contacted Itzel Peña Pérez and Amanda Oglesby in the UNTHSC IRB office to clarify some aspects of the IRB application, such as whether I need to apply for a Waiver of Informed Consent or Waiver of Documentation of Informed Consent if I plan to use a cover letter with my survey.
- Worked on my IRB documents, including the healthcare provider survey, exempt review application, and cover letter.
- Assisted the data manager with filing study discontinuation, drug dispense, and deviation forms into patient charts. Also helped with entering data into an EDC.
- Assisted the regulatory coordinator with finding dates of employment for the research staff and learned where to find that information in physician CVs and delegation of authority (DOA) logs.

Wednesday, November 27, 2013

- Worked on my provider survey today, and came up with the categories and constructs I want to use in my data analysis.
- Helped enter data for one study visit for one patient, and two study visits for a second patient on a different study.
- Assisted in placing reviewed labs, questionnaires, patient drug diaries, target tumor assessment forms, and laboratory requisition forms into patient charts.

Thursday, November 28, 2013

• Did not go into the clinic today due to the Thanksgiving holiday.

Friday, November 29, 2013

• Did not go into the clinic today due to the Thanksgiving holiday.

Week 16: December 2 – December 6

Monday, December 2, 2013

- Completed my IRB documents. Since my project will require informed consent that I will have to submit a protocol summary, so I began working on that.
- Began an audit of regulatory documents and patient charts to locate an original signed informed consent. I went through all the patient charts for that and all the signed ICF copies in the regulatory binders, but did not find the missing ICF.

Tuesday, December 3, 2013

- Made drug labels for two studies, for seven drugs total, with the IP coordinator. Printed labels for 17 drugs.
- Continued to audit patient charts, looking for the ICF from yesterday. Reviewed all the data manager's unfiled documents, followed by the regulatory coordinator's. Did not find the ICF.
- Created lists of currently open studies to laminate and place in each exam room to make it easier for physicians to quickly review them when talking to a patient.
- Sat in on the SCRI teleconference meeting. Discussed pending and active studies, the patients we have in screening and recent accruals, and gathering information on the top three reasons why patients pre-screen fail.

Wednesday, December 4, 2013

- Prepared source documents for the data coordinator.
- Began reviewing each research patient's chart starting with the active patients. Audited all the active patient charts and half of the deceased/ECU patient charts, and did not find the ICF.

- Attended the quarterly CCBD research committee meeting, where an SCRI representative gave a presentation titled "FTW CCBD and SCRI Collaboration." She discussed the strategic sites, that CCBD has contributed to 40 research projects that have been published and that we have been opening one new trial a month. She also emphasized the importance of CCT, stating that compared to past years an AACR report said there are one million fewer cancer deaths, 14 million cancer survivors, and 11 new drugs, three new imaging technologies, and three new approved uses of drugs. She also discussed the delegation of authority, PI responsibility, audits, how studies are becoming more specific due to molecular and genetic testing, offsetting the expense of opening a trial with the fact that specific trials will only enroll 1-2 patients per site, and how deviations are used as a measure of quality.
- Attended the quarterly CCBD research dinner, where the focus was study metrics and regulatory. We discussed using double review of patient eligibility, prescreening using Pathways and utilizing Pathways monthly reports, chemo nurse training and research instructions, increasing trial complexity, the Affordable Care Act and insurance coverage of clinical trials, increased regulatory hurdles, the increased productivity required, wanting to increase awareness of clinical trials in the community, how to make enrollment easier, and that we need to offer a broad assortment of clinical trials.

Thursday, December 5, 2013

- Finished going through the deceased patient charts and did not find the ICF.
- Finished my IRB application, application for waiver of documentation of informed consent, cover letter, survey, and protocol synopsis. Once my survey has been reviewed by Melissa and Dr. Page I will send them to Dr. Gwirtz to submit to the IRB.

Friday, December 6, 2013

• The CCBD clinics were closed today due to bad weather, so I did not go into the clinic today.

Week 17: December 9 – December 13

Monday, December 9, 2013

• Did not go to the clinic today due to an interview.

Tuesday, December 10, 2013

- Created more lists of the open studies for December to put in exam rooms.
- Put away the charts that the monitor and auditor reviewed yesterday.
- Assisted in collecting data from source documents in the EMR and recording it on paper CRFs for a new research patient's pre-treatment and first treatment visits.
- Worked on my provider survey by removing unnecessary items in order to make it a more reasonable length and incorporating the changes that Melissa and Dr. Page suggested.

