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The difficulties of clinical trial recruitment are known, but solutions are not well characterized which leads to recruiting research subjects as a major reason for trial inefficiency. The goal of this practicum project was to survey former and current research patients of Texas Pulmonary & Critical Care Associates, P.A. (TPCCC) to optimize recruitment strategies for the TPCCC Research Center by examining their beliefs and attitudes towards research. The results suggest that patients have a generally positive attitude towards clinical research and join for their improvement and benefitting others. There is a strong agreement that former and current patients would recommend others to participate in research and as far as drawbacks, there was no significant drawback experienced. Internet use was more prevalent in patients over the age of 65 and while interest in using the internet to learn more about clinical research was not overwhelming, contact through the internet by e-mail was desired along with telephone contact. Categorization of the participants’ responses may aid the TPCCC research center in developing strategies to improve recruitment.

PATIENT ATTITUDES TOWARDS CLINICAL RESEARCH

RESEARCH PARTICPANTS' BELIEFS AND ATTITUDES TOWARDS CLINICAL RESEARCH STUDIES

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RESEARCH PARTICPANTS' BELIEFS AND ATTITUDES TOWARDS CLINICAL RESEARCH STUDIES

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 OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

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CHAPTER I

INTRODUCTION

Texas Pulmonary & Critical Care Consultants (TPCCC), P.A is a private group practice with nine offices throughout Tarrant County that includes twenty nine physicians, three sleep laboratories, two treatment centers, and two research centers. The current clinical research trials that are being conducted at the two research centers designed to benefit patients who are suffering from chronic obstructive pulmonary disease (COPD) by treating them with phase III or phase IV investigational new drug (IND). The research population for TPCCC is a mixture of patients within the TPCCC practice and people who have heard or learned about research from advertisements or other means.

Recruiting patients at a research center focused specifically on pulmonary issues can be challenging and TPCCC has countered by introducing multiple recruitment methods to increase enrollment within the target population. The research staff has shown interest in determining

ways to increase enrollment keeping the enrollment methods up to date and efficient. In order to understand what leads patients to consider and participate in clinical research, a survey was created that asked questions to better understand the thoughts and attitudes of former and current research patients. The answers from the survey along with each patient's age, gender, and location were evaluated to refine TPCCC recruiting.

CHAPTER II

INTERNSHIP PROJECT

Background and Literature Review:

Patient recruitment is a mounting challenge for clinical research studies. Roughly 50%-90% of clinical research studies are not completed in the desired time due to lack of viable patient recruits. [1, 2] Delays increase the costs of trials and make the process of bringing new medications to the market inefficient and time consuming. Numerous recruitment tactics have been developed in an attempt to alleviate this problem and minimize cost overruns. Guidelines and structured approaches such as GCP and ICH were designed to focus on understanding protocols and assessing clinical populations.[3] Recruiting situations differs to a certain extent, multiple platforms are used to identify and contact patients, and with the rapid ascension of the internet and social media outlets, methods to contact and engage patient recruits are greatly expanding. However, matching marketing to the desired population requires an understanding of what information is useful, practical, and relevant for the desired population.

By assessing the deterrents to successful patient recruitment, researchers have identified certain key barriers to overcome. These barriers often result from problems related to the investigator, protocol, and subject's problems. [4] Investigator related barriers often stem from the

principal investigator's dual role as a healthcare provider and scientist that can at times put the principal investigator in difficult situations involving patient safety and "good science practice".[5] The barriers associated with the protocol are often necessary to promote maximum understanding of the drug in a safe and effective manner especially when comparing the investigational product to a placebo. So while protocol problems are detrimental, they are necessary for finding recruits that give optimal results. Subject related barriers are commonly addressed by clinical research staff. The most common subject related barriers hindering patient recruitment involve the ability to reach out to potential patient recruits. Factors such as time commitment, distance, or the patient's hesitance regarding the real or perceived risks of the treatment can contribute to this barrier.[6] The main strategy to tackle subject related barriers is to implement an effective and efficient method to advertise clinical research.

Current clinical research advertising ranges from traditional platforms such as radio and print to more unconventional forms, such as blogging done by a patient previously involved in clinical research studies. While each medium has its benefits, great care must be taken to ensure that any form of advertising is not misleading while still engaging the public.[7] The research center is responsible for determining what forms of advertising and in what combination are most effective for recruiting patients. A survey performed on members of the Association of Clinical Research Professionals (ACRP), there were several factors that lead to an increase in recruitment. The most powerful factors were having a physician mention research to the patient and the perceived benefit of the treatment itself. Financial incentive and the recruiter being able to effectively answer any questions were also important factors in increasing recruitment. The

first major factors can definitely be implemented for TPCCC's research practices to improve recruitment but it would be difficult to unequivocally determine the true effectiveness of these procedures. Because TPCCC has a research population is older, there is still some doubt over just how valuable technology is in aiding technology.

With the growing use of the internet and various web based social media sites, there is an increased desire to use this new technology to reach potential research participants. Studies have shown that consumer segments can be broken down into roughly four age groups: Millennial (18-29), Gen X (30-45), Boomer (46-64), and Silent (over 65).[8] A trend is recognized in which the older the age group, the less extensive the of the internet and social media networks thereby diminishing the impact of internet patient recruitment.[8] Several free websites serve to inform possible participants about clinical research such as ClinicalTrials.gov and TrialX.com, yet many people in general are unaware of these sites. The use of technology as the primary tool for patient recruitment is typically not ideal for reaching patients involved with TPCCC studies, since most of these patients fall in the Boomer and Silent age groups. Utilizing technology as an aid to target the secondary market of possible participant's family or friends or to simply educate the potential participant is a prospective but understudied matter. Studies have shown that rather than solely focusing on the latest forms of advertising, giving effort to earlier and more frequent interactions with the patient recruits ultimately leads to an increase in patient enrollment.[8] The locations of TPCCC's 2 research centers in the medical districts of Fort Worth and Arlington, affords ready access to a target population of patients that are of the Boomer and Silent category.

This population enables TPCCC to develop effective and practical methods of recruitment while still determining if there is any interest in promoting the use of technology in patient recruiting.

Specific Aims:

Due to an increasing demand for patient recruitment, the need for optimizing recruitment strategies is at an all-time high. The goal of this practicum project is to discern the ability of TPCCC's patient recruitment strategies to become more efficient and modernized by utilizing technology while maintaining practical recruitment plans that guarantee successful patient recruitment and retention. This goal was accomplished by:

- Assessing former and ongoing patients' attitudes towards clinical research to determine if it correlates with the likelihood the patient would participate in a future clinical research study.
- Assessing former and ongoing patients' attitudes towards recommending clinical research participation to others.
- Identifying factors that encouraged or discouraged the patient from future research study participation, and methods with which to improve the likelihood of a patient enrolling in a clinical research study.
- Determining if former research study participants show interest in using the Internet to gather information regarding clinical research studies.

- Categorizing the data through different demographics such as age, race, location, and gender in order to determine if a more concise plan for patient recruitment can be implemented.

Understanding the attitudes and factors that led to participation for former and current research study patients allows for greater emphasis on what appeals to a potential research participant for TPCCC. Categorizing the data through age, race, gender, and location may help identify the forms of advertisement which are most effective for recruiting specific groups, thereby increasing recruiting efficiency. Gauging the interest in using the Internet to find information about clinical research will allow for a practical assessment of how technologically forward TPCCC should be in order to increase recruitment for potential research patients.

Significance:

With the increase in the number of clinical research studies in the United States, the need for patients to participate continues to grow. By evaluating the factors that motivate former clinical research subjects to participate in future studies, resources and effort can be allocated to support methods for recruiting a greater number of patients in a more practical manner. Although the latest recruiting methods may be effective for certain research centers, they might not be as successful at recruiting patients suitable for many of TPCCC's clinical research studies due to the mature composition of TPCCC's target population. Incorporating questions that cover topics such as whether patients use the internet to identify upcoming research studies and determining how effective certain platforms are for identifying and engaging potential patients,

TPCCC may be able to ascertain if significant promise exists to devote greater effort and understanding of these platforms to promote patient recruitment or to continue focusing on more longstanding forms of media advertisement such as print or telephone.

Determining the platform where possible patient recruits are most likely to notice research study advertisements provides maximum exposure in patient recruitment for TPCCC. Using one of the many sites which connect potential participants to clinical research studies in the participant's vicinity or other forms of web based social media could also strengthen the ability to recruit patients and maintain a viable and modern database for future use. By focusing on how to target a desired demographic while still staying as technologically up-to-date as possible without any disruptions, patient recruitment may show significant improvement.

Research Design and Methods:

This study was a voluntary survey that was conducted over the phone or in person. Each question of the survey was designed to be sufficiently answered through the telephone or on paper. This survey was designed to be user-friendly; pilot testing both in person and via the telephone showed that the survey was estimated to take no more than ten minutes. The survey was approved by the staff at the TPCCC Research Department and by the University of North Texas Health Science Center Institutional Review Board.

