Orozco, Ronnie R., Factors Affecting Referrals from Primary Care Physicians to Clinical Research Trials. Master's Degree (Clinical Research Management), August, 2009, 65 pp., 2 tables, bibliography, 8 titles.

The goal of this project was to reveal what factors affect the willingness of a primary care physician to refer patients to clinical research trials in the Fort Worth area. 50 physicians were contacted and provided with a survey consisting of 14 questions. There was a 26% return rate for the survey, and the participating physicians had an average of 25.15 years in practice. The idea of clinical research is considered to be essential and not a risk among primary care physicians. The biggest obstacle for referrals appears to be based upon the lack of information available to physicians; clinical investigators need to engage the physicians with up to date information regarding any clinical trials that are being conducted.

FACTORS AFFECTING REFERRALS FROM PRIMARY CARE PHYSICIANS TO CLINCAL RESEARCH TRIALS

Internship Practicum Report

Presented to the Graduate Council of the

Graduate School of Biomedical Sciences

University of North Texas

Health Science Center at Fort Worth

In partial Fulfillment of the Requirements

For the Degree of

MASTERS IN CLINICAL RESEARCH MANAGEMENT

By

Ronnie R. Orozco, B.S.

Fort Worth, Texas

August 2009

TABLE OF CONTENTS

LIST OF TABLES

CHAPTER I

Introduction:

Texas Pulmonary & Critical Care Consultants (TPCCC), P.A., is a private practice located in the surrounding Fort Worth area, consisting of ten offices, twenty-nine physicians, two sleep laboratories, a treatment center, and a research center. Currently at the TPCCC Research Center, there are three ongoing clinical trials targeting chronic obstructive pulmonary disease (COPD) and cystic fibrosis. In the past, TPCCC Research Center's study populations for clinical research trials consisted of established patients or subjects who happened to become aware, via recruitment advertisements, of ongoing research trials taking place at the Research Center.

There has been an expressed interest, by TPCCC's research staff, in determining what factors are being considered by primary care physicians (PCPs) when referring patients for secondary care with specialty physicians. In addition, are physicians considering or even discussing clinical research trials for particular diseases with their respective patients? In order to determine what factors physicians consider when referring patients to TPCCC for secondary care, data must be acquired in order to measure the various considerations that go into play for a patient referral. To accomplish this, a survey/questionnaire was developed and administered to a group of PCPs, who in the past have referred patients to TPCCC. The survey was designed to gauge the PCP's idea/understanding of clinical research, comfort level with clinical research, and their current knowledge of clinical research occurring in the surrounding community.

CHAPTER II

Internship Project

Background:

It has been stated that overall, PCPs serve as a gateway for most of the prescribing, investigation, and referral of patients for secondary care within the medical community.[5] However, when one considers how many of those referrals are made for clinical research trials, the number seems to dwindle.

In 2002, a survey was administered to PCPs and specialists across Texas, with results revealing that sixty-five percent of medical specialists would refer a patient to participate in a clinical trial, while only thirty-nine percent of PCPs would do so.[6] One possible reason responsible for low referral numbers among the PCP population is their strong belief of prevention in conjunction with lifestyle modification.[4] The majority of physicians are aware of the importance of conducting clinical trials, yet, fewer than one-half of the PCPs will enroll or recommend a patient for a clinical trial.[7]

Additional evidence for the decreased accrual rates could be referred back to 2004, when a survey revealed the limited exposure PCPs have with clinical trials.[7] Another barrier for referrals could be the lack of information regarding clinical trials available to PCPs.[6] With information not being readily available, there can be a misunderstanding of clinical trial protocols and a lack of knowledge regarding who is eligible to participate in a particular clinical

trial.[6] Factors that continually seem to be mentioned among physicians for the lack of referrals are time constraints, economic constraints, and, surprisingly, the fear of unnecessary paper work.[6,7]

When considering clinical research and clinical practice, one has to remember that most PCPs consider clinical practice to be geared toward providing patients with individualized care, and that their primary responsibility is the patient's interest. In contrast, the idea of care in clinical research is geared toward developing knowledge to help future patients.[3] With the notion of research being seen as beneficial for patients in the future, persuading physicians to refer current patients to long-term research studies could be difficult due to the physician's want of certainty and quick answers.[8]

A physician's reluctance to discuss enrolling in a clinical research trial with patients because of their uncertainty, lack of knowledge, and time constraints, will continue to be obstacles to clinical trial recruitment and enrollment until a greater familiarity is obtained with the clinical research aspect of medicine.[3] Patients are now taking a more active role in learning about clinical trials (e.g. searching National Institute of Health's website, requesting brochures regarding clinical trials for a particular disease) and are increasingly seeking treatment through research instead of, or in addition to, standard clinical care.[3] With an increased interest in clinical research, many insurance providers are now supporting clinical trials, for example, well designed prevention and early detection studies.[8] Most reluctance from insurance providers is seen when their subscribers want to participate in controversial, high risk trials (e.g., metastatic breast cancer patients seeking bone marrow transplants).[8]

The importance of clinical trials extends beyond their significance as research studies, and protocols have been developed to serve as a specialized roadmap to allow physicians to

provide high quality care.[8] The rising inquiries regarding clinical research by patients causes a need for PCPs to consider clinical research as a safe alternative for standard care. With the intense review that all clinical research protocols undergo by institutional review boards, patients participating in clinical research trials can be assured of receiving the best available treatment and follow up care.[8] Many physicians may not be aware that the course of protocol development and approval process requires a thorough review of current activity in a particular disease area, expert discussion, and pre-approval reviews. All of these steps are optimized to design a safe and effective application of promising treatments.[8]

Steps for PCPs to follow in enrolling a patient for a given clinical research trial would be:

- Serve as an intermediate for the patient and the research trial
- Become aware of a given trial
- Decide to alert the patient regarding the trial
- Discuss the clinical trial with the patient

Once the patient is aware of their options, they can then decide whether or not to enroll in the study at the approval of the principle investigator for the clinical trial.[4] While a substantial requirement for research awareness is placed upon the PCP, clinical investigators who are seeking support from referring physicians must be sensitive to the physicians' concerns and exhibit a genuine commitment to the physician and the community they serve.[4] With PCPs recommending their patients to participate in clinical trials, they will help continue the progress of medicine as a scientifically guided practice.[3]

Specific Aims:

Within the clinical research realm of healthcare, there are many misunderstandings that are associated with the overall practice of clinical research trials. These misunderstandings can

include the idea of researchers making all of the medical care decisions, or that the clinical findings of a given trial are not put into context and fail to recommend how the study results can promote programs or additional studies to improve health.[3] However, it is through study findings from previous clinical trials that new treatment options have been developed for some of today's more common illnesses and diseases (e.g. COPD, Asthma, Diabetes). In order to help ensure advanced, cutting edge care for future patients, PCPs must be encouraged to recommend their patients to enroll into clinical trials that could benefit both the patient and future patients as well.[7] The goal of this practicum project was to reveal what factors affect the willingness of a PCP to refer patients to clinical research trials in the Fort Worth area.

This goal was accomplished by:

- Identifying barriers that prevent PCPs from referring patients to clinical research trials
- Estimating the degree of research awareness in PCPs from the surrounding community
- Developing solution(s) to improve clinical research awareness among PCPs in the Fort Worth area

By identifying barriers to patient referrals for clinical research trials and determining the amount of research awareness among area PCPs, the groundwork for increasing the number of patient referrals to clinical research trials in the Fort Worth area (i.e., TPCCC) can be developed.

Significance:

It has been noted that most physicians agree that the majority of medical care today, whether preventive or therapeutic, would not be feasible without the aid of clinical trials.[8] For example, the improvement achieved over the years in treating childhood acute lymphocytic

leukemia would not have been accomplished without the aid of clinical trials. Through clinical research trials, outcomes for acute lymphocytic leukemia increased from twenty percent long term survival to eighty percent survival; in addition, morbidities have been decreased and pediatric oncologists have obtained a better understanding of the disease through their involvement with the clinical research process.[8]

In an article published in December 2008, tiotropium, a long-acting bronchodilator, was labeled as the best option, first-line drug for patients with moderate to severe COPD.[2] Due to the ability of tiotropium to sustain a bronchodilator effect, reduce COPD exacerbations, reduce health resource usage, and most importantly, improve quality of life, it's use is viewed as a great addition to current pharmacologic treatment options.[2] With COPD becoming a disease that is more recognizable over the past few years, clinical trials utilizing tiotropium have become important in determining the best available treatment for patients suffering with COPD.[2]

Another example of clinical trial success can be noted in the administration of imatinib mesylate (Gleevac) in patients suffering from chronic myelocytic leukemia or gastrointestinal stromal tumors.[8] Patients showed no response to the standard treatment regimen at the time, but showed significant improvement in response to the Gleevac regimen.[8] In order to observe continual progress towards new medical breakthroughs, there needs to be an increasing number of studies to help reflect the gradual improvements and an increased number of patients to reflect the improving efficacy of new treatments.[8]

Research Design/Methods:

The research project was based upon a voluntary, observational, cross-sectional (one group) study, with the utilization of a descriptive, self administered survey/questionnaire targeted towards PCPs with a prior history of referring patients to Dr. John Burk at TPCCC for secondary

care. The target population for the study, a total of fifty subjects, was selected from TPCCC's corporate information management system, Versyss®. A thorough review of Versyss® was conducted, and the target population was identified from a compiled list of referring physicians who have referred two or more patients to Dr. John Burk for a pulmonary consultation.

Referring physicians needed to have a history of referring patients to Dr. John Burk at TPCCC for secondary care, and they needed to have a well acquainted history with the overall general practice of TPCCC. Dr. Burk aided in determining whether or not certain physicians were to be considered for the project if their referral percentage was not considered to be significant.

A fourteen question, descriptive, self administered survey was constructed to measure the target population's views, attitudes, and their overall comfort level with clinical research trials. Ten personal attitude/belief questions were measured on a 5-point scale that ranges from strongly agree, agree, neutral, disagree, and strongly disagree. An answer selection was determined by the target population as they answered and completed the survey. The features of the survey clearly delineated the research topic, allowed for a systematic data collection process, allowed for summary/descriptive statistics (at a group level) to be developed, and produced results that reflected the views/attitudes expressed by the individuals within the study.[1] The survey took approximately ten minutes to complete

After the target population was selected and IRB approval had been obtained from the University of North Texas Health Science Center, a letter of request, summarizing the research project and goals, was sent out to the target population. The letter was addressed to the office/nurse manager requesting a ten to fifteen minute face to face interaction to seek their

assistance in administering the survey to their in-house physicians. Dr. John Burk had a role in developing the letter by providing insight and signing off on the final draft of the letter.

If the office/nurse manager was unwilling, or not able, to schedule a meeting or assist in administering the survey, an additional option of directly mailing the survey to the referring physician was available as well. The office/nurse manager was asked which option would be more convenient for their office during a follow-up phone call, which was placed approximately one week after the letter of request had been mailed to the referring physician's office.

Once an appointment had been obtained from the office/nurse manager, a face-to-face meeting was arranged at the physician's office at a time that was convenient for the office/nurse manager and their clinic schedule. During the meeting, the research project and project aims were explained in detail to the office/nurse manager, and any specific questions were answered at that time. After agreement to assist in the research project was obtained, surveys were left with the office/nurse manager to have the research subjects (in-house physicians) complete the survey and then return the completed survey via mail. If there was failure to communicate with the office/nurse manager of the referring physician, the survey was mailed directly to the referring physician; they were instructed to complete the survey if they agreed to participate in the study, and to return the survey in a pre-addressed, pre-stamped envelope provided by the study.