- Contacted one of the new patient navigators in order to find out if patients were given research education materials when they first come to the clinic.
- Got my letter of agreement signed, which says that CCBD acknowledges and approves of my research project.
- Continued reviewing patient charts, searching for the original ICF from last week. I audited one fourth of the follow up patients, which are the majority of research patients at CCBD, but did not find the ICF.

Wednesday, December 11, 2013

- Went to the front desk and made a copy of the patient notebooks that new patients receive when they first come to the clinic and speak with a patient navigator. Discussed with the research manager how patient education materials could be added to the binder to increase patient awareness of clinical trials.
- Continued editing my provider survey by incorporating the changes Melissa and Dr. Page suggested. I also re-wrote my survey cover letter to make it more clear and concise, and edited my IRB application and other documents to reflect any changes I might have made.

Thursday, December 12, 2013

• Did not go to the clinic today due to an interview.

Friday, December 13, 2013

- Finished editing my provider survey. I brought signed hard copies of my IRB application documents to campus for Dr. Gwirtz to sign and submit.
- Audited most of the remaining follow up patient charts, but did not find the ICF.

Week 18: December 16 – December 20

Monday, December 16, 2013

- Submitted my application and required documents to the UNTHSC IRB.
- Reviewed the last of the follow up patient charts but did not find the ICF.
- Downloaded the newest version of StatPlus, which is a statistics software for Mac computers that works with data in Excel. I also reviewed the StatPlus tutorials online for descriptive statistics, comparing means, polynomial regression, rank correlations, and ANOVA.

Tuesday, December 17, 2013

• Attended a PSV for a phase 3 pancreatic cancer study. We discussed the research staff, drug transport between sites, information about the PI and sub-Is, the EDC and EMR, IP, data, SOPs, GCP training, monitoring, and the number of patients CCBD can feasibly enroll a month.

- Dr. Xiong identified barriers to enrollment for this study in that the study requires frequent scans and types of scans that aren't standard practice, which insurance won't pay for. Also CCBD is a community-based practice that isn't affiliated with any surgeons or pathologists and therefore will have a hard time getting referrals without help for outreach, such as through a sponsored physician dinner meeting. CCBD also doesn't enroll uninsured patients.
- Attended the SCRI call and discussed study leads, pending studies, open studies, patients in screening, enrollment, and any issues with monitors.

Wednesday, December 18, 2013

- Attended a PSV for a phase 3 breast cancer study, where we discussed how many patients with certain criteria are seen a month between the four participating CCBD sites.
- Began working on my thesis draft, using the UNTHSC preparation and electronic filing of dissertations (2012) document and my research proposal as a guide.
- Attended the weekly research department meeting. We discussed the social with the chemo nurses, the next research dinner, issues with dry ice and shipping samples from satellite sites, the requirement for EKGs in some studies, presenting accrual numbers by physician at board meetings, incentivizing physicians to increase enrollment, and patients that are ineligible for studies such as prisoners.

Thursday, December 19, 2013

- Re-registered for the internship practicum course in the spring with the correct number of semester credit hours.
- Continued working on the introduction and background sections of my thesis.
- Filed documents into patient charts.
- Assisted the data coordinator in answering data queries for an old study.
- Helped put away the charts and regulatory binders that were monitored today.

Friday, December 20, 2013

- Created drug labels for a lung study and printed them for the IP coordinator.
- Entered adverse events for two patients onto CRFs and added corrections for adverse events based on an audit. I flagged the pages with corrections or new information that needed to be faxed.
- Continued working on the introduction and background sections of my thesis.

Week 19: December 23 – December 27

Monday, December 23, 2013 – Friday, December 27, 2013

• Did not go to the clinic this week due to the Christmas holiday.

Week 20: December 30 – January 3

Monday, December 30, 2013

- Starting today I will only be coming into the clinic in the mornings so I can work on my thesis in the afternoons.
- Began searching for a matching patient to an EQ-5D health questionnaire that is not in a patient chart. I started with all the CCBD patients in a specific area code from the questionnaire and narrowed it down to just female research patients. I then narrowed down the list by age but could not find a matching patient.