The paper survey had 25 questions and the telephone survey had 23 questions due to the manner in which the demographic data questions were grouped. The demographic questions

were used to identify age, race, gender, and zip code of residence. The question about the residential zip code, was an identifier question and the other questions were used to address the aims of the practicum. Nine of the questions were basic yes or no questions, four of which were branched questions that led the participant to either skip the next question or go to a different question. The survey also had nine multiple choice questions with three of which were branching. The use of branching allowed for the participant to select more specific choices, resulting in a more defined profile. The first questions in the survey asked about the participant's participation in TPCCC research trials and other research trials, and were followed by questions that requested a specific response regarding whether or not they would participate in research in the future and if so, their reasons for wanting to participate. Next, the subjects were asked how they first heard about clinical research studies, and next they were asked about the internet and their use of the internet for research purposes. The survey concluded with questions regarding participant contact and the desire to share their experiences.

The target population for this study consisted of current and former research participants that had been enrolled in TPCCC research studies from 2007 to 2013. Patients who were scheduled to be in the research locations were asked to participate and were given a research statement and a printed survey by the student investigator, while former patients were asked for consent and were administered the survey over the telephone by the student investigator. The primary inclusion criteria were patients who had been a part of TPCCC research studies and were not screen failed during the initial visit. Exclusion criteria were patients who were not involved in TPCCC research, patients who screen failed (did not meet the criteria for the study)

during the initial screening visit, and patients who had no current viable contact information. Because the subject identifier was the zip code, informed consent was not exempted by the IRB. Therefore informed consent was read to patients who participated in the telephone survey, while patients in the research centers were given physical copies of the research statement to ensure proper study conduct. Out of the 102 patients who met the inclusion criteria, the ideal sample size was 87 for a confidence interval of 4 and a confidence level of 95%. In this survey there were 90 participants who were able to complete the survey properly.

The data was recorded on data sheets and then the surveys were shredded to protect patient confidentiality. Information from the data sheets was entered onto an excel database that categorized each survey responded by age, race, gender, zip code, and the answers to the questions. Questions that were not answered were left blank and any question with multiple answers was discarded. The data was then divided into contingency tables that allowed for use of X^2 (chi square) tests with multiple variable analyses. Certain demographic information was also combined to provide greater statistical power in addressing the aims. P values less than 0.05 were considered to indicate statistical significance and the X^2 multi variable analysis also identified factors which were not as effective as conventionally believed. Age and gender were the main demographics that were used to compare with the questions. Because so many patients were taken out due to screen failures, the number of Fort Worth research patients and Arlington patients was significantly disproportionate, therefore the zip code was not considered. For ethnicity, the overwhelming majority of the patient population was Caucasian, therefore ethnicity would not be as effective in interpreting the survey results.

Results:

All basic demographic data can be seen on Table 1. From a total of 90 participants, 42 were women and 48 were men. The responses included 5 African Americans, 1 Asian, and 84 Caucasians. For age the analysis was done in two fashions; there was one measurement that assigned subjects to four age groups; 55 and under (n=11), 56 to 65 (n=28), 66 to 75 (n=40), and 76 and up (n=11). The second measurement was broken up into patients who were over 65 (n=51) and under 65 (n=39).

The answers of the participants were taken and incorporated towards addressing the aims. The responses of the participants are given on Table 2. The first aim focused on the questions asking the level of involvement with clinical research, whether they told a doctor about their involvement, and how they first heard about clinical research. Of the 90 patients, 58 (64.4%) had only been involved in 1 study, while 20 (22.2%) had participated in 2 studies, 8 (8.8%) in 3 studies, 2 (2.2%) in 4 studies, and 1 patient in 5 studies, and 1 in 6 studies. Patients were also asked how many studies in which they had participated in that were not associated with TPCCC; 81 of the 90 patients (90%) were only involved in TPCCC research studies and the other 10% were in 1 or 2 studies at other institutions.

Fifty-four (60%) of the patients participated in clinical research for one year, 14 (15.5%) for two years, and 12 (13.3%) participated for 3 or more years. Ten (11%) participants had participated in research studies for less than a year and entered a value of zero years. Patients when asked the primary reason they were involved in clinical research, 52 (57.8%) of the

participants joined because they were seeking a different treatment plan, 15 (16.7%) because they wanted to be involved in research that would benefit others, 9 (10%) for the financial compensation, 6 (6.7%) because their physician recommended they look into clinical research, and 8 (8.9%) for other reasons.

To determine how patients first heard about research, a branched question format was used. Patients were asked in general how they first heard about research and then were asked in greater detail regarding the manner by which they learned of it. Thirty-four (37.8%) first heard about research studies through advertisements, 33 (36.7%) were from staff, 8 (8.9%) heard from family and friends, and 15 (16.7%) found out from other methods. Of the 34 who learned about research studies through ads, 21 (61.8%) saw printed ads first, 8 (23.5%) found out about research through television, and 5 (14.7%) patients first learned about research through the internet. Of the 33 patients who had first learned about research from TPCCC staff, 19 (57.6%) heard from their doctors, 12 (36.3%) were first contacted about research from clinical research staff, and 2 (6.1%) learned about research from a nurse practitioner or physician assistant.

The second aim regarding patient attitudes towards recommendation for participating in research consisted of questions about whether they would recommend research for others, if they are willing to share their experiences, and the best methods for contacting them and other potential patients. For recommending research to potential patients, 87 of the 90 (96.7%) responded yes and the remaining 3 (3.3%) responded no. For the best method to be contacted about research for themselves, 68 of the 90 (75.6%) participants selected the telephone, 16

(17.8%) chose the internet, 4 (4.4%) chose print, 3 (3.3%) selected a doctor recommendation, 2 (2.2%) chose television, and 5 (5.6%) indicated that other methods would be better. In regards to what method would be best to contact others about research, 61 (67.8%) went with the telephone, 10 (11.1%) selected the internet, 8 (8.9%) chose printed methods, 5 (5.6%) selected other methods, 5 (5.6%) indicated contact through a doctor, and 1 (1.1%) participant selected television. When asked if they would be willing to share their experiences with potential patients, 68 (75.6%) of the participants said yes to sharing their experience while 22 (24.4%) did not wish to share their involvement with research.

For the third aim, the questions considered the drawbacks of clinical research and the reasons why a subject would participate in the future. Thirty-five patients left the drawbacks question blank because they reported no drawbacks involving clinical research participation. For the 55 who did answer the drawbacks question, 12 (21.8%) cited the drawback of the medication not being as effective, 14 (25.4%) felt that the time commitment was the major drawback, 6 (10.9%) chose the distance as the main drawback, and 23 (41.8%) selected other reasons.

The fourth aim was to assess the use of the internet for research purposes and possible interest in it. Patients were asked about their internet use, where they use it, for how long, if they had used the internet to look up research, and if there was any interest in using the internet to learn about research. 74 (82.2%) of patients used the internet and 16 (17.8%) did not. Of the 74 who used the internet, 70 (94.6%) had it at home, 3 (4.1%) used it at work, and 1 (1.3%) participant used their cellphone. For days spent on the internet, 44 of the 74 (59.5%) participants

used the internet 5 or more days per week, 17 (23.2%) used the internet for roughly 1 to 3 days per week, 8 (10.8%) used the internet for roughly 2 to 4 days per week, and 5 (6.5%) patients who had the internet did not use it. When asked if patients have used the internet to look up research, 72 (80%) said they had not and 18 (20%) said they had. Of the 72 who had not used the internet to look up research, 28 (38.9%) expressed interest in doing so and 44 (61.1%) had no interest in using the internet to look up research.

For the fifth aim, the population was to be divided by gender, age groups, and ethnicities. However with 93.3% of the surveyed population was Caucasian, so ethnicity was not used to address the aims. Instead gender and age were the main criteria considered along with location for an idea of where the participant population was located. Because many of the contingency tables including gender were 2 x 2 tables, the Yates correction for continuity was to ensure that the X^2 test statistic was more accurate.

Gender

For gender the answers to every question asked were divided between the 48 males and 42 females. X^2 testing was used to evaluate the questions, and all but one showed that each of the results of the tested variables were independent. There was correlation in participants who had learned about clinical research through ads. 6 females learned of research through print, 6 through television, and 5 through the internet. 15 males learned of research through print, 2 males learned about research via television, and no male learned about research because of the internet. These results indicate that males were primarily attracted to research through

advertisement while the distribution for females was much more even. While the other questions showed the independence of each variable there were some conclusions to be supported that will be further explained in the discussions section. For being contacted and contacting other participants both males and females primarily chose telephone and internet contact over all else. In being contacted, 30 women and 31 men chose telephone (67.8%) and 6 women and 10 men selected the internet (17.8%). Thus 86.6% of the participants preferred these two methods of contact over the other four methods listed on the survey. For contacting others both genders primarily chose the telephone, with 28 of the 42 (66.7%) females selecting telephone and 33 of the 48 (68.6%) men collectively, these results show a natural inclination towards telephone use in general and perhaps a developing interest in internet use.