Upon receiving the completed surveys, the results were analyzed, with a mean score being computed for each physician. As described above, the answer choices for each question were assigned a value from strongly agree to strongly disagree. A mean score was calculated after all returned surveys had been verified as completed. Additional statistical analyses were conducted after reviewing the final results utilizing SPSS® (statistical software); but due to the

small population and similarity of responses for majority of the questions, some of the calculations were considered void. Chi-square calculations were considered void due to some of the observed outcomes having a sample size less than five.

In order to track which surveys are returned, each survey was assigned a number that would only identify the clinic where the survey was sent. The physician's name or any other identifier was not placed on the surveys. An official tracking list was kept confidential, where only study personnel had access to the list. The tracking list was a way to identify the clinics with high/low response rates so that study personnel will be able to follow-up accordingly.

Results:

A total of 50 physicians were contacted, via research letter, about participating in the project. From the target population, 11 office/nurse managers (responsible for 20 physicians) expressed willingness to learn more about the research project. Of those 11, 2 managers assisted in setting up a face-to-face meeting with their respective physician; while the remaining 9 managers requested that the surveys be mailed to them. Four out of the nine offices had their physicians (6 total) complete the survey; 1 physician decided he/she was no longer interested; 2 physicians declined to participate since they did not consider themselves primary care physicians; and 2 other offices never returned phone calls or made any additional contact with the research project.

For the remaining 30 physicians, the survey and study cover letter was mailed directly to the physician to decide whether or not they would participate in the research project. Of the 30 surveys mailed, 5 surveys were completed and 2 surveys were returned with "unable to deliver" stamped on the envelope. The addresses on the surveys marked "unable to deliver" were cross-referenced by the address listed in Versyss® and a physician listing handbook issued in 2008.

The address listed on the envelope matched our records, so no error was made in listing the wrong address for the referring physician.

Overall, out of the 50 surveys sent out, 13 surveys were completed, for a success rate of 26%. As shown in Table 1, the participating physicians had an average of 25.15 years in practice, with 7 years being listed as the least number of years and 40 being listed as the most number of years in practice. The target population was asked if they had ever participated in clinical research in the past; 8 physicians (62%) marked "yes" and 5 physicians (38%) marked "no". The average number of years in practicing medicine for those who marked "yes" was 28 years; for those who marked "no", the average number of years in practice was 20.6. Of the 13 physicians responding to the survey, 11 physicians (85%) have referred some of their patients to a clinical trial before, while 2 physicians (15%) had no prior history of making any referrals to a clinical trial. Only 1 of the 13 physicians responded "no" to ever to having any of their patients participate in research protocols in the past.

Table 1 Target Population's General Background Characteristics

	Response to Survey Questions	Average number of years in practice
1. How many years have you been practicing medicine?		25.1538
2. Have you participated in clinical research in the past?		
	YES: 8 (62)	28
	NO: 5 (38)	20.6
3. Have you referred any of your patients to a clinical research trial before?		
	YES: 11(85)	28.18
	NO: 2 (15)	8.5
4. Have you had patients who have participated in research protocols in the past?		
	YES: 12(92)	26.67
	NO: 1 (8)	7

* Values in parentheses are number percentage out of 13 participants

Table 2 Survey Questions and Physician Responses

	Agree	Disagree
5. I have a general understanding of clinical research, in which, I can make a referral to a clinical trial willingly.	11 (85)	2 (15)
6. I believe clinical research is needed in healthcare today.	13 (100)	0 (0)
7. I believe that surrounding clinical research centers provide enough information on current and upcoming clinical research trials.	2 (85)	11 (15)
8. I frequently request information regarding current and upcoming clinical research trials being conducted at surrounding clinical research centers.	0 (0)	13 (100)
9. I receive a constant flow of communication, regarding clincal research information, which helps reinforce the availabile clinical research trials in my area.	2 (15)	11 (85)
10. I believe a synopsis of current clinical research trials that are being conducted at surrounding area research centers, would help enable myself to discuss clinical trial issues with my patients.	12 (92)	1 (8)
11. During a patient's visit, I present clinical research trials as an option for additional treatment.	0 (0)	13 (100)
12. I believe that if a patient is referred to a clinical research trial, they will become more compelled to receive treatment within a clinical research setting in the future.	8 (62)	5 (38)
13. I believe that a professional relationship must be developed, with a clinical investigator and research center, prior to any patient referrals are made.	4 (31)	9 (69)
14. I feel that patient safety is jeopardized in clinical trials.	1 (8)	12 (92)

* Values in parentheses are number percentage out of 13 participants

For the personal attitude/belief questions (Table 2), the physicians had the option of choosing one of five choices: strongly agree, agree, neutral, disagree, and strongly disagree. Due to the small sample population and similarity of responses, the questions were broken down into two categories, agree and disagree (responses marked neutral were combined with those marked disagree/strongly disagree since the physician chose to not to fully agree with the statement).

Eleven physicians (85 %) felt as if they had a general understanding of clinical research, in which they could make a referral to a clinical trial willingly; 2 physicians (15%) either disagreed or reported a neutral stance. All participants agreed that clinical research is necessary in health care today, and 11 participants (85%) did not agree that surrounding research centers

provided enough information on current and upcoming clinical trials. However, all 13 participants (100%) disagreed or had a neutral stance on requesting information regarding current and upcoming clinical trials being conducted at surrounding clinical research centers.

Eleven physicians (85%) disagreed or were neutral with the idea of receiving a constant flow of communication regarding clinical trial information from research centers in their surrounding area. When asked if a synopsis, of current clinical trials being conducted at area research centers would better enable themselves to discuss clinical trial issues with patients, 12 physicians (92%) agreed with the idea. All 13 physicians (100%) reported to either disagree or have a neutral stance on presenting clinical research trials as an option for additional treatment during one of their patient's visits. Eight physicians (62%) reported to believe that if a patient were to be referred to a clinical research trial, the patient would become more compelled to receive treatment within a clinical research setting in the future.

The belief that a professional relationship must be developed with a clinical investigator and research center prior to any patient referrals are made was disputed by 9 of the 13 physicians (69%) who did not agree with the statement. When the issue of patient safety was mentioned, 12 of the physicians (92%) did not agree that safety is jeopardized in clinical trials.

Discussion:

The goal of this practicum project was to reveal what factors affect the willingness of a PCP to refer patients to clinical research trials in the Fort Worth area. This was accomplished by identifying barriers that prevented referrals to clinical trials from being made, and determining the amount of research awareness surrounding PCPs possessed. As a result of contacting 50 physicians regarding the research project, 13 physicians (26%) participated in the study.

Entering into the research project, expectations for a high return rate for the survey were being kept to a minimum for a couple of reasons. First and foremost, getting physicians and their office staff to participate or assist was seen as a potential obstacle. Initial contact was made with only 20 of the 50 physicians (40%) targeted for the study; yet of those 20 physicians, 8 (40% of the physicians in which contact was made through their office/nurse managers) participated in the study. The remaining 5 participants (16.6% of the remaining 30 physicians) came from directly mailing the survey to the physician, via "cold contact" approach. It appears that utilizing the office/nurse manager to assist in getting the physician to participate was of some benefit. Second, utilizing a self administered survey with physicians could often time end up being overlooked due to a physician's already busy schedule. With the success rate of only 26% for the project, a higher success rate would have been appreciated but the value does fall in line with reported response rates from various publications.

Most studies utilizing a "cold-contact" survey (i.e. no prior contact was made with the target population regarding the survey prior to the study) tend to have a lower response rate than studies that are able to conduct a personal interview[1]; for this project, only 2 personal interviews were granted, while the rest of the surveys were conducted by mail. Surveys that are associated with a federally sponsored national health agencies usually produce a response rate of 60 to 70 percent.[1] Overall, a general idea of physician's attitudes towards referring patients to clinical research trials can be developed through this project.

Clinical experience among the participating physicians ranged from 7 years to 40 years of practicing medicine. With a range of 33 years being reported among the group, survey results were expected to be varying; however, to much surprise, they were similar but yet contradicting. For every question, a majority of the respondents (over 50%) would either agree or disagree with

the given statement. When asked on whether they have participated in clinical research and have referred patients to clinical research in the past, 62% and 85%, respectively, of the physicians responded yes. In addition, 92% of the physicians claimed that their patients had participated in clinical research trials previously. With well over 50% of the respondents having some interaction with clinical research trials, one could assume that the group would be in favor of clinical research.

The assumption is reiterated when all of the participants agreed that clinical research is needed in health care today, and 85% claimed that they possessed a general understanding of clinical research in which they could make a referral to a clinical trial willingly. The contradiction among the results comes into play when 100% of the physicians claimed that they did not present clinical research trials as an option for additional treatment to their patients during a regular clinic visit. With majority of the group having a personal experience in clinical research, one would guess that presenting clinical research as an option to their patients would be seen in a positive light. One possible reason for the avoidance of mentioning clinical trials to their patients could be the idea of patients becoming compelled to receive treatment within a research setting rather than the physician's practice setting. Based upon the survey results, 62% of the physicians agreed with that idea.

However, losing patients to a clinical research setting is not the only possibility for a lack of referrals to clinical trials by PCP's. When asked on whether they believed that surrounding clinical research centers provided enough information on current or upcoming clinical trials, 85% claimed that they did not believe so. With the lack of information not being provided, a constant flow of communication regarding clinical research at the surrounding research centers is

lacking as well. In contrast, 100% of the participants claim to not request any information regarding current and upcoming clinical trials being conducted at surrounding research centers.

With physicians not making an effort in requesting any current information on clinical trials being conducted in their surrounding area of practice, the idea of having a synopsis provided, regarding current trials, is somewhat enlightened. Having a synopsis on hand would help enable the physicians to discuss clinical trial issues with their patients; of the 13 physicians who completed the survey, all but one (92%), agreed that a synopsis would be of good use. A constant flow of information, from clinical investigator to PCP, regarding clinical trials could be seen as the breakthrough for an increase in referrals to clinical research trials.

The notion of PCP's needing to have an established professional relationship with surrounding clinical investigators/research centers, prior to ever making a referral for a clinical trial, is refutable based upon the survey results. This is suggested by the findings that 69% of the physicians did not feel as if an established relationship was needed to make a referral. In addition, the thought of patient safety being jeopardized in clinical trials can be considered null, due to 92% of the respondents claiming they do not consider safety to be a point of concern.

Further investigation of other possible setbacks for PCP referrals to clinical trials could enhance the results of this project. The addition of follow up questions to certain responses within the survey could aid in determining or inferring additional insight from the physicians. The utilization of open ended questions, where physicians could voice their own opinion regarding certain topics in the clinical research trial process and overall referral process, would allow for direct insight from the participating physicians to be incorporated into the survey results.

In order for clinical research to continue to provide much needed information regarding some of today's mind boggling diseases, referrals and the utilization of clinical research must be made by PCP's. With the field of clinical research being considered essential in the advancement of medicine today, an influx of patients into clinical trials is going to be needed in the coming years.