Tuesday, December 31, 2013

• I continued searching for the patient that matches the EQ-5D. I utilized a list of research patients that had registered for a study in the past few years, cross checked those patients in the EMR for age and gender, and then checked with the study protocols on site and on clinicaltrials.gov to see if they required an EQ-5D. I narrowed down the list to three patients; however, the documents for those closed studies are kept at the Weatherford site so I am not able to narrow it down any further for now.

Wednesday, January 1, 2014

• The clinic was closed today for New Year's Day.

Thursday, January 2, 2014

- I learned how to check and complete quality measures in the EMR from the head of the IT department, who gave me a list of CCBD patients to check measures for. Clinical quality measures (CQMs) measure many aspects of patient care, including health outcomes, clinical processes, patient safety, efficient use of healthcare resources, care coordination, patient engagements, population and public health, and clinical guidelines. More specific examples of CQMs are whether or not visits were completed within a certain time frame, or whether or not certain cancer screenings were performed for at risk patients. Tracking these measures helps ensure that patients are receiving effective, safe, efficient, patient-centered, equitable, and timely care.
- I checked and completed quality measures for 165 patients.

Friday, January 3, 2014

• I continued to check and complete CQMs in the EMR. I checked and completed the quality measures for 195 patients from the list I was given yesterday.

Week 21: January 6 – January 10

Monday, January 6, 2014

• I continued to check and complete CQMs in the EMR. I checked and completed the quality measures for 140 patients, finishing the list I was given last week.

Tuesday, January 7, 2014

• I reorganized the documents in several patient charts. I made sure the documents were in the right place and in chronological order. If there were any data clarification documents I attached them to the original source documents that they referred to, and if there were central lab documents I attached them to the local lab and shipping documents.

Wednesday, January 8, 2014

- Set up the monitoring room for today. I pulled the charts, regulatory binders, CVs, and certifications for the three studies that are being monitored today and set up the computer.
- Attended the weekly research department meeting. Discussed pending protocols, possible advertising for clinical trials, identifying patients through pre-screening, SAE reporting, the patient population at Arlington, and specific protocols.
- For a breast cancer study that recently closed, I placed all the study documents and patient charts into a storage box to be kept on site for two years.
- Replaced a protocol for two studies with the most recent protocol addendums, and stored the old protocols in separate binders. I also created new regulatory binders for those studies and the old protocols.

Thursday, January 9, 2014

- I scanned my IRB approved study documents and printed copies of the cover letter and survey.
- Reorganized all the binders for a study with paper CRFs.
- Assisted in entering data from four follow up visits.

Friday, January 10, 2014

- Attended the weekly data meeting, where we discussed SAE submission, RECIST reads, recent data audits, tracking AEs for FU patients, AE logs, and scans.
- I met with the clinical research manager to arrange to send the surveys out to the potential study participants through the CCBD mail courier system. I put together and labeled the envelopes to be sent containing the cover letter, survey, and pre-labeled return envelope and put them in the mail box to be picked up Monday.
- Attended an amendment training presentation for a breast study protocol.

Week 22: January 13 – January 17

Monday, January 13, 2014

• I was sick today and did not go into the clinic.

Tuesday, January 14, 2014

- Assisted in completing two DCFs for a paper study. I also filled out the information for an additional follow up visit for database reconciliation as suggested by the monitor.
- I changed and added AEs using a study coordinator's final notes from an AE audit for a patient on a paper CRF study.

Wednesday, January 15, 2014

- Escorted the monitors for today to the research department.
- I finished changing and adding AE information for the paper study and marked any changes that needed to be faxed for the sponsor.
- Attended the weekly research department meeting, where we discussed that the focus of the next research dinner is enrollment, how the study coordinators can pre-screen all new patients, that CCBD needs to increase enrollment since they have doubled the research staff, giving the laminated study list directly to the physicians, and the 15 pending studies.

Thursday, January 16, 2014

- Asked the study coordinator to add two AEs that I found while doing the CRFs yesterday to that patient's AE log, and placed the AE log in the physician's folder to review and sign.
- Asked the data coordinator to review and sign off on any changes I made to the paper CRFs yesterday.
- For the seven surveys I have received back, I coded and collected the data into an excel sheet.
- Sat in on a SCRI webinar covering audits and inspections, including the CFR parts and subparts that apply.