Age

All 90 participants were first broken down into four age groups consisting of 55 and under (n=11), 56- 65(n=28), 66 -75(n=40), and finally 76 and over (n=11). The results can be seen in tables 3 and 4. For the four age groups, two X^2 tests showed dependent variables. The first correlation was between patients who had told their doctors they were involved in research. All 11 participants in the ≥76 group and 35 participants in the 66 -75 age group told their physicians, while 9 participants in the 56 - 65 age range and 6 patients in the ≤55 group shared that they did not inform their doctor of being involved in research. There was a direct relationship to whether or not their physician was informed about their research participation. The second relationship discovered was between whether or not the patient used the internet and

their age. 8 of the 11 participants in the ≤55 group and 18 participants in the 56-65 age group said they used the internet. The two older age groups had 38 and 10 participants using the internet, when the groups were combined into 2 categories, ≤65 and ≥65, 26 of 39 (67%) of the younger age group used the internet versus 48 of 51 (95%) of the older age group. A X^2 analysis of these results revealed a statistically significant difference between the two age groups. The finding of other participants were more likely to use the internet was unexpected. Some other observations from the other X^2 tests could be determined by grouping the data into the aforementioned four age groups. The primary age range for TPCCC patients was from 56-75, and by focusing on the results of the two age groups combined (56 -65 and 66-75) it can be noted that this combined age group primarily joined research because of the need for different treatment plans. 14 participants in the 56-65 age group (16%) and 26 participants in the 66- 75 age group (29%) joined for this reason. For the 72 patients who indicated they would to participate in future research, 15 in the 56-65 age group (21%) and 19 in the 66-75 age group (26%) wanted to join to find a different treatment plan. The combined age group showed a higher inclination for this reason in both questions compared to the other selections give.

Discussion:

Clinical trials provide a tremendous resource for developing effective, safe medication. More emphasis has been placed on randomized clinical trials, which are crucial before new treatments can implemented[9]. As the number of trials increases, the need for patients continues to grow. With a defined target population consisting of people with COPD, TPCCC is able to focus its

recruiting efforts to populate the growing number of COPD research studies. Despite success in patient enrollment, there is still much more that can be done to improve results.

Because COPD occurs from long term damage to the lungs, most people manifest COPD past the age of 60 [10]. Most of the target population fits into two age groups; Silent (over 65) and the older end of the Boomer (46-64) group[8]. Indeed, in the sample population 51 people (56.7%) were over the age of 65. Moreover, the two biggest age groups in this study fell into the Silent age group with the 28 people (31.1%) being aged 56 to 65 and 40 people (44.4%) aged 66 to 75. With 75.6% of the population fitting into this Silent category it is best to understand the tendencies, thoughts, and attitudes of this specific target population to further improve patient recruitment and enrollment.

From assessing patient attitudes towards clinical research there was no direct relationship to whether the patient would participate in a future clinical research study. 80% of the sample population expressed desire in participating in future research and the two main reasons were searching for a different treatment plan (n= 42) or the potential benefits to others (n=18). Regardless of how the patient learned about research, the main criteria for patients wanting to continue participating was if the research would potentially help them or others. Assessing former patients' attitudes towards recommending others to participate showed an overwhelming response to recommending potential patients. 87 of the 90 (96.7%) surveyed would recommend research to potential patients and 68 of the 90 (75.6%) surveyed were willing to share their experiences with those potential patients.

Survey responses indicated that the majority of patients were encouraged by their experience to continue in clinical research as long as the treatment plans were different and improved. 52 of the 90 surveyed enrolled in research for the different treatment options, and of the 72 participants who expressed willingness to participate in future research, 42 identified a change in their treatment plan as the major factor. Determining the factors that discouraged patients proved more difficult since 35 of the 90 patients surveyed identified no drawbacks from research and therefore left the question unanswered. Of the 55 who responded to this question, 23 (41.8%) chose "other" reasons as the main drawback. These results and the lack of correlation for specific drawbacks when compared with age and gender, the best method to address the discouraging factors would be to emphasize the positive factors that did draw patients to clinical research.

Five questions were asked toward the end of the survey that to assess interest in using the internet to gather information regarding clinical research studies. A general desire to stay modern and technologically relevant is inherent in research; websites such as TrialX.com and Researchmatch.org aid in helping the potential patient to identify and contact sites conducting clinical trials. The problem lies in the fact that very few potential patients are aware of their eligibility for clinical research studies[10]. Even with 74 (82.2%) of the sample population having access to the internet, only 21 of those participants (28.4%) had used the internet to investigate clinical research. Examination of the two major age groups within the sample population (the 56 -65 and 66-75 age groups) showed that only 14 of these 68 people (20.6%) have used the internet to research. These figures suggest that focusing on social web media may not be as effective as

focusing on conventional, well-tried methods such as telephone contact. Instead of an internet based approach to this population group, a simpler approach such as e-mailing potential patients within the TPCCC research database would be more effective.

By categorizing the data through different demographics such as age and gender, a comprehensive strategy for recruitment can be developed. By working on bolstering the TPCCC research population database through collection of information such as phone numbers and email addresses, a multi modal approach can be implemented. Contacting potential patients by telephone is the most desired method for contact about research (66.7%) and using e-mail as a secondary form of contact would be practical since 82.2% of the sample surveyed possessed the internet. Because an age of ≥66 is associated with a low likelihood of using the internet for research, a simpler approach, such as email, might be a more effective method in recruiting patients in this age group. Moreover, a high fraction of men were responsive to advertising and this might be a valuable method in to ensure continued recruitment.

In the future, another direction to continue this research could be to survey different research centers' patient populations or patients that did not meet the research requirements during their initial visits about their attitudes towards research. More effort should be made to detect and address possible drawbacks that the patient could experience with clinical research. As more potential patients are entered in the TPCCC research database, greater effort should be devoted to maintaining and monitoring this database. With such an increase in clinical research trials, it would be ideal for TPCCC to not over emphasize the internet. By catering to the target

population and emphasizing popular forms of contact such as telephone use and print advertising, a more effective approach to recruiting and enrolling for patients could be achieved.

Limitations:

The primary limitation of this study was the two distribution sites in Fort Worth and Arlington, Texas which limits the number of potential participants. Both of these sites focused primarily on COPD research in a target population that is typically over 40 years old in Tarrant County. A more diverse patient population from a broader geographical area would expand the scope of future studies. Another limitation is the patient population recruited for this study. Roughly 115 patients completed the survey, however several were not eligible to continue in the study after the first visit or they met exclusionary criteria was found before their initial visit, thus leading them to be excluded from the study. This led to a smaller sample size of 102. In future studies different criteria could be used to lead to a larger sample size or perhaps combining patients from multiple studies.

Another limitation is the method of distributing the surveys. Presenting a survey in person and over the telephone could impose some level of bias, as varying time restrictions, events going around the participants, or other challenges could leave to a certain level of bias due to the use of two different methods of presenting the survey. For future studies, perhaps one method of communication would be more effective. Contacting the patient population through telephone was another limitation since several of the telephone numbers were out of service. In

future studies, maintaining up to date telephone numbers in the research database would be helpful in overcoming this limitation.

The self-reporting method of data collection is another potential limitation. The patient's poor memory, misunderstanding of the question, or apathy can lead to inaccuracies in the survey and in the data. Creating questions that were easier to understand, better answer choices, or providing explanatory material could serve to ameliorate these problems in future studies.

GENERAL INTERNSHIP ACTIVITIES

The Texas Pulmonary & Critical Care Consultants, P.A. is a private practice in Tarrant County consisting of nine offices, three sleep centers, three sleep labs, and two research sites. TPCCC has twenty nine physicians of which eight are involved in research to varying extents. To recruit patients, TPCCC focuses on recruitment of patients primarily through contacting established patients in the TPCCC network or local printed advertisements. The internship activities primarily took place at the Fort Worth research center, with occasional visits to the Arlington research center.

Both the Fort Worth and Arlington research centers have four ongoing studies on treating various stages of chronic obstructive pulmonary disease (COPD) with inhaled medications from two sponsors, Forest Research Institute, Inc. and Novartis. The Forest LAC-MD-31 study is a phase three, randomized, double blinded, placebo controlled study that compares two fixed dose combinations of aclidinium bromide/formoterol fumarate, formoterol fumarate, aclidinium bromide, and placebo. This 24 week study uses a multi-dose dry power inhaler developed by Almirall. Patients that have completed this can then be enrolled into Forest's LAC-MD-36 continuation of this study. The goal of this 28 week extension study is to evaluate the long term effects of the two fixed dose combinations stated for the LAC-MD-31 study. Forest's LAC-MD-32 is a randomized phase three study that evaluates the effect of aclidinium bromide and formoterol administered twice daily at a dosage of 400 µg /12 µg through an Almirall inhaler. This study focuses on the treatment's effects on patients with moderate to severe stable COPD

and lasts for 52 weeks. The Novartis 2340 is a 52 week phase 3 study that has no placebo and is designed to assess the safety of QVA 149, which is a fixed combination of a long acting beta agonist (LABA) Indacaterol maleate and a long acting muscarinic agonist (LAMA) Glycopyrronium bromide. The safety and tolerability of this treatment is given in two measurements: QVA149 27.5/12.5 µg b.i.d. and QVA149 27.5/25 µg b.i.d.