Summary:

Overall, the idea of clinical research is considered to be essential and not a risk within the primary care field. PCP's appear to be well aware of clinical research, based on past experience, and possess a general understanding of clinical trials. Based on our results, a possible hindrance in the lack of referrals to clinical trials could be based upon the lack of information regarding current clinical research trials being sent out to PCP's. Financial loss for PCP's, due to patients becoming compelled to receive treatment in a research setting rather than in a clinical setting, could be an additional reason for the lack of referrals. With PCP's not taking the initiative to request information regarding any current and upcoming clinical research trials, clinical investigators/research centers need to engage the physicians with up to date information (in form of synopsis) regarding any clinical trials that are being conducted. With an increase in communication concerning clinical trials between both clinical investigators and PCP's, presenting and making referrals to clinical trials could be enhanced in an effort to provide the best of care for the patients of today and tomorrow.

CHAPTER III

Internship Experience:

During my time at TPCCC Research Center, my internship experience consisted of becoming familiar with and assisting in various facets of the day-to-day operations of the Research Center. The majority of my internship assignments had to do more with administrative work, but the experience was worthwhile and educational at the same time. As a Graduate Student Intern, I was not able to perform any pulmonary function procedures or perform any invasive procedures; such as drawing a subject's blood sample needed for the clinical trials.

While at TPCCC Research Center, some of the duties that I was assigned or involved in included:

- Institutional Review Board interaction/communication
- Writing and editing a Research Proposal
- Writing and editing a Protocol and Protocol Synopsis
- Observing the informed consent process
- Data collection
- Constructing & verifying source documents
- Maintaining study files and study binders
- Interacting with study personnel
- Onsite and Field Monitoring

- Observing Drug/Device accountability
- Assisting in patient recruitment
- Observing Adverse Event reporting
- Electronic Data Capture

Some of the duties that I participated in were directly involved with my own research project, such as IRB interaction/communication, writing/editing a research proposal, writing/editing protocol and protocol synopsis, data collection, and patient recruitment.

I had the opportunity to review protocols for closed studies that were conducted at TPCCC Research Center within the past year; by being able to do this, I obtained a better understanding of the various clinical trials that were and will be conducted at the Research Center. In addition to reviewing old protocols, I was able to work closely with Mr. Phil Hickman, RRT, CPFT, Clinical Research Coordinator for TPCCC Research Center, in various aspects of the current clinical trials that were ongoing at the Research Center. Mr. Hickman allowed me to observe the process of answering queries, protocol deviations, and filling out adverse event forms for some of the past clinical trials, along with some of the current trials. Mr. Hickman was instrumental during my internship to help ensure that any questions that I might have pertaining to clinical research were met.

I attended an IRB meeting at the Baylor Research Institute (BRI) with Dr. John Burk, where I was able to observe the overall process that takes place to get a research study approved for clinical use. While writing my research proposal, I was in direct contact with the University of North Texas Health Science Center IRB as I submitted my proposal for approval. My firsthand observation of BRI's IRB allowed me to appreciate the in depth review process that takes place for study approval, and gave me much needed insight of how to properly write and

ensure that all vital information pertaining to my research study was included within my proposal. The overall approval process for my proposal did not go as smoothly as we had planned, due to wording or clarification of protocol; but the experience was indeed insightful.

Mr. Phil Hickman assigned me various duties with the three ongoing trials that were being conducted at TPCCC Research Center. The three trials were Boehringer Ingelheim trial no. 0205.0339 (the use of Tiotropium Bromide in cystic fibrosis subjects), Novartis trial no. CQAB149B2349 (double blind study comparing the use of Indacaterol to salmeterol for superiority in moderate to severe patients with COPD), and Forest Research Institute Trial no. LAS-MD-33 (study of efficacy and safety of aclidinium bromide at three dose levels vs. placebo when administered to patients with moderate to severe COPD). I constructed and reviewed visit sheets/source documents, and I had an active role in patient recruitment for all three of the studies. I was able to conduct a Baseline Dyspnea Index and a Transtional Dyspnea Index for subjects enrolled in the Novartis study. Other responsibilities included transferring visit information into the case report form or electronic case report form after a visit was completed and maintaining regulatory binders (including filing and daily logs).

There were several opportunities to observe a site monitor visit for the Novartis study, as well as a couple of initial site/site selection visits for a couple of potential studies that might take place at TPCCC Research Center in the near future.

APPENDIX

Appendix A

Approval Letter for IRB Exemption Status

UNIVERSITY of NORTH TEXAS
HEALTH SCIENCE CENTER at Fort Worth
★
Education, Research,
Patient Care and Service

DATE: 19 March 2009

Office for the Protection of Human Subjects
3500 Camp Bowie Boulevard
Fort Worth, Texas 76107-2699

TO: John R. Burke, MD, FACP
(with student Ronnie Orozco)
Department of Physiology
Graduate School of Biomedical Sciences

PROTOCOL: #2009-035

"Factors Affecting Referrals from Primary Care Physicians to Clinical Research Trials"

IRB BOARD ACTION AND NOTICE OF APPROVAL

The Institutional Review Board (IRB) of the University of North Texas Health Science Center (UNTHSC) has reviewed your protocol and has granted approval for **EXEMPT** status as specified in Federal Regulations 45 CFR 46.101(b), category (2).

Note that you are responsible for complying with all UNTHSC IRB and OPHS policies, decisions, conditions and requirements regarding projects involving human subjects. You are responsible for insuring that the research is implemented as specified in the approved protocol. Unless otherwise authorized by the UNTHSC-IRB, you are responsible for notifying subjects that their participation and information will be used for research purposes. In addition, you are required to use ONLY the IRB approved documents, materials and/or process designated for this protocol.

You must report to the Chair of the IRB any changes affecting the protocol upon which this certification is based. **No changes may be made without prior approval by the IRB** except those necessary to eliminate immediate hazards.

If you have any questions, please contact Ms. Heather Cline, Human Subject Protection Coordinator, at phone (817) 735-5457 in the Office for the Protection of Human Subjects, or send email to her at hcline@hsc.unt.edu

Sincerely,

Brian Gladue, PhD
Chair, UNTHSC Institutional Review Board

cc: H. Cline, OPHS

Appendix B

IRB Approved Letter of Request

UNIVERSITY of NORTH TEXAS
HEALTH SCIENCE CENTER at Fort Worth
★
Education, Research,
Patient Care and Service

Department of Integrative Physiology

Dear _____,

I am currently a second year graduate student, attending the University of North Texas Health Science Center. I am completing my internship requirements for a Master's degree in Clinical Research Management. My internship is being conducted at Texas Pulmonary & Critical Care Consultants, P.A. (TPCCC), with Dr. John Burk serving as my principle investigator. A requirement of my internship is to conduct a practicum project regarding clinical research trial management.

There has been an expressed interest in determining what factors primary care physicians consider when referring patients for secondary care with specialty physicians. In addition, are clinical research trials, for particular diseases, ever considered or discussed by primary care physicians with their respective patients? We are conducting a research project to determine what critical factors play a pivotal role when referring patients to specialty care (i.e. TPCCC) for participation in a clinical research trial.

I am seeking permission to meet at your office, at a time convenient to you, to discuss conducting a survey/questionnaire with your group of primary care physicians, who in the past have referred patients to TPCCC. The survey will take no more than 10-15 minutes, and is designed to gauge the physician's idea/understanding of clinical research, comfort level with clinical research, and their current knowledge of clinical research occurring in the surrounding community.

I would appreciate your assistance in my pursuit of my degree. I will be contacting your office in order to schedule a possible meeting time with you to discuss the project in greater detail. Thank you so much for your consideration of my request. Any help is greatly appreciated.

If you have any questions regarding the research project, please feel free to contact Ronnie Orozco (roorozco@hsc.unt.edu) at (806) 543-0047.

Sincerely,

Ronnie R. Orozco, BS
CRM, GS-II
Student Co-Investigator

John R. Burk, M.D., F.A.C.P
Principle Investigator

817-735-2080 • FAX 817-735-5084
Texas College of Osteopathic Medicine • Graduate School of Biomedical Sciences • School of Public Health • Institutes for Discovery • Physicians & Surgeons Medical Group
3500 Camp Bowie Boulevard, Fort Worth, Texas 76107-2699 • 817-735-2000

Appendix C

IRB Approved Survey Cover Letter

Factors Affecting Referrals from Primary Care Physicians to Clinical Research Trials

Principle Investigator: John R. Burk, MD, FACP
Texas Pulmonary & Critical Care Consultants

Co-Investigator: Ronnie R. Orozco, BS, GS-II
Graduate School of Biomedical Sciences/UNT Health Science Center

Institution: University of North Texas Health Science Center

Introduction:
We are conducting a research project to determine what critical factors play a pivotal role when referring patients to specialty care for participation in a clinical research trial. There has been an expressed interest in determining what factors primary care physicians consider when referring patients for secondary care with specialty physicians. In addition, are clinical research trials, for particular diseases, ever considered or discussed by primary care physicians with their respective patients?

You are invited to participate in this research study survey because you have a history of referring patients to Texas Pulmonary & Critical Care Consultants for secondary care. This survey will gauge your idea and understanding of clinical research, comfort level with clinical research, and your current knowledge of clinical research occurring in the surrounding community. The survey will take no more than 10-15 minutes.

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 benefits of this survey will allow us to formulate what factors affect primary care physician referrals to specialty care and clinical research trials, and allow us to develop solution(s) to help increase clinical research awareness among primary care physicians in the Fort Worth area.

Agreement to Participate:
Participation in the study is completely voluntary. If you decide to participate, you can complete and return the survey in the attached pre-addressed, pre-stamped return envelope.

Confidentiality:
You will not be asked for your name or any other identifying information on the survey. The name of your practice will remain confidential and will not be used in any presentation or publication.

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:

- Principle Investigator: John R. Burk, MD, FACP: jburk@texaspulmonary.com
- Student Co-Investigator: Ronnie R. Orozco: roorozco@hsc.unt.edu or (806) 543-0047

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.

Appendix D

IRB Approved Survey

The following survey is part of a UNTHSC practicum to fulfill internship requirements for a Master's Degree in Clinical Research Management
All data and information will be kept confidential and will be used for this study's purpose only.