Friday, January 17, 2014

- Collected and organized the data on revenue from the research department by month and by quarter from 2009-2013.
- Boxed up 22 patient charts on 15 different studies for short term storage on site and long term storage off site.
- Assisted in resolving several data queries for one patient in the EDC.
- Assisted in assessing AEs based on a study's protocol.

Week 23: January 20 – January 24

Monday, January 20, 2014

- Filed drug and chemo instructions into a patient chart.
- Created and laminated lists of the open clinical research studies at CCBD for the clinicians for the month of January.

• Collected and organized the data on the number of studies that were open each month and each quarter from 2009-2013.

Tuesday, January 21, 2014

- Checked the newly added and modified AEs from AE audits for two patients with their medical histories. Also checked to make sure the date for similar AEs did not overlap. For AEs that did overlap with the medical history or had dates that overlapped, I marked them and made notes for the data coordinator to review.
- Collected and organized data on the number of patients that were referred and enrolled each month and quarter from 2009-2013.

Wednesday, January 22, 2014

- Set up the EMR for two of the monitors today by removing access to patients that were not on the studies being monitored and adding patients that were.
- Put up the patient charts that were monitored yesterday.
- Unmarked source documents and filed them into patient charts.
- Attended the weekly research department meeting. We discussed how and why CCBD joined SCRI, the goals of the research department for the year, and the need to increase enrollment by opening studies which CCBD has eligible patients for and finding ways to get the physicians engaged.

Thursday, January 23, 2014

- Put away the patient charts that were monitored yesterday.
- Checked the EMR to make sure source documents had been scanned in properly. If they were not the documents were faxed downstairs to be re-scanned.
- Discussed the data I plan on using with the research manager. Decided that it may be more helpful to look at the data for quarters instead of months, and that revenue data would not be helpful if my focus is on barriers to enrollment.

Friday, January 24, 2014

- For a study that had recently ended a data lock, I scanned the paper CRFs from 18 cycles and emailed them to the monitor of that study.
- Received nine surveys through the CCBD mail system. Coded and recorded the responses from those participants in my survey data excel sheet.
- Created a patient chart and transferred some documents from the old chart.

Week 24: January 27 – January 31

Monday, January 27, 2014

• Put away patient charts and regulatory binders from monitor visits last week.

• Assisted in finding a DCF that a monitor requested be signed off on by going through several patient charts and CRF binders. Found the DCF and had it signed off on, and then faxed it to the sponsor.

Tuesday, January 28, 2014

- Set up the monitoring suite for one monitoring visit and one close-out visit today.
- Sat in on a teleconference PSV for a phase III randomized open-label lung study, where a sponsor representative discussed the eligibility requirements, enrollment expectations, EDC and IVRS access, tissue sample processing, IP storage, and gathered information about the participating CCBD sites and PI.
- Using the PI CVs, I began counting the number of studies each PI has participated in and the breakdown of those studies by type of cancer for future PSVs.

Wednesday, January 29, 2014

- Attended a SIV for a breast study, where the study monitor discussed monitoring visits, study document storage, required serology tests, the two treatment arms, follow up time, inclusion and exclusion criteria, EDC and IVRS access, randomization, drug instructions, and patient reported outcomes (PRO) questionnaires. The PI pointed out that the standard therapy in the protocol differed from the standard of care at CCBD, but that it shouldn't be a problem.
- Stored all study documents for the study that closed yesterday, including regulatory documents and patient charts. I wrote down the long term, off-site storage label and gave the information to the regulatory coordinator.
- Made folders for four new research patients.

Thursday, January 30, 2014

- Continued counting the number of studies that the PIs had participated in. For Dr. Young I also counted how many studies involved breast cancer treatments that were first line, adjuvant, or neoadjuvant.
- Read an article that Dr. Page forwarded to me titled "Doctors: Too Few Cancer Patients Enroll in Studies."
- Reviewed good clinical practice guidelines and new drug and device regulatory procedures with the regulatory and data coordinators.

Friday, January 31, 2014

- Finished counting the number of studies that the PIs had participated in and sent the document to the regulatory coordinator.
- Assisted in entering data for two RECIST readings for target and non-target lesions into the EDC.
- Removed the lab kits for a breast study that recently closed from the storage area. In their place I organized the lab kits for a breast study that is opening next week.

Week 25: February 3 – February 7

Monday, February 3, 2014

- Pulled the patient charts to be monitored this week. I also assisted in answering any outstanding data queries for the study.
- Filed several source documents into patient charts, including pathology and radiology reports, adverse event logs and reports, and copies of faxed DCFs.