In the Arlington research center there were four studies unique to that research center. The first study was sponsored by KaloBios and dealt with dealing with granulocyte macrophage colony-stimulating factors (GM-CSF) that can lead to inflammation and asthma exacerbations. This randomized study was a phase 2, double blinded, placebo controlled study that tested an anti GM-CSF drug known as KB003 to deal with treating asthma exacerbations and flare ups over a 36 week period. This study was eventually shut down due to the lack of patients that were able to successfully enroll. Forest Research Institute, Inc. also had a randomized study that dealt with the effect of Roflumilast on exacerbation rates for COPD patients who were treated with a LABA and an inhaled corticosteroid. This study known as ROF MD-07 is a double blinded, placebo controlled, parallel-group study to evaluate the effect of Roflumilast over 52 weeks. There is also the Novartis 2317 study which is a 12 week study that tested the efficacy and safety of NVA237 in stable COPD patients as a multi-center, randomized, double blind, and placebo controlled study. For the Fort Worth research center, the studies present here that are not at the Arlington office would be the Novartis 2337 study, the BI 205.452, and the BI 205.478 studies. Unlike the other research studies previously mentioned, the Novartis 2337 study is only a 12 weeks long with 12 hour visits. It is still a phase 3, randomized, double-blind, parallel group,

placebo, and active controlled study that still assesses the investigational drug QVA149. The BI 205.452 trial is a randomized, double blind, and double dummy trial that compares the effects and tolerance of 2.5 µg and 5 µg tiotropium bromide that is administered through the use of the Respimat inhaler. This trial is designed to continue until there are approximately 1,266 fatal adverse events reported with estimates believing this will take about three and a half years. The BI 205.478 study is a phase 4 trial that is randomized, placebo controlled, double blind, and parallel group that assesses tiotropium bromide in an 18 µg dosage through the use of the HandiHaler inhaler. This trial is expected to last 2 years with its primary endpoint being the trough FEV1 at 12 weeks. This study is a sister study of the BI 205.477 being conducted in Arlington and the primary endpoint of both studies combined is the time to the next adverse COPD event, defined as the combined endpoint of death, COPD exacerbation, and re-hospitalization.

Appendix A:

IRB Approval

UNT Health Science Center
Office for the Protection of Human Subjects
Institutional Review Board
BOARD ACTION

IRB Project #: 2012-206 Date Submitted: December 3, 2012

Principal Investigator: Robert T. Mallet, PhD with CRM student Rohan K. Thamby

Project Title: Research Participant's Beliefs and Attitudes Towards Clinical Research Studies

Sponsor Protocol #:

Department: Integrative Physiology / GSBS Contact Info:

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project. Approval, when given,is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

The Principal Investigator must notify the IRB immediately if any new potential Conflict of Interest arises or if CITI educational training lapses for any of the Key Personnel involved with the study.

☑ Project has received approval through: **January 2, 2014**

☑ Informed consent(s*) approved as submitted on : **January 2, 2013**

You **MUST** use the version (s) attached rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

*Including: Verbal Consent Script and Research Statement

☑ Study Protocol dated **January 2, 2013** approved as submitted.

☐ Investigator's Brochure approved as submitted.

☑ Protocol Synopsis approved as submitted on: **January 2, 2013**

☐ Amendment to the protocol approved as submitted.

☐ Progress Report/Continuing Review completed, project has received approval through:

☐ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "tracked changes" version showing the markup and one "clean" copy of the revised protocol synopsis, informed consent, and advertisements to the IRB for review. ***YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.***

☐ Project is disapproved for the reason(s) outlined (see attached).

☐ Consideration of the project has been **DEFERRED** pending resolution of the issues(s) outlined (see attached).

☐ Completion of project is acknowledged and all required paperwork has been received.

☐ Special Findings/Other

Project meets the necessary requirements to qualify for EXPEDITED category research. Approval granted under the provisions of 45 CFR 46. 110 (b) (1) category (5) and (7). Please follow the approved protocol. Any change to the protocol requires IRB review prior to implementation. Please use the approved/stamped version of the research documents.

Chairman, Institutional Review Board

January 2, 2013
Date

IRB Form 2 (revised September 2012)

University of North Texas Health Science Center
Office for the Protection of Human Subjects
Institutional Review Board

Protocol Synopsis for Research Involving Surveys

1. Protocol Information

Title of the Project: Research Participant's Beliefs and Attitudes Towards Clinical Research Studies

Principal Investigator (Faculty): Robert T. Mallet, Ph.D

Co-Investigators (Faculty/Staff):

Student Investigators/Residents: Rohan K. Thamby

IRB APPROVED
JAN 02 2013
University of North Texas
Health Science Center

2. Purpose of the Study (brief summary of project concept)

The purpose of this project is to discern the ability of Texas Pulmonary & Critical Care Consultant's patient recruitment strategies to become more efficient and modernized by utilizing technology while maintaining practical recruitment plans that guarantee successful patient recruitment.

Objectives:

1. To assess former and current patients' beliefs and attitudes towards clinical research to determine if it correlates with the likelihood the patient would participate in a future clinical research study.

2. To assess former and current patients' beliefs and attitudes towards recommending to others to participate in clinical research.

3. To identify what factors encouraged or discouraged the patient from future research study participation, and methods in which to improve the likelihood of joining a clinical research study.

4. To determine if former research study participants show interest in using the Internet to gather information regarding clinical research studies.

5. To obtain demographic data in order to determine if there is a more concise plan for patient recruitment.

3. Background and Significance (brief summary of project importance)

Current Texas Pulmonary & Critical Care Consultants (TPCCC) studies at the research center examine the safety and efficacies of FDA approved medications compared to investigational drugs and/or placebo. Patient recruitment is a constant challenge for clinical research studies and understanding the beliefs and attitudes of current and former participants in studies may aid researchers in maximizing patient recruitment.

Understanding the beliefs and attitudes of participants and combining the knowledge of TPCCC's patient demographics could potentially allow for a more concerted focus on what platforms of media work best for patient recruitment.

4. Other

Will you contract with an organization (agent) outside UNTHSC to conduct this survey?

☐ **yes*** ☒ **no**

***If yes, please provide information about the agent and their role in the conduct of this study:**

5. Methodology

How will the survey will be conducted (select all that apply):

☒ **in person**

Describe the location(s) where the survey will be distributed and who will oversee this process: Rohan Thamby will use the TPCCC research patient database to identify research patients who will be coming into the two locations and will oversee distribution of the survey only to current clinical study participants in the public waiting areas at the Research Center of Texas Pulmonary & Critical Care Associates, P.A. located at 909 8th Avenue, Fort Worth, TX 76104 and the Research Center at the North Arlington office located at 911C Medical Centre Drive, Arlington, TX 76012.

☐ **internet survey (using software such as Survey Monkey, Zoomerang, etc.)**

☐ **email**

Describe how you will obtain the email addresses:

☐ **mail survey (US Postal Service, campus mail, etc).**

Describe how you will obtain the mailing addresses:

☒ **telephone**

Describe how you will obtain the phone numbers: Rohan Thamby will use the TPCCC research patient database to obtain phone numbers of former research participants. Three call attempts will be given to each participant before removing them from the potential subject list.

6. Subject Recruitment-*Describe how subjects will be recruited to participate in the survey. Please include all recruitment flyers, emails, phone scripts, etc. that will be used in the recruitment process for review/approval with the IRB Application*

Describe how subjects will be recruited to participate in the survey. Please include all recruitment flyers, emails, phone scripts, etc. that will be used in the recruitment process for review/approval with the IRB Application: Current participants arriving at the TPCCC research center will be asked if they would be willing to participate in the survey while in the waiting room before meeting with the researcher. The participants will be given a printed research statement for review before being given the survey in person.

Former participants who have given consent to be recontacted for additional studies will be called and recruited to participate in the survey. If agreed upon, a verbal statement of the research statement is given and the survey can proceed.

The student investigator will be facilitating all aspects of patient recruitment and will be present to answer any questions regarding the survey during its administration.