1. How many years have you been practicing medicine? _____

2. Have you participated in clinical research in the past? Yes_____ No_____

3. Have you referred any of your patients to a clinical research trial before? Yes_____ No_____

4. Have you had patients who have participated in research protocols in the past? Yes_____ No_____ Uncertain_____

Indicate how much you agree/disagree with the following statements...	5 Strongly Agree	4 Agree	3 Neutral	2 Disagree	1 Strongly Disagree
5. I have a general understanding of clinical research, in which, I can make a referral to a clinical trial willingly.	SA	A	N	D	SD
6. I believe clinical research is needed in healthcare today.	SA	A	N	D	SD
7. I believe that surrounding clinical research centers provide enough information on current and upcoming clinical research trials.	SA	A	N	D	SD
8. I frequently request information regarding current and upcoming clinical research trials being conducted at surrounding clinical research centers.	SA	A	N	D	SD
9. I receive a constant flow of communication, regarding clincal research information, which helps reinforce the availabile clinical research trials in my area.	SA	A	N	D	SD

	5	4	3	2	1
	Strongly Agree	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
10. I believe a synopsis of current clinical research trials that are being conducted at surrounding area research centers, would help enable myself to discuss clinical trial issues with my patients.	**SA**	**A**	**N**	**D**	**SD**
11. During a patient's visit, I present clinical research trials as an option for additional treatment.	**SA**	**A**	**N**	**D**	**SD**
12. I believe that if a patient is referred to a clinical research trial, they will become more compelled to receive treatment within a clinical research setting in the future.	**SA**	**A**	**N**	**D**	**SD**
13. I believe that a professional relationship must be developed, with a clinical investigator and research center, prior to any patient referrals are made.	**SA**	**A**	**N**	**D**	**SD**
14. I feel that patient safety is jeopardized in clinical trials.	**SA**	**A**	**N**	**D**	**SD**

Appendix E

Daily Activities Journal

Practicum Daily Activity Log

Master's of Science
Clinical Research Management Internship
Ronnie Orozco

Site: Texas Pulmonary & Critical Care Consultants, P.A.
Clinical Research Office, Ft. Worth, TX
Date of Internship: December 15, 2008 through June 30, 2009

Date	**Daily Activities**
December 5, 2008	ADVISORY COMMITTEE MEETING • Met at Texas Pulmonary & Critical Care Consultants (TPCCC) Research Center • Patricia Gwirtz, PhD, John R. Burk, M.D., Phil Hickman, RRT, and myself discussed what would be entailed during my internship - Michael Smith, PhD could not attend the meeting due to a schedule conflict. • Discussed the ongoing and upcoming clinical trials that are taking place at TPCCC • Several topics were discussed as possible research projects - Look into factors that prevent PCP's from referring to clinical trials - Look into retention rates in studies that have monetary benefits for subjects traveling a certain distance to participate in a clinical trial →Would coincide with ongoing Cystic Fibrosis study • *Master of Science Designation of Advisory Committee* and *Master of Science Degree Plan* were reviewed and signed by the advisory committee (Dr. Smith signed at a later time) • Signed employee confidentiality agreement for TPCCC
Week 1 December 15, 2008	Orientation • Signed Employee Handbook Agreement • Searched for articles pertaining to possible research topics
December 16, 2008	Orientation • Attended TPCCC staff meeting • Looked over electronic data for a closed GlaxoSmithKline research trial dealing with asthmatics (FFA 107687) • Searched for articles pertaining to possible research topics
December 17, 2008	Orientation • Turned in my *Master of Science Designation of Advisory Committee* and *Master of Science Degree Plan* to Graduate School of Biomedical Sciences office at UNTHSC • Searched for and read Journal articles pertaining to possible research topics at UNTHSC's Lewis Library
December 18, 2008	Orientation • Searched and printed journal articles for possible research topics • Read over TPCCC's Research Center SOP manual • Introduced to protocols for upcoming studies that will take place at

December 18, 2008 (cont'd)	TPCCC Research Center within the upcoming months **Christmas Holiday Break December 19, 2008 – January 2, 2008** - Reviewed journal articles and searched for additional articles at Texas Tech University Health Science Center Preston Smith Library in Lubbock, TX.
Week 2 January 5, 2009	• Searched for additional articles to supplement my research question • Discussed with Phil Hickman the different trials that have ended and the ones that will start or have started at TPCCC • Began to read a completed Novartis study trial (CQAB149B2346) targeting subjects with COPD and the use of Indacaterol, goal was to become familiar with the design and terminology of a typical research study manual
January 6, 2009	• Continued to read over the completed Novartis CQAB149B2346 study manual
January 7, 2009	• Finished reading over the completed Novartis CQAB149B2346 study manual • Worked with Phil Hickman in filing study documents for the current Boehringer Ingelheim trial no. 0205.0339 study manual. The study is targeting Cystic Fibrosis subjects and the use of Tiotropium Bromide - I will have an active role in administrative filing and handling of IRB/study correspondence throughout the study • Searched for an additional journal article at UNTHSC's Lewis Library
January 8, 2009	• Spoke with Dr. Burk regarding attending an IRB meeting next month so that I can become familiar with the overall set up and proceedings of a typical meeting - I will be given documents regarding the studies to be discussed at next month's IRB meeting to review prior to the meeting (documents will be given at the end of the month) • Met with Dr. Gwirtz to go over some of the details for the internship and my research proposal • Read over journal articles regarding my research question • Contacted several departments at UNTHSC to get direction on developing and conducting a survey. - Dr. Kathryn Cardarelli recommended a book by Lu Ann Aday that she has previously utilized as a guide when developing surveys for previous trials conducted through UNTHSC • Checkout *Designing and Conducting Health Surveys*, by Lu Ann Aday, from UNTHSC Lewis Library
January 9, 2009	• Reviewed *Designing and Conducting Health Surveys* by Lu Ann Aday. • Began to develop ideas on how to develop the survey that I will be passing out to various Family Medicine Physicians.

Week 3 January 12, 2009	• Continued to review *Designing and Conducting Health Surveys* - Was able to develop a general idea on what to focus on when constructing the survey questions and document • Contacted (via email) several faculty members at UNTHSC to try and set up meetings in an effort to get some input on the proper way to design and conduct a research survey • Sent out my initial research question, objectives, and hypothesis to my Advisory committee for clearance to proceed with writing the rough draft of the research proposal
January 13, 2009	• Attended TPCCC staff meeting • Spoke with Kathy Kwaak, Office and Clinical Research manager for TPCCC, regarding a meeting time to sit down and discuss her role in the Clinical Research Department at TPCCC • Worked on constructing possible survey questions for the research project • Began to write my research proposal to send out to my Advisory Committee within the next week
January 14, 2009	• Attended the monthly Pulmonary Function Meeting consisting of various Respiratory Therapist from the surrounding TPCCC clinics and a service representative for VMAX 6200 Body Box - Representative was present to answer any general questions regarding the Body Box. The Body Box will be utilized at the Research Center for the Boehringer Ingelheim trial no. 0205.0339 targeting Cystic Fibrosis subjects and the use of Tiotropium Bromide, lung volumes will be measured via the Body Box • Observed a Pulmonary Function Test (PFT) performed on a patient from TPCCC. - While observing, I was able to get acquainted on the overall process, the measurements (lung volume, lung diffusion of CO, pre/post bronchodilator therapy spirometry), of a PFT for a given patient • Continued to work on the research proposal
January 15, 2009	• Observed Phil respond to data queries for a subject enrolled in the Novartis study trial no. CQAB149B2335SE - There was some question regarding some of the data entries listed on the server • Continued to work on the research proposal • Met with Kathy Kwakk, TPCCC's Office/Clinical Research Manager - Discussed her role within TPCCC Treatment Research

January 15, 2009 (cont'd)	Center and received input from her regarding the proper way to obtain a list of referring physicians from TPCCC's information management system, Versyss - Kathy brought me up to date on how the research office was started, and how she was incorporated into her current role with TPCCC - Discussed what was expected from me in regards to the clinical aspect of TPCCC's daily operations - Ideas were exchanged on how to effectively make the most out of the internship experience (most of the ideas were already discussed with Phil Hickman in a previous meeting)
January 16, 2009	• Continued to work on Research Proposal
Week 4 January 19, 2009	• Rounded with Dr. Burk at Harris Methodist Hospital - During the rounds I was able to observe two different fiber optic bronchoscopies (biopsy sampling and lavages took place) and get a general idea of the type of patients Dr. Burk sees in a given day • Attended Sleep Consultants, Inc meeting with Dr. Burk
January 20, 2009	• Constructed Survey questionnaire and permission letter • Attended Asif Ali's Practicum Defense at UNTHSC • Met with Dr. Gwirtz to discuss my survey questionnaire and permission letter that will be mailed out to physician offices - Reviewed the permission letter and made some slight revisions - Discussed who to get into contact with in regards to seeking assistance with the survey…some of the faculty members at UNTHSC SPH are out of pocket and will return back to work at an unknown date and time • We will contact Dr. Kathryn Cardarelli to schedule a possible meeting to go over the final draft of the survey and receive any input that she might see fit
January 21, 2009	• Observed Phil Hickman back up a previous study's records for a final time before the laptop, PFT machine, patient diaries, and back up cards are sent back to the sponsor. • Emailed the rough draft of the survey and permission letter to Advisory Committee • Emailed Dr. Kathryn Cardarelli, UNTHSC faculty, seeking assistance in reviewing/editing survey for the research project

January 22, 2009	• Reviewed articles provided by Dr. Burk regarding ethics, informed consent, and overall quality research • Read on quality measurements for surveys, *Designing and Conducting Health Surveys* • Set up meeting with Dr. Shawn Jeffries, UNTHSC SPH faculty, for Monday at 3:00 - Dr. Jeffries has worked and conducted surveys in the past, and we are to discuss the overall format and quality of survey to used for the research project
January 23, 2009	• Received email from Dr. Michael Smith, committee member, regarding feedback on the permission request letter and survey • Continued to review articles provided by Dr. Burk for general review
Week 5 January 26, 2009	• Met with Dr. Shawn Jeffries, UNTHSC SPH faculty, to discuss my current survey - Recommendations were made on the question writing (keeping the questions in the same tense), grading scale format (Strongly Disagree/1 → Strongly Agree/10), and overall informed consent - Dr. Jeffries also recommended to get in contact with Dr. Raquel Hampton, she has a more expansive background in survey methodology…Dr. Hampton is currently out on personal leave for medical reasons
January 27, 2009	• Began making revisions to the current survey…changed the question-tense format to all 1st person • Worked on revising visit sheets that will be utilized for the Novartis CQAB149B 2349 Trial - The sheets will be utilized as a checklist to ensure that all scheduled assessments are completed for a given visit during the study
January 28, 2009	• TPCCC was closed due to inclement weather • Worked on revising the survey at home • Sent email out to Advisory Committee seeking feedback regarding Research Proposal
January 29, 2009	• Finished revising visit sheets for the Novartis CQAB149B 2349 Trial - Sent the finished version to Phil Hickman to review and edit for any modifications that are needing to be made • Filed loose research documents for Novartis trial no. CQAB149B 2349, Novartis study trial no. CQAB149B2335SE, and Boehringer

January 29, 2009 (cont'd) January 30, 2009	Ingelheim trial no. 0205.0339 study manuals • Worked on revising some source documents that will be utilized for the Novartis trial no. CQAB149B2349
Week 6 February 2, 2009	• Worked on revising some source documents that will be utilized for Boehringer Ingelheim trial no. 0205.0339 • Reviewed journal articles that Dr. Burk gave me to read over regarding several topics in clinical research
February 3, 2009	• Attended TPCCC staff meeting • Met with Carla Peveto, TPCCC-Cooper Street business manager, regarding the referring physician spreadsheet - I was able to get the spreadsheet to start reviewing for potential research subjects out of the pool of referring physicians • Finished revising source documents for Boehringer Ingelheim trial no. 0205.0339 • Contacted Dr. Gwirtz regarding research proposal deadline…received email regarding proposal feedback
February 4, 2009	• Went to UNTHSC to retrieve an edited proposal from Dr. Gwirtz. • Searched online for a sample informed consent for a research survey - Was able to find a template from the University of Wisconsin • Worked on developing a rough draft of an Informed Consent for the research project
February 5, 2009	• Worked on making revisions to my survey, permission request letter, and research proposal • Attended Baylor Research Institute's Institutional Review Board meeting with Dr. John Burk - Reviewed the studies that were to be presented during the IRB meeting - Dr. Burk gave me a brief overview of what each study entailed - During the meeting, I was able to observe a principle investigator and research team, who had submitted a study for approval, defend and give their reasoning for approval of their proposed study ➔ Being able to observe this allowed me to gain an appreciation on what all is entailed in gaining approval for a research study…the study appeared