Tuesday, February 4, 2014

- Created 20 lists of the open studies for the research physicians for the month of February from the SCRI Clinical Trial Review website.
- Assisted the IP coordinator with changing the drug labels to include standard of care administration instructions in addition to protocol-specific instructions.
- Reviewed all the patient charts and binders for an old study in order to identify when each patient signed informed consent, were enrolled, and came off study and why in order to assess what data was still outstanding.

Wednesday, February 5, 2014

- Sat in on a SIV for a randomized double-blind, placebo-controlled phase III breast cancer study. The sponsor representatives discussed the phase I findings, the study treatment, inclusion/exclusion criteria, assessments, AEs and dose modifications, concomitant medications, and vendors. They also reviewed study equipment that the sponsor will be providing for the multiple CCBD sites.
- Documented the number of paper CRFs we have on-site for a study to report to the study monitor.

Thursday, February 6, 2014

- I modified Dr. Young's binder that contain ICFs and protocols for all breast studies. I separated everything out into two binders, with one for open studies, and the other for studies that are closed to accrual but still have follow-up patients. I checked the regulatory binders for each study to verify that the most recent versions of the protocol and ICF were in Dr. Young's binders, and if not I made copies and added them. I also added studies that had recently opened.
- Checked several charts to find out when the patients were consented and enrolled in order to enter the date into the newest patient database.

Friday, February 7, 2014

• Attended the weekly research department meeting, which has been moved from Wednesday afternoons to Friday mornings. We discussed pending, closed, and open studies, time to study activation, figuring out ways to prospectively prescreen patients through Pathways, upcoming monitor visits and PSVs, answering follow up letters

electronically, and placing a tumor dashboard icon on the desktops in the physician offices and exam rooms.

• Put away the patient charts that had been monitored this week.

Week 26: February 10 – February 14

Monday, February 10, 2014

- Assisted in filling out paper CRFs for 9 follow up visits for one study. I flagged the case report form review section in each visit for the PI to review and sign, and placed them in his research folder.
- Properly destroyed 26 lab kits for a study that recently closed. I removed all studyspecific information and placed them in the shred box. I also disposed of any potentially hazardous materials and placed them in the proper containers.

Tuesday, February 11, 2014

- The clinic delayed opening this morning due to inclement weather.
- Put away patient charts that had been monitored.
- Located and copied all the most current protocol versions for the 15 studies with the most patients enrolled, and then placed them into protocol binders by PI and type of cancer, such as breast, GI, lung, etc. for the data coordinator.

Wednesday, February 12, 2014

- Looked up the most recent amendment date for a GI protocol for the data coordinator.
- Located and copied the most current protocols and ICF versions from the regulatory binders for 10 studies. I organized them into a binder for the study coordinators to keep at the Burleson clinic.
- Assisted in answering data queries for two patients about their lost to follow up dates and documentation of attempts to contact them. Pulled source documents from the patient charts to fax to the monitor.

Thursday, February 13, 2014

- Attended a PSV for a multicenter, randomized, double-blind, placebo-controlled, phase III breast cancer study with an oral medication. The sponsor representative presented an overview of the IVRS and EDC systems, monitor visits, imaging and labs, EKGs, inclusion/exclusion criteria, and the timeline of the study.
- Put away the patient charts and regulatory binders for a breast study and genitourinary study that were monitored today.
- Entered 45 AEs and 48 conmeds for a lymphoma study onto the electronic AE log from the paper log that had been edited by the study coordinator and assessed by the study PI.

Friday, February 14, 2014

- Assisted in clarifying data on CRFs using my notes from a previous AE audit, finding the date that the procedure for printing off lab values to be assessed was changed, and locating a patient chart.
- Attended the weekly research department meeting, where we discussed the next research dinner, creating a research dashboard to put on desktops that would contain links to study protocols, training slides, and ICFs, response time to follow up letters, creating a study startup tracker to track CCBDs metrics, pending protocols, enrolled patients, and upcoming monitor visits.
- Filled out the follow up CRFs for two patients that withdrew consent and did not agree to be followed.
- After today my time will be dedicated to the completion of my internship practicum report and preparation for my defense. In addition, I will be working on a short presentation for the quarterly CCBD research dinner on February 26th, where I will briefly discuss my project and findings with the CCBD research department and physicians.

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