Please provide a description of the survey instrument: The survey will be given in person for patients who are in the research center and through the telephone for patients who are not in the research center. The survey will take no longer than 10 minutes and consists of twenty one questions. Of these twenty-one questions, eleven are of the close-ended format that focuses on the patient's participation in clinical research and their desire to be a part of future clinical research studies. The remaining nine questions branch out and enable a more exacting response regarding patient attitudes toward clinical research, primary source of exposure to clinical research, internet exposure, and willingness to use the internet. The hard copies of the survey will be returned directly to the researcher and stored in a secure file cabinet inside a locked room

located in the TPCCC research center.

7. Subject Information

Will any individual identifying information (names, addresses, and phone numbers, email addresses) be used to recruit subjects for this study?

☒ **yes*** ☐ **no**

***If yes:**

a) **Describe the source and process for obtaining this information:** The phone numbers and names of the patients will be pulled from the TPCCC research database in order to contact the former participants through telephone and to take note of participants currently enrolled in TPCCC research studies. The names of the patient will be used to identify them but will not be included in the survey in order for the survey to stay de-identified.

b) **Will any of the identifying information collected during the recruitment process be "linked" to individual survey responses or the survey data?** Yes the participant's demographic information which will be asked in the survey, will be linked to their survey responses in order to identify effective methods for patient recruitment in particular areas in the Fort Worth and Arlington areas.

Will you ask the subject for any identifying information on the survey instrument (name, address, phone number, social security number, employee ID, etc)?

☐ **yes*** ☒ **no**

*** If yes, describe the identifying information that you will collect:**

How many subjects will participate in this study? 200

How will you obtain informed consent from the subjects before they begin the survey?

☐ **Written (signed) informed consent**

☒ **Study cover letter/research statement***

☒ **Oral consent***

***Please complete a request for "Waiver of Documentation of Informed Consent" form and submit with your IRB application**

A copy of the consent document, study cover letter/research statement, and/or oral consent script should be included with the IRB submission.

Inclusion Criteria-*Describe the age, gender, and racial/ethnic breakdown of subjects who will participate in the survey:* Male and female patients who are have participated or are participating in clinical research studies. No racial/ethnic groups will be excluded.

Exclusion Criteria: Subjects under the age of 18.

8. Health Information

Will you ask the subject for any health information on this survey?

☐ **yes*** ☒ **no**

***If yes:**

Please describe the health information that you will collect on the survey:

PHI under HIPAA is any information about health status, provision of health care, or payment for health care that can be linked to a specific individual. Will the health information that you collect be linked (connected) to any of the following subject identifiers collected during recruitment or on the survey instrument?

1. **Names;**
2. **All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.**
3. **All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;**
4. **Phone numbers;**
5. **Fax numbers;**
6. **Electronic mail addresses;**

7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

☐ yes* ☒ no

***You will need to complete a HIPAA Research Waiver, or attach a HIPAA Authorization For Use of Protected Health Information in Research to the consent document. Contact OPHS staff for guidance to determine if your project will need a HIPAA Waiver or Authorization Addendum to the Consent document.**

9. Risk Assessment

In your opinion, will this survey pose any <u>informational risk</u> to subjects who complete it (i.e. if the subject's responses were made known to someone other than the researchers could this cause harm to the subject's reputation, employment, student status, civil or criminal liability)?

☐yes* ☒no

***If yes, please describe the procedures that will be in place to help reduce/manage this informational risk to subjects (i.e. describe how you will manage this risk):**

Please describe any other potential risks associated with this study, and how those risks will be managed: There are no foreseeable risks associated with participating in this study.

Will you re-contact or follow up with subjects after they complete the survey?

☐yes* ☒no

***If yes, please describe the procedures for re-contacting subjects (note any telephone scripts, follow up letters, emails, etc that will be used to follow up with subjects should be**

submitted with the IRB application for review and approval):

10.Subject Compensation

Will subjects be compensated for completing this survey?

☐ **yes*** ☒ **no**

***If yes**

1) Describe how much subjects will receive and the form of the subject payment:

2) Describe how subjects will receive the compensation (i.e. in person, check sent via postal mail, etc):

Note: If you plan to include subject compensation, we recommend that you contact the UNTHSC Accounting Department prior to IRB submission to determine their requirements and work out the appropriate details to prevent future protocol modifications.

11.Data Storage and Confidentiality-*Describe how the data will be secured during storage. The investigator must take necessary steps to maintain confidentiality of the data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to the data. State who will have access to the data. If data with subject identifiers will be released, specify the person(s) or agency to whom the information will be related and the purpose of the release.*

Research data in hard copy or electronic form (online database and flash memory drives) will be stored and managed in a secure fashion that adheres to the NIH guidelines along with state and institutional policies and procedures.

Flash memory drives and portable data storage devices will only contain research data and be accessible only to research personnel. No personal data or information will be kept with study data at any time during the study. The principal investigator will be responsible for any data transfer, storage, retention, and loss. Any misuse or loss of data will be reported to the appropriate federal agencies as directed by current federal guidance.

Research data in hard copy form that has subject data will be stored in secured drawers and file cabinets in a locked room at the TPCCC research center to guarantee confidentiality that adheres to standard document management practices. Research data in hard copy form is only accessible to authorized TPCCC research personnel.

Research data in electronic form is stored through online database and flash memory drives.

This data possess subject information and identifiers and is stored on a TPCCC Research Center laptop that is password protected and has a full subscription to Microsoft Security Essentials in order to prevent forms of cyber attacks on the laptop. Only key personnel authorized by the Principal Investigator have access to the passwords in the TPCCC laptop.

All personnel will be properly trained and supervised in properly handling the confidential materials. The Principal Investigator assumes full responsibility for such training, supervision, and conduct.

12. Key Personnel *List all individuals directly involved in the conduct, design, or reporting of research involving human subjects in the study, and describe their role.*

ROBERT T. MALLET WILL ADVISE THE STUDENT INVESTIGATOR, ROHAN K. THAMBY. ROHAN K. THAMBY WILL CREATE AND DISTRIBUTE THE SURVEY, GATHER DATA, AND ANALYZE AND INTERPRET THE RESULTS INTO THE CONTEXT OF THE PROJECT.

13. Signatures *Required from the Principal Investigator as well as the student/medical resident Co- Investigator(s).*

Signature of Principal Investigator: _____ **Date:** _____

Signature of Student Investigator/Resident: _____ **Date** _____

Signature of Student Investigator/Resident: _____ **Date** _____

Signature of Student Investigator/Resident: _____ **Date** _____

Board Action-page 2

PI: Robert Mallet, PhD

IRB Project #: 2012-206

Date: 01/02/2013

SPECIAL FINDINGS:

☐ CHILDREN: The Board found the participation of children to be approvable under Subpart D of the federal regulations. Specifically, the research satisfies the requirements of:

☐ **45 CFR** ☐ **21 CFR**

☐ COGNITIVELY IMPAIRED: The Board found the participation of cognitively impaired subjects to be approvable under federal regulations. Specifically, the research satisfies the requirements of:

☐ **45 CFR 46.111 (b)** ☐ **21CFR 56.111 (b)**

☐ PREGNANT WOMEN: The Board found the participation of pregnant female subjects to be approvable under Subpart B of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.204 (a) - (i)**

☐ FETUSES/NEONATES: The Board found the involvement of fetuses/neonates to be approvable under *Subpart B* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR**

☐ PRISONERS: The Board found the participation of prisoners to be approvable under *Subpart C* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.305 (a), (b) and (c)**

☐ OTHER:

OTHER

☑ **Expedited Review Procedures (under 45 CFR 46)**

Project ☑ Approved ☐ Approved for Continuation ☐ Modifications approved **under the provisions of:**
45 CFR 46.110 (b) (1) category (5) **45 CFR 46.110 (b)(1) category (7)**

Category (6) research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis); and Category (7) research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

☐ **45 CFR 46.110 (b) (2)** minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

☐ **HIPAA Waiver:** The Board finds this study meets all legal requirements for a Waiver of Individual Authorization under HIPAA pursuant to 45 CFR 164.512 (i) (2) (i)-(v) and approves the request under:

☑ **Informed Consent Waiver:** The Board finds this project qualifies for a **Waiver of Documentation of Informed Consent** under the provisions of **45 CFR 46.117 (c) (2)**

☑ **Other IRB Approved Research Documentation Includes:**

Research Survey and Recruitment Scripts

☐ **Other Comments:**

UNIVERSITY *of* NORTH TEXAS HEALTH SCIENCE CENTER OFFICE *for the* PROTECTION *of* HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD	***Request for Waiver of Documentation of Informed Consent*** **Form A**

IRB #

Investigator's Name: Robert T. Mallet, Ph.D

Title of Project: Research Participant's Beliefs and Attitudes Towards Clinical Research Studies

Documentation of consent means that participants are required to sign a consent form, thereby documenting their consent. A waiver of documentation means that the UNTHSC IRB is waiving the requirement to obtain the participant's signature. Even if this waiver is granted, a consent process must still be in place. The consent process must contain all the required elements of consent and usually consists of a consent form/verbal script that is read aloud to them.