February 5, 2009 (cont'd)	to have good quality merit, however, there was language in either the protocol or consent form that made the IRB hesitant to approve the study after the initial review • Spoke with Dr. Burk at length regarding my research project…I was able to get some helpful insight as to what he was expecting from the research project - He gave some input on how to expand the study population…wants to possibly survey a Ft. Worth population and compare to a Dallas population (Dr. Burk gave me some names and said that we would have to meet with Carla Peveto to finalize a target group) - Discussed how to approach the study population physicians…instead of going from site to site and handing out the surveys, I should schedule a meeting with the various office/nurse managers and seek their assistance in getting the physicians to complete the survey and then have them mail/return the completed surveys - Posed the idea of having a trial run with the current survey…Dr. Burk wants to send the survey to a couple of physicians who have referred in the past and have them give some feedback on their thoughts of the survey • Rounded with Dr. Burk at Harris Methodist - Was able to watch in on a bronchoscopy and rounded on several patients
February 6, 2009	• Worked on making revisions to research proposal
Week 7 February 9, 2009	• Received feedback, via email, from Dr. Burk on the research proposal - He gave some suggestions on adding an addition question to the survey regarding patients history in participating in a research protocol - Additional suggestions were given regarding the wording within the research proposal • Made revisions to the research survey • Spoke with Phil Hickman regarding possible research articles pertaining to the current study trials at TPCCC Research Center - Currently seeking an journal article that gives another possible example of a study trial dealing with pulmonary disease…currently, I have examples, mentioned in the research proposal, of study trials dealing with cancer • Emailed Dr. Gwirtz to schedule a meeting time within the next two days to discuss the research proposal • I was given the research cell phone to take calls for the next

February 9, 2009 (cont'd)	two days that Phil and Kathy are out of the office attending an Investigators Meeting • Filed loose research documents into the study binders for Novartis trial no. CQAB149B 2349 and Boehringer Ingelheim trial no. 0205.0339
February 10, 2009	• Worked on revising research proposal • Took a few phone calls from potential research patients - A message was taken, and they were informed that Phil Hickman was out of town attending a research meeting…they will be contacted later on this week regarding possible enrollment into of the current studies being conducted at TPCCC Research Center
February 11, 2009	• Met with Dr. Gwirtz - Discussed the time line for submitting proposal for IRB approval - The idea of including a Dallas group of physicians into the target group for the research project was discussed…seems to be a good idea but with the limited time frame available to complete the internship, it might be best to only focus on the Ft. Worth group instead - Discussed the idea of requesting a waiver for a formal informed consent since the research project will not be involving any invasive procedures and only consist of a survey being administered to physicians ➔ UNTHSC's IRB website lists their requirements for informed consents to be waived, and my current "request for permission" letter contains all of the requirements that would be needed for a cover letter that would be substituted in place of an informed consent - She reiterated the need to only focus on the main goal of the project, which is to determine factors that are considered by PCP's when referring patients to clinical trials, and not consider a lot of other ideas in order to keep the project from getting to expansive and out of scope - Also mentioned that I would need to take the last six weeks of the internship to focus solely on writing my thesis and developing my defense presentation • Searched for another journal article pertaining to pulmonary clinical trials, to include in the research proposal • Continued to work on revising research proposal, request letter, and survey

February 12, 2009	• Continued to work on revising research proposal, request letter, and survey • Informed Phil Hickman of the messages left on the research phone from potential research subjects • Emailed the revised research proposal, request letter, and survey to my Advisory Committee - If everyone approves, then I can proceed with IRB and GSBS Office submission
	February 16th-20th : Medical Leave of Absence for the birth of my daughter
Week 8 February 23, 2009	• Submitted Research Proposal to GSBS office (via Dr. Gwirtz) for approval by Dr. Jamboor Vishwanatha, Dean of UNTHSC GSBS, and the UNTHSC IRB • Was briefed by Phil Hickman on the Research Offices activities that took place the previous week - Was informed of the number of research subjects consented for the Novartis trial no. CQAB149B 2349
February 24, 2009	• Met with Phil Hickman and Kathy Kwaak regarding current Novartis study - Subjects that have been consented were discussed and their charts were reviewed to ensure that all necessary information was obtained prior to scheduling visit 2/screening visit - I was able to ask Kathy questions regarding previous studies and how certain issues were handled in the past ➔ e.g.: how did they go about obtaining information regarding certain patients if they were being seen by multiple physicians, to what extent did the past medical records need to cover (# of yrs),
February 25, 2009	• Filed loose documents into the study binder for the current studies • Met with Phil Hickman in the morning to discuss what needed to be accomplished regarding the Novartis trial no. CQAB149B2349 - Searched for any requirements that were needed for sample storage (freezing/refrigeration) within the Study Laboratory Manual - Reviewed TPCCC's visit sheets/source documents and compared them to the study's eCRF guidelines needed for data input ➔ We are wanting to ensure that all information needed for data entry would be captured on the source documents during the scheduled visit • Spoke with Dr. Burk regarding previous emails that I had sent

February 25, 2009 (cont'd)	him pertaining to my research proposal and attending an Investigator Training Seminar at Baylor Research Institute - Dr. Burk wants me to go ahead and complete a trial run for my research proposal and survey with a couple of physicians who have referred to him in the past ➔ I have obtained addresses and phone numbers for Dr. Greg Phillips and Dr. Robert Keller to send the survey information to their office managers for the trial run - Dr. Burk also confirmed with me that he would like for me to attend the Investigator Training with Phil Hickman and requested that I forward the information to both Dr. Gary Jones and Dr. David Plump, both are TPCCC physicians, regarding the seminar ➔ I spoke with Phil regarding the seminar and we both faxed in our registration to attend
February 26, 2009	• Look over a data base that has been compiled by a previous intern…a lot of the information within the database can be utilized for future use in pt recruitment • Dr. Burk informed both me and Phil of the need to send out letters regarding current research activities taking place at TPCCC Research Center
February 27, 2009	• Worked on sending out letters to previous research patients to update them on the current research activities taking place at TPCCC Research Center. • Confirmed with Phil Hickman on the patients that we were aiming to reach…about forty patients were notified via mail of the current and upcoming studies
Week 9 March 2, 2009	• Out for Dr. Appointment
March 3, 2009	• Attended TPCCC Staff meeting • Spoke with Kathy Kwaak regarding physicians for my research project…she gave me some names of physicians on who she thought would be ideal to have included in the subject population • Worked on reviewing spreadsheets that have been utilized in the past by TPCCC Research Center - Spoke at length with Phil Hickman regarding what was wanted out of the updated spreadsheets/database - We both felt as if a spreadsheet with a pt population that was organized by diagnosis would be better utilized within the Research Center for current and future studies

March 3, 2009 (cont'd)	• Dr. Burk approached me with a request for overall pt total and pt totals for the Arlington and Hurst/Euless/Bedford communities that are listed in the current Research Center pt spreadsheet - the numbers are needed for an upcoming meeting regarding possible start up research programs at surrounding TPCCC sites • Dr. Burk also requested that we continued with letter send-outs regarding Research Center Activities • Was able to sit in and observe a Site Monitor visit for a potential study from Forest Research Institute - Observed what all was taken into account to determine whether a sited is deemed suitable to perform/maintain a research study - Was able to obtain a better appreciation of what all is considered by a study sponsor when interviewing a both the P.I. and study coordinator to ensure that a study site is staffed with qualified personnel • Made up hours for Monday's absence by staying late and was able to email Dr. Burk the pt totals that he requested
March 4, 2009	• Worked on reviewing Research Center pt. spreadsheets • Discussed with Phil on what all to include in the updated spreadsheet • Began an updated spreadsheet that is organized by diagnosis and TPCCC provider • Contacted the Field Test physician offices that Dr. Burk is wanting me to use prior to sending out my survey to the actual project population • Stayed late to make up time for Monday's absence…continued to work on the updated pt spreadsheet
March 5, 2009	• Worked on Research Center pt. spreadsheet…Dr. Burk notified me of wanting only COPD pt totals for Arlington and Hurst/Euless/Bedford areas - Originally, I gave him total pt numbers for the entire spreadsheet and for Arlington, HEB area - I was able to obtain total number of COPD pts in the spreadsheet for the two populations that he was requesting • Spoke with Phil Hickman regarding some the possible scheduling issues that might arise with the Novartis trial no. CQAB149B2349 - we might have to juggle some of the pt's f/u visits to help lessen the burden for some of the back to back study visits take place

March 5, 2009 (cont'd)	• Mailed out the request letter and survey to the two field test physicians that Dr. Burk had mentioned - I sent the survey to Dr. Greg Phillips since he does not have an office manager according to his Research Nurse Ann - Dr. Robert Keller only received a request letter seeking approval to meet with his Office/Nurse Manager ➔ A follow up phone call will be made next week to try and schedule a meeting with his Office/Nurse Manager regarding the survey • A meeting was scheduled with Dr. Gwirtz for Tuesday, March 10th, to discuss my current research work and also to get some additional info regarding my last six weeks of my internship • Stayed late to make up time for Monday's absence…completed filing of loose documents for the study manuals for Novartis trial no. CQAB149B 2349 and Boehringer Ingelheim trial no. 0205.0339
March 6, 2009	• Attended a Clinical Research Compliance Management Seminar at Baylor University Medical Center, in Dallas, TX, with Phil Hickman - The seminar was presented by MedTrials, CRO group based out of Dallas, TX, and hosted by Baylor Research Institute - Focused on general compliance issues, Corrective and Preventative Action plans, proper training of clinical research staff, and up to date hot topics currently going on in the FDA realm of Clinical Research - Small group sessions were engaged dealing with case studies regarding protocol deviations, compliance, proper research training, and research fraud - CME's were offered for those who qualified for educational credits
March 7, 2009	• Looked over the referring physician spreadsheet - Started to filter out those with few referrals from those who have a larger number of referrals to TPCCC - I am mainly looking at the physicians who have referred to Dr. Burk in the past
Week 10 March 9, 2009	• Met Kristen Stark, Study Monitor for the Novartis trial no. CQAB149B2349 • Worked on physician referral spreadsheet for my research project - I was able to filter out the physicians who have the most

March 9, 2009 (cont'd)	referrals to TPCCC (Dr. Burk) - Looked up addresses for the physicians • Went through electronic data capture training with Kristen Stark for the Novartis trial no CQAB149B2349 - I was trained on how to answer queries, input data from the CRF's, and how to correct mistakes within the electronic data capture system - Obtained my user log on name and password, in order to be able to access the EDC system
March 10, 2009	• Observed a clinical visit (visit 2) for the Novartis trial no. CQAB149B2349 - Observed the interview process, con med list review - Observed the spirometry portion of the visit and the study device training and rescue device training • Worked on making additional modifications to the referral physician spreadsheet for my research project • Continued to revise the TPCCC pt recruitment spreadsheet • Sat in a Site Initiation Visit for a potential upcoming study - I was able to get an appreciation for what all went into consideration for a study to be approved for a particular site - Became familiar with what the study would be seeking to accomplish • Spoke with Dr. Burk regarding the TPCCC pt recruitment spreadsheet - He was wanting an update on how the spreadsheet was coming along - I informed him of the lack of information that was found within the spreadsheet - Informed him of the amount of expired patients that were found in the spreadsheet
March 11, 2009	• Met with Dr. Gwirtz regarding my internship and practicum - I was able to get a clear understanding of what I was needing to do during the last 6 weeks of my internship - Became aware that my proposal was not yet approved by the UNTHSC IRB • Gathered all of the forms and documents that are needed for the IRB submission - Spoke with Itzel Pena at UNTHSC IRB/OPHS office for assistance on what to submit and what forms to fill out since I had a vague understanding of what was needed
March 12, 2009	• Obtained Dr. Burks signature on my GSBS Proposal form and

March 12, 2009 (cont'd)	IRB Exemption form that was needed for re-submission • Worked on TPCCC pt recruitment spreadsheet • Continued to obtain Office/Nurse Manager information for the physicians that will be targeted for my research project • Set up a meeting with Dr. Gwirtz for 3/13 to have her sign the required documents for re-submission • Observed a clinical visit (visit 2) for the Novartis trial no. CQAB149B2349 - Observed the interview process, con med list review - Observed the spirometry portion of the visit and the study device training and rescue device training
March 13, 2009	• Met with Dr. Gwirtz at UNTHSC - Obtained her signature on the GSBS Proposal form - Obtained Dr. Michael Smith's signature on the GSBS Proposal form • Submitted the IRB Exemption Form, Protocol Synopsis, Survey, Request Letter, and a copy of my Research Proposal to the UNTHSC Office for the Protection of Human Subjects for IRB review and approval • Submitted my Research Proposal to GSBS Office for approval • Worked on recruitment posters that will be placed in various TPCCC offices within the upcoming weeks • Revised the visit sheet for Visit 2 for the current Novartis study taking place at the Research Center - I added a table for easier recording of the urinalysis dipstick readings that is required in Visit 2 • Filed loose documents into the Novartis trial no. CQAB149B2349 study binder • Continued to work on obtaining Office/Nurse Manager information for the physicians that will be targeted for my research project
March 14, 2009	• Received notification of a Pre-Review IRB response for my research project from Heather Cline, MPA, from UNTHSC's OPHS • In their review, they noticed that the project involved an extensive amount of interaction with office/nurse managers at physician offices. - It has been their experience that office managers tend to be very concerned with "guarding the time" of the physicians for whom they work. - Additionally, it has been their experience that the office managers tend to be extremely busy themselves, which may impact their ability to correspond or meet with me in person.

March 14, 2009 (cont'd)	- They felt as if these factors may negatively impact study recruitment. • I replied back stating my awareness of the potential pitfalls…I will be making revisions to the protocol synopsis and overall research scheme to accommodate their recommendations of eliminating the Office/Nurse Manager and sending the research survey directly to the referring physician instead
Week 11 March 16, 2009	• Received a follow-up notification regarding my IRB submission from Heather Cline, MPA, from UNTHSC's OPHS - In her follow up she made several suggestions in regards to the IRB application and requested additional documents • Worked on making revisions to my Research Proposal/Project - Wrote a study cover letter, that will serve as an informed consent, as requested by Heather Cline, MPA - Wrote a phone/interview script for when I make follow-up phone calls to the office/nurse manager ➔ The script discussed and highlighted the main points that will be covered during the interaction - Revised Protocol Synopsis regarding the total number of subjects for the study - Revised the IRB application regarding the Age requirement for the research subjects that will take part in the study - Revised the Letter to Office/Nurse Manager as requested by Heather Cline, MPA • Obtained Dr. John Burk's signature on the revised IRB application
March 17, 2009	• Submitted the revised IRB application packet to UNTHSC's OPHS for IRB approval • Worked on making revisions to Research Flyers for TPCCC's Research Center • Revised Study Visit Sheets for the Novartis trial no. CQAB149B2349 • Received a second review notification from Heather Cline, MPA, from UNTHSC's OPHS - There are still some modifications that need to be completed prior to a final approval ➔ Wording in the protocol synopsis, office/nurse manager letter, research proposal, and phone call/interview scripts needed to be revised in minor details - The study will qualify for Exemption Research Study (a

March 17, 2009 (cont'd)	full IRB review will not be needed) • Worked on making the suggested revisions to the Research Proposal, Protocol Synopsis, Office/Nurse Manager letter, and phone call/interview scripts - Emailed the revised documents with tracking changes to Heather Cline, MPA for an initial review, before hard copies were submitted to UNTHSC's OPHS for a final review • Filed loose study documents into the study manuals for Novartis trial no. CQAB149B 2349 and Boehringer Ingelheim trial no. 0205.0339
March 18, 2009	• Received notification from Heather Cline, MPA, from UNTHSC's OPHS regarding my study cover letter. - she suggested that I make additional revisions to the format - I made the revisions and emailed them to her…one was similar to an example that she sent me to go off of, the second was a revised copy of what I had previously submitted - Heather Cline emailed me back regarding my submitted documents…recommended additional changes that were minor in detail…once completed, she advised me to submit IRB packet for final approval • Obtained a copy of "Instructions for Administration of Baseline & Transition Dyspnea Index" from Phil - I will need to review them for the upcoming visit 3 for the Novartis trial no. CQAB149B2349…I will be administering the BDI and TDI survey to the enrolled subjects for the future visits where the surveys will be needed • Reviewed BDI/TDI survey administration instructions provided by Novartis…discussed with Phil Hickman some concerns regarding me administering the survey to the research subjects. - Phil is to email both Dr. Burk and Kristin Stark regarding my qualifications to administer the survey • Made the suggested modifications to IRB documents…submitted IRB application and necessary documents to UNTHSC's OPHS for IRB approval
March 19, 2009	• Received notification from Heather Cline, MPA, that my Research Proposal has been approved by UNTHSC's OPHS/IRB • Completed electronic data capture for Novartis trial no. CQAB149B2349

March 19, 2009 (cont'd)	- Completed demography for all subjects who have been consented for the study - Completed screening failure information for the two subjects who did not qualify for the research study - Discussed with Phil Hickman some concerns regarding EDC on the research subjects who needed to complete a second consent visit…Phil emailed Kristin Stark to get a final confirmation on what we were to do • Filed loose study documents into the study manuals for Novartis trial no. CQAB149B 2349 and Boehringer Ingelheim trial no. 0205.0339 • Notified Dr. Gwirtz of my IRB approval and emailed her my final versions of IRB approved documents for her records… • Picked up IRB packet of approved forms from UNTHSC's OPHS
March 20, 2009	• Worked from home on a final spreadsheet of referring physician information to be used during the research project
Week 12 March 23, 2009	• Administered a Baseline Dyspnea Index questionnaire to a research subject in the Novartis trial no. CQAB149B2349 • Observed the first part of the morning session of the research subjects visit #3 • Reviewed a print out of pt's seen by Dr. Burk and his nurse practitioners during the past year - The list will be a reference to go off of for the research recruitment spreadsheet • Worked on mailing out the initial request letters to the referring physicians office/nurse managers for my research project - Made address labels for the letters going out - Revised the referring physician spreadsheet - Mailed out the request letters • Made copies of all IRB approved forms for future use • Worked on the research pt recruitment spreadsheet - Crossed checked the previous list on the initial pt spreadsheet with the recent print out of all the patients seen under Dr. Burk's name during the past year of 2008
March 24, 2009	• Observed Visit #4 for research subject in Novartis trial no. CQAB149B2349 • Performed EDC for visits 1, 2, & 3 for subject #1 for Novartis trial no. CQAB149B2349 - Discussed with Phil Hickman several issues that came up as data entry was being performed - Email was sent to Kristin Stark regarding some data

March 24, 2009 (cont'd)	entry questions that we stumbled upon • Filed loose documents into the study manual for Novartis trial no. CQAB49B2349 • Continued to work on updating TPCCC Research spreadsheet
March 25, 2009	• Worked on Referring Physician spreadsheet for my research project - Called physician offices that I have not been able to get through due to morning office hours or being closed • Continued to work on updating TPCCC Research spreadsheet • Discussed with Phil Hickman an ongoing SAE report for a pt in the Boehringer Ingelheim trial no. 0205.0339 - Was brought up to date on what all has transpired with the pt and his 2 hospital admissions - Reviewed the previous SAE report forms with Phil Hickman - Observed Phil fill out new report forms to be sent to BI for further notification/documentation
March 26, 2009	• Pt in the Novartis trial no. CQAB149B2349 that was scheduled for his Visit #3 failed to report for the visit… - Phil Hickman has attempted to contact the pt with no success - With pt no-showing for the scheduled visit, there is question on how to go about the missed visit in regards to the protocol • Reviewed the Novartis study manual to follow guidelines for reporting missed scheduled visit by the pt…reported to Phil what Novartis needs in terms of documentation of missed visits and what the Research Center needs to complete if the pt does not follow up on the missed visit • Updated on new developments in the SAE reporting by Phil - There was several revisions that BI was wanting made and Phil reviewed what all they wanted changed and gave their reasoning for the changes - There was discussion by BI on how to properly label/classify the developments in the SAE…there was questions on whether to consider the pts status as a new event or an ongoing event • Received a phone call from one of the referring physicians office managers regarding the research study - Appt to meet at his office has been made for April 2, 2009 - Physician has expressed interest in completing the survey for the study

March 27, 2009	• Worked on Referring Physician spreadsheet for Research Project
Week 13 March 30, 2009	• Out of the Office for Dr. Appointments
March 31, 2009	• Contacted Referring Physician's offices for Request Letter follow-up - Was able to get several physician offices to agree to participate in the research project - Have to resend the request letter via fax due to several offices claiming that they never received the letter
April 1, 2009	• Mailed out the surveys to the offices who have agreed to participate in the research project • Faxed the request letters to the offices that have yet to receive the letter regarding the research project • Called Referring Physician's offices for Request letter follow-up • Assisted Phil Hickman with data collecting for a subject's urine analysis for Visit #2 in Novartis trial no. CQAB149B2349
April 2, 2009	• Logged onto the Novartis trial no. CQAB149B2349 EDC system to check for any new queries for previously entered data - There were a couple of flagged items…mainly dealt with medical history and one had was related to the visit date - Spoke with Phil Hickman about the flagged items…we will look at them together in the morning to decide how we want to go about correcting and making follow-up comments for Novartis • Met with Dr. James Parker at his office in regards to the Research Project - Dr. Parker completed the survey and gave some feedback on what he considered was needed from the Clinical Research realm regarding marketing and public relation matters • Filed loose documents into the Novartis trial no CQAB149B2349 and Boehringer Ingelheim trial no. 0205.0339 study manuals • Made follow-up phone calls to referring physician office's to set up meeting times to discuss my research project in greater detail - Was able to schedule a meeting time with Estella Hernandez, Dr. Robert Kelly's office manager, for Monday April 6, 2009
April 3, 2009	• Made follow-up phone calls to referring physicians offices for the research project - The follow-up phone calls are to previous calls where messages where left…attempting to make actual