For the UNTHSC IRB to grant this waiver, your research project must meet one of the following conditions. ***Please initial the line next to the appropriate condition and explain why your research meets the condition in the space provided.***

_____ *(initial)* **Condition 1-** The only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from the breach of confidentiality. This refers to instances where participants could be seriously harmed if it became known that they were participants in the research.

Explanation:

OR

RTM *(initial)* **Condition 2-** The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Explanation:

This research has current research participants being provided with a printed research statement for review before completing a printed survey. Former research participants will have informed consent read to them before given a survey over the telephone. After giving the surveys, contact information will be provided again and any further questions or concerns will be answered.

Investigator's Signature _____ **Date** 11/29/12

IRB Chair's Signature _____ **Date** 1/2/13

Informed Consent Waiver Application Form A version 09/09

Appendix B:

Research Survey Instrument

RESEARCH STATEMENT

RESEARCH PARTICIPANT'S BELIEFS AND ATTITUDES TOWARD CLINICAL RESEARCH STUDIES

Principal Investigator: **Robert T. Mallet, Ph.D.**

Co-Investigator: **Rohan K. Thamby**

Institution: University of North Texas Health Science Center

Introduction:
We are conducting a research project to determine the ability of TPCCC's patient recruitment strategies to become more efficient and modernized by utilizing technology while maintaining practical recruitment plans that guarantee successful patient recruitment.

You are invited to participate in this research study survey because you were involved or are currently involved in a clinical research study conducted by Texas Pulmonary & Critical Care Consultants (TPCCC). This survey will gauge your beliefs and attitudes toward clinical research studies. The survey will take no more than 10 minutes and will consist of several yes or no closed ended questions along with a few multiple choice questions. When you are completed with the survey, the co-investigator will collect the surveys.

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/interview will allow us to evaluate the beliefs and attitudes of former and current clinical study participants in the TPCCC network.

Agreement to Participate:
Participation in the study is completely voluntary. If you decide to participate, you can continue to the next page and complete the printed survey. Your participation or non-participation will not affect your involvement in any current or future TPCCC studies.

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

Leaving the Study:
You may stop the survey at any time. Since the survey is not identifiable, there will be no way to withdraw from the study once you complete the survey. The survey is voluntary, and while you are encouraged to fill out all the questions, you have the right to skip questions or not complete the survey if you choose to do so.

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

- Principal Investigator: Robert T. Mallet (817) 735-5084.
- Co-Investigator: Rohan K. Thamby (817) 332-5599.

You will be given a copy of this sheet for your records. 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.

IRB APPROVED

JAN 02 2013

University of North Texas
Health Science Center

Rohan Thamby
Printed Survey

1) What is your age? _____

2) What is your gender? _____

3) What is your ethnicity? _____

4) What is your zip code? _____

5) Have you participated in any clinical research studies since your last one with Texas Pulmonary? (*if yes go to #6*)

☐ Yes ☐ No

6) How many studies have you been a part of that were not with TPCCC?

_____

7) All told, how many total studies have you been a part of?

_____

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8) How many years total have you spent being a part of a clinical research study?

_____

9) Would you participate in another clinical study? (*if yes go to #10, if no then skip #10*)

☐ Yes ☐ No

10) What would be the main reason you would want to participate in another clinical study?

☐ Wanted a different treatment plan ☐ Beneficial to others ☐ Doctor recommended it ☐ Financial compensation ☐ Other

11) What was the main reason you were part of a clinical study?

Rohan Thamby
Printed Survey

☐ Wanted a different treatment plan ☐ Beneficial to others

☐ Doctor recommended the study ☐ Financial compensation ☐ Other

12) What was the main drawback of participating in a clinical research study?

☐ Distance ☐ Time ☐ Study medication did not work ☐ Other

13) Did you tell your doctor that you were a participant in a clinical research study?

☐ Yes ☐ No

14) Would you recommend others to participate in a clinical research study?

☐ Yes ☐ No

15) How did you first learn about clinical research studies? (*If answer is advertisement go to question 16, if answer is clinical staff go to question 17*)

☐ Advertisement ☐ Clinical staff ☐ Friends and family ☐ Other

16) What type of advertisement was it?

☐ Print ☐ Internet ☐ TV ☐ Other

17) Who was the clinical staff member?

☐ Physician ☐ Recruiter or coordinator

☐ Physician Assistant or Nurse Practitioner ☐ Other

18) Do you have Internet access at home? (*if no then go to question 19)*

☐ Yes ☐ No

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19) Do you have Internet access elsewhere?

☐ Yes ☐ No

20) How many days a week do you use the Internet?

☐ 5 or more days ☐ 2 to 4 days ☐ 1 to 3 days ☐ Do not use the Internet

Rohan Thamby
Printed Survey

21) Have you used the Internet to locate clinical research studies? (*If yes then skip #22, if no then go to #22)*

☐ Yes ☐ No

22) Would you like to find out more about clinical research studies through the Internet?

☐ Yes ☐ No

23) What do you think is the best method for contacting you about clinical studies?

☐ Print ☐ Internet ☐ TV ☐ Physician ☐ Telephone ☐ Other

24) What do you think is the best method for contacting others about clinical studies?

☐ Print ☐ Internet ☐ TV ☐ Physician ☐ Telephone ☐ Other

25) Would you be willing to discuss the positive and negative aspects of being in a clinical research study to potential patients?

☐ Yes ☐ No

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Health Science Center

Rohan Thamby
Verbal Informed Consent

IRB APPROVED
JAN 02 2013
University of North Texas
Health Science Center

Verbal Informed Consent

The purpose of this research is to determine former and current research study participants' thoughts and attitudes towards clinical research. To do this you will be asked to answer this over the phone. There is no more than minimal risk involved in this study and the direct benefits to you are none. The benefits of this survey will allow Texas Pulmonary & Critical Care Consultants to evaluate the beliefs and attitudes of former and current clinical study participants in the Texas Pulmonary & Critical Care Consultants network to increase patient recruitment. This survey takes no longer than ten minutes to complete and all information given will be kept confidential. Participation or non-participation in this research project will not affect your status or involvement in any current or future TPCCC research studies, or affect any other benefit they are otherwise entitled to. All information for this study will be kept confidential at the Texas Pulmonary & Critical Care Consultants' Research center. The University of North Texas Health Science Center's Office for the Protection of Human Subjects, the Institutional Review Board, and the Texas Pulmonary & Critical Care Consultants' Research department may review information related to this research study.

You will not be compensated for your time and participation is completely voluntary. Since the survey contains no personal identifiers it will be de-identified, there will be no way to withdraw from the study once the survey is completed. In the event that there is any presentation or publication from this research, no personally identifiable information will be shared. If you have any questions or concerns please contact the Principal Investigator, Robert T. Mallet, Ph.D at (817) 735-5984 or the Co-Investigator, Rohan Thamby at (817) 332-5599. 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. Do you have any questions? If no, let's begin.

Rohan Thamby

Telephone Survey

"May I speak to (*state name*)? This is Rohan Thamby from the UNT Health Science Center. I am a student researcher doing my internship at the Texas Pulmonary & Critical Care research center. I am calling with information about a research study I am involved in regarding current and former research study participants' thoughts and attitudes toward research studies. I am contacting you because you were or currently involved in research studies through TPCCC, and your contact information was in the TPCCC research records. I have received permission from TPCCC investigators/researchers to contact participants for this separate research project and I wanted to ask if you are willing to participate in this survey. You don't have to answer any questions you don't want to, and you can end the interview at any time. The interview takes no more than ten minutes and any information you give me will be kept completely confidential. Are you willing to participate?"

- If yes: "Great! Is now a good time for you? *If yes proceed with* ***informed consent****. If not a good time, set up a date and time for the interview and use the call back script.*
- If no: Thank the subject and end the phone call.

If leaving message on voicemail:

"Hello, this message is for (*say name*). It is (*say the date*) at (*say the time*). This is Rohan Thamby from the UNT Health Science Center. I am a student researcher doing my internship at the Texas Pulmonary & Critical Care (TPCCC) research center. I am calling with information about a research study I am involved in regarding current and former research study participants' thoughts and attitudes toward research studies. I am contacting you because you were or currently involved in research studies through TPCCC, and your contact information was in the TPCCC research records. I have received permission from TPCCC investigators/researchers to contact participants for this separate research project and I wanted to ask if you are willing to participate in this survey that takes no longer than 10 minutes. Please contact us at 817-332-5599 if you are interested. We hope to hear back from you soon

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JAN 02 2013
University of North Texas
Health Science Center

Rohan Thamby

Telephone Survey

If the potential subject calls back, proceed with the following:

Hi, thank you for calling us back. We would like to see if you would be interested in participating in this research study regarding current and former research study participants' thoughts and attitudes toward research studies being conducted the Texas Pulmonary & Critical Care (TPCCC) research center. It will involve a survey over the phone that will take no longer than 10 minutes. Would you be willing to participate?