April 3, 2009	contact with the office/nurse manager regarding the study • Reviewed a recruitment letter for the Boehringer Ingelheim trial no. 0205.0339 that will be sent out to Cystic Fibrosis pt's for possible enrollment into the study - Made some revisions to the letter and discussed with Phil Hickman • Printed address labels for the CF mailing list and mailed out recruitment letters to potential subjects for the B.I. CF study
Week 14 April 5, 2009 April 6, 2009 April 7, 2009	• worked on revising the TPCCC Research subject spreadsheet • Conducted a BDI survey for a research subject in the Novartis trial no. CQAB149B2349 • Contacted Referring Physician's office to follow up on Project Request Letter • Worked on revising the TPCCC Research Subject Spreadsheet • Met with Estella Hernandez, office manager for Dr. Robert Kelly, regarding the research project - I explained the purpose of my research project and what I was aiming to accomplish - Left a survey with her for Dr. Kelly to fill out • Brought up EDC for Novartis trial no. CQAB149B2349 to check for any new queries • Completed the open queries prior to Kristin Stark arrived for her scheduled Site Monitoring visit for the ongoing Novartis study • Filed loose documents into the Novartis trial no CQAB149B2349 study manual • Emailed a project update to Dr. Burk, Dr. Gwirtz, and Kathy Kwaak to keep them informed of what all is going on with the research project • Emailed Dr. Gwirtz to set up a meeting with her next week regarding forms/documents that need to be submitted to the GSBS office by May 8, 2009 - Meeting is scheduled for 4/14/09 at 12:00 pm at UNTHSC • Sat in a chart review for a research subject in the current Novartis study with Phil Hickman and Kristin Stark • Spoke with Dr. Burk regarding some ideas that I have come up with during a recent conversation with a participating physician in the research project - Idea of mentioning some of the comments that physicians make or provide during an

April 7, 2009 (cont'd)	encounter/interview (or make on the survey itself) in my thesis and presentation was discussed with Dr. Burk - I did not request for permission to include physician comments in my initial IRB approval application, so the idea is new and the need for approval is what I had questions on…Dr. Burk feels as if it would not be in any way an IRB violation if I were to include the comments in my thesis and final presentation • Entered data into the EDC system for a research subject in the current Novartis study
April 8, 2009	• Out of Office for Dr. Appt
April 9, 2009	• Spoke with 2 of the referring physicians offices regarding the research project - Dr. Ruston Jennings has agreed to participate in the project…survey was mailed to Sharon Hunter, office manager, to have Dr. Jennings complete the survey - A group of physicians have agreed to participate in the study as well, surveys were mailed to Susan Waggoner to have the physicians complete the survey • Worked on the TPCCC Research Subject spreadsheet
April 10, 2009	• OFFICE CLOSED FOR GOOD FRIDAY • Mailed the surveys to Sharon Hunter and Susan Waggoner to have their respective physicians complete the surveys for the research project • Worked from home on TPCCC Research Subject Spreadsheet
Week 15 April 13, 2009	• Worked on TPCCC Research Subject Spreadsheet
April 14, 2009	• Worked on Research Project survey results - Built a spreadsheet to list the responses marked by the participating physician - Built in a function to list the total sum and average of the responses • Logged onto the Novartis EDC system to check for any open queries • Completed EDC for a research subject in the Novartis study who completed her V3 and V4 today • Met with Dr. Gwirtz at UNTHSC regarding graduation forms that need to be completed by May 8th • Worked on TPCCC Research Subject Spreadsheet

April 15, 2009	• Filed loose documents into the study manuals for Novartis trial no. CQAB149B2349, Boehringer Ingelheim trial no. 0205.0339, and Novartis study trial no. CQAB149B2335SE • Worked on TPCCC Research Subject Spreadsheet • Logged onto Novartis EDC for CQAB149B2349 to check for any open queries • Reviewed the schedule for future study visits for the current research subjects - While trying to sync my calendar to Phil's calendar I noticed that a visit was scheduled on Memorial Day, May 25th …TPCCC Research office is closed for that day and the visit would not be completed that day - I reviewed the protocol to search for any leniency in terms of moving the visit up or back a day…the protocol did not mention of any so Phil emailed Kristin Stark and Bernie Kotyuk with Novartis for clarification on what we should do - We were given the go ahead to reschedule the visit to the following day, May 26th
April 16, 2009	• Worked on Referring Physician spreadsheet for the Research Project - Contacted two offices that have received surveys to complete but have yet to complete/return them…one office informed me that they were no longer interested in participating - Mailed out three more surveys to physicians whose office managers were non-responsive in returning my phone calls - Looked up address information for other physicians who have a lower number of referrals to Dr. John Burk….I will mail surveys to the physicians in an effort to get them to participate in the survey • Received a phone call from Kay Barrett, office manager for a group of referring physicians…informed me that the completed surveys are in the mail and that I should receive them within the next few days
April 17, 2009	• Made survey packets for additional referring physicians…this will be the second group of physicians to be contacted about participating in the research project - This group of physicians will have the survey mailed directly to them in order to save time due to the limited amount of time that is remaining for the research project

April 17, 2009 (cont'd)	- Trying to make contact with their office/nurse manager has been somewhat difficult and time consuming due to some reluctance or non-compliance from the managers in returning messages that have been left on more than one occasion
April 18, 2009	• Finished preparing the survey packets & placed them in envelopes to be mailed out - Made address labels and return address labels for the envelopes that will be mailed out
Week 16 April 20, 2009	• Finished working on mailing out survey packets
April 21, 2009	• Received 5 completed surveys from referring physicians for the research project - This brings the total number of completed surveys to 8 • Spoke with Phil Hickman to be brought up to date on what has taken place over the weekend regarding any of the research studies - We will need to make contact with additional COPD subjects to inform them of the new upcoming research study that will be starting within the next few weeks - I will need to contact them via phone later this week to try and recruit them for the study • Mailed out the second batch of surveys to referring physicians • Spoke with Dr. Burk…informed him of the total of completed surveys now being 8 - During our conversation, he assigned me to clean out a crash cart that will be utilized for the an upcoming study • Completed EDC for two research subjects in the current Novartis study - Also made changes that were needing to be made to previously entered data …most of the changes were findings that Kristin Stark noted from her last visit • Worked on TPCCC Research Subject Spreadsheet
April 22, 2009	• Received a phone call from Condra Able, office manager for a group of referring physicians. She informed me that one of the referring physicians will participate in the research project - I faxed over the survey and cover sheet for Dr. David Jordan to fill out • Logged into the Novartis EDC to check for any open queries - There were no queries as of this morning • Made a simple spreadsheet that contained potential research

April 22, 2009 (cont'd)	subjects who have inquired about research studies that are or will be taking place at TPCCC ResearchCenter - I emailed this to Phil Hickman so that he can contact a few of them while he is out of the office attending an Investigator Meeting for an upcoming COPD study • Cleaned out a cart that will be utilized as a crash cart for an upcoming study
April 23, 2009	• Worked on TPCCC Research spreadsheet - Worked on filtering out the names of pt's that Dr. Burk has seen in the past year - The filtered list of names seen in the past year can be utilized for possible recruitment into the two upcoming research studies at TPCCC Research Center
April 24, 2009	• Began to read up on some possible statistical applications that could be utilized and applied for my research project - I will be required to present statistical analysis on my project results during my Thesis/Practicum Defense
Week 17 April 27, 2009	• Received an email from Kristin Stark pertaining to an open query for Research Subject #2 - I logged on the Novartis EDC system and checked for any additional queries…answered the open query for Subject #2 • Spoke to Phil Hickman regarding an email that I received from Carla Peveto, TPCCC Business Manager, that pertains to an upcoming study dealing with pt's diagnosed with Asthma/COPD and Coronary Artery Disease or Diabetes and Heart Disease - We will go thru the attachment that was sent with the email and try and filter out potential research subjects for the upcoming Astellis study • Received a completed survey that was faxed to the Research Office over the weekend • Discussed with a Phil Hickman, a COPD Exacerbation that a Research Subject experienced…we discussed what all needed to be done in regards to Study forms - According to eCRF manual, only documentation that needs to be completed is within the eCRF itself
April 28, 2009	• Logged onto the Novartis EDC System to check for any additional open queries…nothing new was flagged for correction • Worked on filtering out potential research subjects for an upcoming Astellas study dealing with COPD/Asthma pt's with

April 28, 2009 (cont'd)	Coronary Artery Disease or Diabetes/Hypertension/Hypercholesterolemia (must have 2 of the latter) - Was able to obtain a list of 38 potential research subjects who have seen Dr. Burk at TPCCC and meet the study's inclusion criteria - List was given to Phil Hickman and then later passed onto Dr. Burk for an initial review and verification that the selected subjects could be contacted regarding the study. • Began to complete some of the required graduation forms that will need to be filled with UNTHSC prior to my Thesis/Practicum Defense
April 29, 2009	• Worked on Research Subject List for the upcoming Astellas Study - I emailed the updated list to Phil Hickman so that he would have access to the current list to begin contacting the potential subjects for the study • Was on UNTHSC Campus for a orientation for the incoming interns for the Clinical Research Management program…Dr. Gwirtz had emailed several current interns/CRM students to attend and give some insight to what our experiences have been like during our time at our given internship sites • Met with Financial Aid office to clear up some matters regarding Summer Financial Aid
April 30, 2009	• Continued to work on Research Subject List for the upcoming Astellas Study - Was able to finish going through and filtering out potential research subjects who have seen Dr. Burk or Dr. McDonald with TPCCC - I forwarded the spreadsheet to Phil Hickman for initial review and to discuss with Dr. Burk once the study is underway • Filed loose paperwork/documents into the Novartis trial no. CQAB149B2349 study binder • Worked on updating my CV/Resume that will need to be submitted to UNTHSC GSBS office and Student Services Office to complete a graduation requirement
May 1, 2009	• Continued to work and finalize my CV • Began to review a Biostatistics Textbook for different statistical applications to utilize for the research project

Week 18 May 4, 2009	• Finalized my CV - Emailed it to a potential job offer for initial review…informed them that a finalized draft will be submitted to them once I complete all requirements for my Master's Degree • Emailed Dr. Gwirtz to schedule a quick meeting to have her sign my Intent to Graduate form…the form needs to be submitted to GSBS office by this Friday, May 8th - I received an automatic reply email from Dr. Gwirtz that she was out of her office for the entire week and that she would be returning on May 11th - I emailed Carla Lee, Director of GSBS, for further input • Logged onto the Novartis ECD system to check for any new queries…nothing new was reported; however, the initial query from last week was still labeled as open - Spoke with Phil Hickman regarding the open query, since no further notification has been made since last week, we will wait for it to be closed unless something changes and we are told by Novartis that we need to look into the matter again
May 5, 2009	• Reviewed a journal article that Dr. Burk sent regarding patient attitudes and preferences about recruitment and participation in clinical trials • Entered study visit information into the Novartis EDC system • Began to review Lu Ann Aday's book, "Designing and Conducting Health Surveys", for further insight on how to apply statistical analysis to my research project • Received another completed survey in the mail…this brings the total # of completed surveys to 13
May 6, 2009	• Worked on making study visit sheets for the Forest trial no. LAS-MD-33…TPCCC is currently recruiting subjects for the study • Met with Andy Axom, Student Development Counslor for UNTHSC, to review my CV • Submitted my Intent to Graduate Form into the GSBS office
May 7, 2009	• Continued to work on making the study visit sheets for the Forest trial no. LAS-MD-33…reviewed the final draft and sent to Phil Hickman to review to ensure completeness for what was needed for the given study visits • Entered Study Visit information for a Research Subject into the Novartis EDC system • Filed loose source documents/paperwork into the Novartis trial