- If yes: "Great! Is now a good time for you? *If yes, proceed with* ***informed consent****. If no, set up a date and time for the interview and use the call back script.*
- If no: Thank the subject and end the phone call.

If calling back subject (re-contacting):

"Hello, this is Rohan Thamby from the UNT Health Science Center. I am calling about the study regarding current and former research study participants' thoughts and attitudes toward research studies that you agreed to participate in. We had set up this time to conduct the survey over the phone. Is this still a good time for you?"

- If yes: "Great! I would like to get your consent to participate before we begin." *Proceed with* ***informed consent****.*
- If no: "I am sorry. Would you like to reschedule for another date/time?" *Proceed as appropriate for rescheduling.*

If the potential subject is no longer interested in participating, thank them and end the call.

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Rohan Thamby

Telephone Survey

1 What is your age, gender, and ethnicity?

2 What is your zip code?

3 Have you participated in any clinical research studies since your last one with Texas Pulmonary? (*if yes go to #5*)

4 How many studies have you been a part of that were not with TPCCC?

5 All told, how many total studies have you been a part of?

6 How many years total have you spent being a part of a clinical research study?

7 Would you participate in another clinical study? (*if yes go to #9, if no then skip #9*)

8 What would be the main reason you would want to participate in another clinical study?

☐ Wanted a different treatment plan ☐Beneficial to others

☐ Doctor recommended it ☐ Financial compensation ☐ Other

9 What was the main reason you were part of a clinical study?

☐ Wanted a different treatment plan ☐ Beneficial to others

☐ Doctor recommended it ☐ Financial compensation ☐ Other

10 What was the main drawback of participating in a clinical research study?

☐ Distance ☐ Time ☐ Study medication did not work ☐ Other

11 Did you tell your doctor that you were a participant in a clinical research study?

12 Would you recommend others to participate in a clinical research study?

13 How did you first learn about clinical research studies? (*If answer is advertisement go to question 15, if answer is clinical staff go to question 16*)

☐ Advertisement ☐ Clinical staff ☐ Friends and family ☐ Other

14 What type of advertisement was it?

☐ Print ☐ Internet ☐ TV ☐ Other

15 Who was the clinical staff member?

☐ Physician ☐ Recruiter or coordinator

☐ Physician Assistant or Nurse Practitioner ☐ Other

16 Do you have Internet access at home? (*if no then go to question 18)*

17 Do you have Internet access elsewhere?

18 How many days a week do you use the Internet?

☐ 5 or more days ☐ 2 to 4 days ☐ 1 to 3 days ☐ Do not use the Internet

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Telephone Survey

19 Have you used the Internet to locate clinical research studies? (*If yes then skip #21, if no then go to #21)*

20 Would you like to find out more about clinical research studies through the Internet?

21 What do you think is the best method for contacting you about clinical studies?

☐ Print ☐ Internet ☐ TV ☐ Physician ☐ Telephone ☐ Other

22 What do you think is the best method for contacting others about clinical studies?

☐ Print ☐ Internet ☐ TV ☐ Physician ☐ Telephone ☐ Other

23 Would you be willing to discuss the positive and negative aspects of being in a clinical research study to potential patients?

Thank the patient for their time and effort, ask if they have any questions or concerns, and then end the call.

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Appendix C:

Survey Responses and Relationships

Table 1. Demographic Data

Characteristic	Response
Age	
• ≤ 55	11
• 56 – 65	28
• 66 – 75	40
• 76 ≤	11
Gender	
• Female	42
• Male	48
Ethnicity	
• African American	5
• Asian	1
• Caucasian	84

Table 2. Survey Answers (taken from data sheets)

Question	Response
Number of studies participated?	
• 1	58
• 2	20
• 3	8
• 4	2
• 5	1
• 6	1
Number of studies not with TPCCC?	
• 0	81
• 1	5
• 2	4
Total years spent being a part of a clinical research study?	
• 0	10
• 1	54
• 2	14
• 3	7
• 4	3
• 5	1
	1

• 6	
Future participation?	
• Yes	72
• No	18
Reason for future participation?	
• Different Treatment Plan	42
• Beneficial to Others	18
• Financial Compensation	3
• Doctor Recommended	2
• Other	7
Reason for past participation?	
• Different Treatment Plan	52
• Beneficial to Others	15
• Financial Compensation	9
• Doctor Recommended	6
• Other	8
Drawbacks?	
• Medication Didn't Work	12
• Time	14
• Distance	6
• Other	23
Told doctor about involvement?	
• Yes	70
• No	20
Would you recommend others?	
• Yes	87
• No	3
How did you first learn about research?	
• Ads	34
• Staff	33
• Family & Friends	8
• Other	15
What form of advertisement?	
• Print	21
• TV	8
• Internet	5
• Other	0
Which staff member did you talk to?	
• Physician	19

• Recruiter / Research Coordinator	12
• Nurse Practitioner / Physician Assistant	2
Do you have access to the Internet?	
• Yes	74
• No	16
Where do you have Internet access?	
• Home	70
• Work	3
• Phone	1
Days a week with the Internet?	
• 1-3 days	17
• 2-4 days	8
• ≥ 5 days	44
• Don't Use the Internet	5
Do you use the Internet to look at clinical research studies?	
• Yes	21
• No	69
Do you have interest in using the Internet to look up clinical research studies?	
• Yes	31
• No	38
Best method for contacting you?	
• Telephone	60
• Internet	16
• Print	4
• TV	2
• Physician	3
• Other	5
Best method for contacting others?	
• Telephone	61
• Internet	10
• Print	8
• TV	1
• Physician	5
• Other	5
Willing to share with potential patients?	
• Yes	68
• No	22

Table 3. Percentages for the first 10 questions

Questions	Male	Female	≤55	56-65	66-75	≥76
Number of studies participated						
• 1	28	30	9	19	24	6
• 2	12	8	2	6	9	3
• 3	5	3	0	1	5	2
• 4	1	1	0	1	1	0
• 5	0	1	0	0	1	0
• 6	1	0	0	1	0	0
Number of studies not with TPCCC						
• 0	42	39	11	25	36	9
• 1	3	2	0	2	2	1
• 2	3	1	0	1	2	1
Total years spent being a part of a clinical research study						
• 0	5	5	3	3	4	0
• 1	28	26	7	17	23	7
• 2	11	3	1	5	6	2
• 3	3	4	0	1	6	0
• 4	1	2	0	1	1	1
• 5	0	1	0	0	1	0
• 6	0	1	0	1	0	0
Future participation						
• Yes	38	34	9	25	28	10
• No	10	8	2	3	11	2
Reason for future participation						
• Different treatment plan	23	19	3	15	19	5
• Beneficial to others	6	12	3	6	6	3
• Doctor recommended	1	1	0	0	2	0
• Financial compensation	1	2	2	1	0	0
• Other	5	2	1	3	1	2
Reason for past participation						
• Different treatment plan	23	29	5	14	26	7
• Beneficial to others	10	5	2	5	7	1
• Doctor recommended	5	1	0	3	2	1
	4	5	3	4	2	0

• Financial compensation	6	2	1	2	3	2
• Other						
Drawbacks?						
• Medication Didn't Work	8	4	1	1	7	3
• Time	7	7	1	6	7	0
• Distance	3	3	0	4	1	1
• Other	12	11	2	8	9	4
Told doctor about involvement?						
• Yes	38	32	5	19	35	11
• No	10	10	6	9	5	0
Would you recommend others?						
• Yes	47	40	9	27	39	12
• No	1	2	1	1	1	0
How did you first learn about research?						
• Ads	17	17	5	12	14	3
• Staff	18	15	2	9	16	6
• Family & Friends	3	5	1	3	3	1
• Other	10	5	3	4	7	1

Table 4. Percentages for the last 10 questions

Questions	Male	Female	≤55	56-65	66-75	≥76
What form of advertisement?						
• Print	15	6	3	7	8	3
• TV	2	6	0	4	1	3
• Internet	0	5	2	0	3	0
Which staff member did you talk to?						
• Physician	10	9	1	4	9	5
• Recruiter / Research Coordinator	7	5	1	5	6	0
• Nurse Practitioner / Physician Assistant	1	1	0	0	1	1

Questions	Male	Female	≤55	56-65	66-75	≥76
Do you have access to the Internet?						
• Yes	39	35	8	18	38	10
• No	9	7	3	10	2	1
Where do you have Internet access?						
• Home	37	33	8	15	38	9
• Work	1	2	0	3	0	0
• Phone	1	0	0	1	0	0
Days a week with the Internet?						
• 1-3 days	11	6	0	6	9	2
• 2-4 days	3	5	3	0	5	0
• ≥ 5 days	25	19	5	10	23	6
• Don't Use the Internet	1	4	0	3	1	1
Do you use the Internet to look at clinical research studies?						
• Yes	7	11	3	4	10	1
• No	41	31	8	2	30	10
Do you have interest in using the Internet to look up clinical research studies?						
• Yes	16	12	2	8	15	3
• No	25	19	6	16	15	7
Best method for contacting you?						
• Telephone	31	30	6	20	26	8
• Internet	10	6	3	3	8	2
• Print	2	2	1	1	2	0
• TV	1	1	0	1	1	0
• Physician	2	1	0	1	1	1
• Other	2	3	1	2	2	0
Best method for						

Questions	Male	Female	≤55	56-65	66-75	≥76
contacting others?						
• Telephone	33	28	6	20	30	5
• Internet	6	4	2	4	2	2
• Print	5	3	1	1	5	1
• TV	0	1	0	1	0	0
• Physician	3	2	0	2	2	1
• Other	1	4	2	0	1	2
Willing to share with potential patients?						
• Yes	35	33	9	22	32	5
• No	13	9	2	6	8	6

Direct Relationships

Table 5. Direct Correlations: Relationship between Gender and First Learning about Research

	Method		
Gender	Print	TV	Internet
Female	6	6	5
Male	15	2	0

Chi-square observed value: 10.857

Chi-square critical value: 3.841

Degrees of Freedom: 2

P-value: 0.004

Alpha: .05

The risk to reject the null hypothesis H_0 that the rows and columns are independent is less than .44%.