May 7, 2009 (cont'd)	no. CQAB149B2349 study binder and Boehringer Ingelheim trial no. 0205.0339 study binder
May 8, 2009	• Emailed Carolyn Polk, GSBS Secretary, to schedule a time for me to come in and review some past thesis' of CRM students • Reviewed Lu Ann Aday's book to form an idea of how to manage the data for analysis for the thesis and presentation • Arranged to meet with Kathy Kwaak, TPCCC Research Manager, next Tues to discuss the research budget for the Research Center
Week 19 May 11, 2009	• Logged onto Novartis EDC system to check for any open/new queries…no new queries were reported • Contacted Dr. Gwirtz, via email, to schedule a meeting to sit down and discuss my thesis in detail • Reviewed Lu Ann Aday's book to continue to form an idea of how to manage the data for analysis for the thesis and presentation
May 12, 2009	• Met with Kathy Kwaak, Office/Research Manager for TPCCC, to discuss how she comes up with the research budget for studies taking place at TPCCC • Went to UNTHSC and reviewed previous Clinical Research Management students thesis - I was able to get an idea of how to go about writing my thesis and how to format the thesis as well - I will still need to get some insight on the results section though
May 13, 2009	• Logged onto the Novartis EDC system to check for any new queries - No new queries were reported • Entered information into the EDC for a subject's study visits - Had to confirm a few details from the study visit with Phil Hickman…subject had made an error in administering the study drug • Began to work on updating and writing/formatting my thesis
May 14, 2009	• Contacted GSBS administrative office regarding my Intent to Graduate form - Spoke with Jan and she assured me that the form had been signed and everything was set for Summer 2009 graduation • Scheduled a meeting with Dr. Gwirtz for Monday, May 18th, to discuss my thesis and my remaining time at TPCCC Research

May 14, 2009 (cont'd)	Center • Logged onto the Novartis EDC system to check for any new queries • Entered Information into the EDC for a subject's who completed his visit 5 & visit 6 today at TPCCC Research Center
May 15, 2009	• Worked on Thesis
Week 20 May 18, 2009	• Met with Dr. Gwirtz on campus regarding my Thesis - Discussed Thesis guidelines and possible dates for Thesis defense - Obtained permission for taking time away from TPCCC Research Center to work on writing thesis and organizing my thesis defense ➔ I will be away from the research center for a week at a time during the final six weeks at TPCCC Research Center to work solely on my thesis • Spoke with Kathy Kwaak regarding the final six weeks at TPCCC Research Center and to verify when Dr. Burk will be available for my Thesis defense - She agreed with me taking time away from the Research center to work on the thesis as well • Worked on an open query for the Novartis study - Had Phil Hickman sit down with to go over the EDC/eCRF data input for future use • Emailed Dr. Sejong Bae, with UNTHSC's SPH/Biostatistics Department, seeking assistance with statistical analysis for my research project • Worked on building the study binder for the upcoming Forest trial no. LAS-MD-33
May 19, 2009	• Worked on writing the Internship Experience portion of my Thesis • Communicated with Kathy Kwaak via email throughout the day regarding Dr. Burk's availability on June 30th for my Thesis Defense - She is working on having another physician with TPCCC to cover Dr. Burk's day call for a couple of hours on the 30th of June so that he can be available for the defense • Logged onto the Novartis EDC system to check for any new queries
May 20, 2009	• Received confirmation from Kathy Kwaak that Dr. Burk will

May 20, 2009 (cont'd)	be available on the 30th of June from 1:30 – 3:30 p.m. for the Thesis defense • I emailed my Advisory Committee to confirm the date of June 30th is still available for everyone. - Dr. Gwirtz, Dr. Smith, and Phil Hickman all confirmed availability and the defense date is set - Dr. Gwirtz mentioned that she would make the reservation for a room (on campus) for that day • Met with Dr. Bae at UNTHSC's SPH...we went over the survey results and he gave some insight on how to possibly go about performing statistics for the Thesis • Received confirmation from Dr. Gwirtz on the room reservation…Lib-110 is where the defense will take place • Worked on revising the survey results as recommended by Dr. Bae
May 21, 2009	• Spoke with Phil Hickman regarding the Monitor visit with Kristin Stark…she came across a couple of entries on source documents for several patients that needed to be looked at and re-verified - Phil and I spoke about some of the findings briefly • Obtained signatures from my Advisory Committee for my Intent to Defend Form…submitted the form to the GSBS Office to be filed • Worked on computing some statistical analysis on my survey results - Reviewed old lecture notes from a previous BioStats course that I took to help refresh on some of the statistical applications - Reviewed the use of SPSS, a statistical software, via online tutorials made by the Statistics Department at the University of California at Los Angeles and Texas A&M University - Hand calculated some Chi-square statistics for some of the survey results…compared several questions to determine whether or not the given survey results were independent of each other • Went to UNTHSC's Gibson Library to use the SPSS software in the computer lab…verified my calculations with the software's output
May 22, 2009	• Met with Phil Hickman and Candace Copeland, TPCCC study coordinator, regarding the grading of previous BDI questionnaires...Candace was needing some verification on the proper way to grade some previous questionnaires that she had administered to some of the research subjects

May 22, 2009 (cont'd)	• Worked on finishing up my statistical analysis • Emailed my statistical outputs to Dr. Bae for review…I had previously asked him if he would be willing to review the output to help ensure that the statistical analysis was done correctly
Week 21 May 25, 2009	• **MEMORIAL DAY:** TPCCC Research Center office closed for the holiday
May 26, 2009	• Worked on Thesis
May 27, 2009	• Worked on Thesis • Reformatted survey results table to be included in the Thesis • Received reply from Dr. Bae on the review of my survey results…he reiterated for me to utilize descriptive statistics, but that Fisher's Exact Test could be of use as well
May 28, 2009	• Worked on Thesis • Reviewed Fisher's Exact Test statistical application - With the small sample size that is utilized in my research project, Chi Square tests are not conducive to report accurate statistical analysis - Fisher's Exact Test is more suited to report output for a smaller sample size
May 29, 2009	• Worked on Thesis
Week 22 June 1, 2009	• Spoke with Phil Hickman to catch up on any research activity that took place while I was out of the office • Filed loose paperwork into the study binders for the Novartis trial no. CQAB149B2349 study binder and the Forest trial no. LAS-MD-33 binder • Emailed Carolyn Polk to schedule a time to go and review a previous thesis for further insight - Meeting time is set up for 6/2 at 3:00 pm
June 2, 2009	• Spoke with Phil Hickman regarding a notification of a query and some additional information being needed for several research subjects - Some of the info needed is in regards to an A.E./COPD exacerbation that has taken place with a research subject • Logged onto Novartis EDC system to correct a query for a research subject - Worked with Phil in completing the queries and adding

June 2, 2009 (cont'd)	additional information into the EDC as requested by Study Monitor • Reviewed a previous CRM student's thesis to have a general idea of how to go about writing my discussion portion for my thesis • Worked on writing the discussion portion of the thesis
June 3, 2009	• Logged onto the Novartis EDC system to recheck on a query that we were notified of by the Study Monitor - Query was answered again - Phil Hickman has contacted Kristin Stark, Study Monitor, to notify her of the change/entry in the EDC • Continued to work on writing my thesis • Emailed Dr. Gwirtz the 1st draft of my Thesis for initial review
June 4, 2009	• Formatted thesis…fixed margins according to UNTHSC's guidelines • Formatted Table of Contents for the thesis • Logged onto the Novartis EDC system to recheck the query that TPCCC research center was notified of - Kristin Stark notified Phil Hickman that the query was not answered with an additional note attached to the correction
June 5, 2009	• Worked on Thesis
Week 23 June 8, 2009	• Worked on Thesis
June 9, 2009	• Began working on power point presentation for the oral defense • Reformatted my Daily Activity Journal according to UNTHSC's guidelines
June 10, 2009	• Continued to work on power point presentation for oral defense
June 11, 2009	• Continued to work on power point presentation for oral defense
June 12, 2009	• Worked on editing thesis • Continued to work on power point presentation for oral defense
Week 24 June 15, 2009	• Logged onto the Novartis EDC system to check on any new queries - Worked with Phil Hickman in answering the queries • Filed loose paperwork into the study binders for the Novartis, B/I, and Forest studies • Contacted Dr. Gwirtz regarding revisions for the rough draft of

June 15, 2009 (cont'd)	thesis
June 16, 2009	• Worked on making edits and additions to the thesis • Administered a Transitional Dyspnea Index to a research subject in the Novartis study • Worked on writing the abstract for my thesis • Phil Hickman received an email from Kristin Stark regarding some additional queries, along with some of the current queries that are still unresolved. • Logged onto Novartis EDC system to check into the queries that were brought up - Corrected the queries and attached notes within the EDC system • Entered visit information for subject 01's visits 7 & 8 into the Novartis EDC
June 17, 2008	• Met with Dr. Gwirtz review my 1st Draft of the Thesis • A meeting was scheduled for June 25th to practice my defense
June 18, 2009	• Filled out a Final Progress Report form to turn into UNTHSC's IRB office, this will officially close out my research project • Worked on making revisions to my Thesis
June 19, 2009	• Submitted my revised thesis to my advisory committee for their review • Submitted my Final Progress Report for my research project to UNTHSC's IRB
Week 25	
June 22, 2009	• Worked on making revisions to oral presentation
June 23, 2009	• Worked on making revisions to oral presentation • Emailed Dr. Gwirtz my presentation slides to review prior to our meeting on Thursday
June 24, 2009	• Emailed Advisory Committee seeking any new revisions that are needed to be made to my Thesis - Phil Hickman notified me of a couple of grammatical errors made
June 25, 2009	• Filed loose documents into the study binders for the Novartis and Forest studies • Made revisions to my thesis • Reviewed my oral presentation prior to meeting with Dr. Gwirtz • Met with Dr. Gwirtz to go over my oral presentation

June 26, 2009	• Made some revisions to my oral presentation
Week 26 June 29, 2009 June 30, 2009	• Reviewed my Oral Presentation • Administered TDI questionnaire to a research subject in the Novartis study • Thesis Oral Defense

BIBLIOGRAPHY

1. Aday LA. Cornelius LJ. *Designing and conducting health surveys: a comprehensive guide*. Third edition (2006). San Francisco, CA: Jossey-Bass.
2. Chen AM. Bollmeier SG. Finnegan PM. Long-Acting Bronchodilator Therapy for the Treatment of Chronic Obstructive Pulmonary Disease. *The Annals of Pharmacotherapy.* 42(12):1832-42 2008, December.
3. Chen DT. Miller FG. Rosenstein DL. Clinical research and the physician-patient relationship. *Annals of Internal Medicine*. 138(8):669-72 2003, Apr 15.
4. Frayne S. Mancuso M. Prout MN. Freund KM. Attitudes of primary care physicians toward cancer prevention trials: a focus group analysis. *Journal of National Medical Association*. 93(11):450-7, 2001 Nov.
5. Little P. Dorward M. Warner G. et. al. Importance of patient pressure and perceived pressure and perceived medical need for investigations, referral, and prescribing in primary care: nested observational study. *British Medical Journal*. 328(7437):444, 2004 Feb 21.
6. Ortolon K. Putting patients on trial: Barriers keep cancer patients from clinical investigators. *Texas Medicine*. 99(4):37-9 2003, Apr.
7. Weinberg A. Cooper HP. Mejia NI. Spiker CA. Attitudes of primary care physicians and specialists about cancer clinical trials: a survey of Texas physicians. *Texas Medicine*. 100(4):66-72 2004, Apr.

8. Yates JW. Clinicians in community practice are major contributors to clinical trials in cancer prevention, early detection, and treatment. *A Cancer Journal for Clinicians*. 53(2):69-72, 2003 Mar-Apr.