Table 6. Direct Correlations: Relationship between Four Age Groups and Informing the Doctor about Research Involvement

	Answer	
Age	Yes	No
≤55	5	6
56-65	19	9
66-75	35	5
≥76	11	0

Chi-square observed value: 13.574

Chi-square critical value: 7.815

Degrees of Freedom: 3

P-value: 0.004

Alpha: 0.05

The risk to reject the null hypothesis H_0 that the rows and columns are independent is less than .35%.

Table 7. Direct Correlations: Relationship between the Four Age Groups and Using the Internet

	Answer	
Age	Yes	No
≤55	8	2
56-65	18	10
66-75	38	2
≥76	10	2

Chi-square observed value: 10.674

Chi-square critical value: 7.815

Degrees of Freedom: 3

P-value: 0.014

Alpha: 0.05

The risk to reject the null hypothesis H_0 that the rows and columns are independent is less than 1.36%.

Table 8. Direct Correlations: Relationship between Two Age Groups and using the Internet (with Yates Continuity Correction)

	Answer	
Age	Use the Internet	Don't Use the Internet
≤65	27	12
≥65	47	4

Chi-square observed value: 6.456

Chi-square critical value: 3.841

Degree of Freedom: 1

P-value: .011

Alpha: .05

The risk to reject the null hypothesis H_0 that the rows and columns are independent is less than 1.11%.

Appendix D:

Practicum Daily Activity Log

PRACTICUM ACTIVITY DAILY LOG

Master of Science

Clinical Research Management Internship

Rohan Thamby, BS

Site: Texas Pulmonary & Critical Care Consultants, P.A.

Clinical Research Center, Fort Worth, TX

Date of Internship: 20 Aug 2012 – 19 Mar 2013

Week 1 08/20/12	● First day of internship, was introduced to the staff in the office located in the Medical District of Fort Worth by Kathy, and signed patient confidentiality documents. ● Organized, filed, and approved protocol amendments and serious adverse event reports for four clinical trial studies consisting of LAC-MD-31, LAC-MD-36, LAC-MD-32, and BI 205.452. ● Read the protocols of clinical trials LAC-MD-31, LAC-MD-36, LAC-MD -32, and BI 205.452. ● Discussed potential research ideas with Dr. Burke, Kathy, and Sondra.
08/21/12	● Researched and read journal articles on Google scholar that related to clinical trials and clinical trial recruitment. ● Reviewed over IRB information through the Good Clinical Practice Reference Guide in preparation for meeting with the Forest Research Institute monitor. ● Went over IRB monitoring and the proper methods for completing a checklist to ensure proper trial conduction at the site through EDC and IWRS systems with Forest Research Institute monitor Dennis Williams.
08/22/12	● Worked on developing a proper proposal and streamlining ideas for my project with Sondra. ● Went over shipment of malfunctioned and used drug devices with Forest Research Institute monitor Dennis Williams. ● Went to the Texas Pulmonary office located in north Arlington to go over protocol and criteria for the clinical trials BI 205.478 and KaloBios's KB003-04.
08/23/12	● Read several issues of the Monitor, a collection of peer

	reviewed articles distributed by the association of clinical research professionals. ● Began to work on establishing potential research topics.
Week 2 08/27/12 08/28/12 08/29/12 08/30/12 08/31/12	● Read more issues of the Monitor, focusing on articles on patient recruitment and retention. ● Filed and copied documents for the LAC-MD-31, LAC-MD-32, and the BI 205.452 studies. ● Began writing down concrete ideas for a research proposal. Wrote down 4 or 5 viable proposal ideas and began to look into each possible selection. ● Began working on the transcripts for the survey questions. ● Learned how to unpack and enter new drugs and devices coming into the clinic. ● Learned what documents to mail to potential patient recruits and what questions to ask them in terms of finding pertinent information to see if they initially qualify for clinical trials. ● Worked on creating survey questions that would be easy to understand and still be viable statistically. ● Listened to a conference call going over protocol for the BI 205.477 study. ● Read the protocol for the BI 205.477 study and researched the mechanisms of tiotropium bromide. ● Began researching different websites that promoted different recruiting methods and strategies. Mainly focused on the websites clinicalconnection.com and trialx.com. Contacted trialX about possibly involving them in the practicum to gauge potential patient interest in using the internet to find clinical research studies. ● Researched on PMRs and EMRs, why they could work in theory and why they haven't. ● Aided in recruiting two patients and gave them information regarding our clinical trials. ● Created, refined, and edited a possible paper survey. ● Worked on locating an online survey format to see how a proper online survey should be designed. ● Started typing up dialogue for a telephone survey, and began searching for suitable telephone survey designs.
Week 3 09/04/12	● Continued working on the telephone survey. ● Learned about where to store and dispose of lab kits and how

	to record the temperature in the drug room. ● Began forming a patient database and determining a sample size needed for the practicum.
09/05/12	● Continued working on questions for the telephone survey and went to www.surveymonkey.com to see if there were any valid questions. ● Started creating an excel chart that organized older patients' information in a presentable format. ● Read excerpts and ordered *A Guide to Patient Recruitment and Retention* by Diana L. Anderson. ● Continued working on my research proposal.
09/06/12	● Recorded temperatures and pressure in the drug room and spirometry room. ● Learned where to get emergency inhaler samples and how to distribute them to patients who need to get more rescue inhalers. ● Worked on the research and design methodology for the proposal. ● Timed the length of the telephone survey by practicing giving the survey to four people.
09/07/12	● Went into the Research center for a couple of hours and read through issues of the Monitor. ● Gave samples of Qvar to a patient who had run out of his rescue inhaler. ● Went to the library and checked out two books, *Clinical Trials: a Practical Approach* by Stuart J. Pocock and *Strategies and Statistics in Clinical Trials* by Joseph Tal to read for a better understanding on clinical trials, statistics, and creating a proper proposal for the practicum.
Week 4 09/10/12	● Received shipment of emergency inhalers and boxing supplies, marked them as received, filed them, and put up the shipment. ● Read the book *A Guide to Patient Recruitment and Retention* by Anderson. ● Worked on questions for the survey focusing on patient attitudes towards research.
09/11/12	● Worked on the proposal and began editing process with Sondra. ● Tested survey on a few more volunteers to assess the time and to see if the questions were not confusing. ● Continued reading *A Guide to Patient Recruitment and Retention* by Anderson.

09/12/12 09/13/12 09/14/12	● Updated the study reference sections of the Forest LAC-MD-31, LAC-MD-32, LAC-MD-36, and BI 205.452 regulatory binders. ● Learned how and where storage materials go in the drug room. ● Began editing the telephone survey to include thoughts about the internet and accessing the internet for finding clinical trials. ● Worked on receiving LAC-MD-31 and LAC-MD-36 drug shipment, entering it in, storing it, and reporting it stored. ● Learned how to enter in adverse events (AEs) and emergency drug distributions manually and online. ● Helped add to the patient database, began refining and updating it, removing any patient that was cold called or no longer interested in clinical research studies. ● Finished reading *A Guide to Patient Recruitment and Retention* by Anderson. ● Worked in the library on the survey and proposal, continued revising it. ● Read another issue of the Monitor for some ideas regarding the practicum.
Week 5 09/17/12 09/18/12 09/19/12 09/20/12	● Set up the BI 205.477 regulatory binder and all of its supporting documents within the binder. ● Finished up the rough draft of the survey and proposal, sent it to Dr. Burk. ● Went to Dr. Burk's office and discussed possible ideas for the proposal. Also talked about methods and means to improve and refine the proposal before the committee meeting. ● Read through and took notes on the BI 205.477 protocol to help with finding patients suitable for the trial. ● Started working through the TPCCC research database by creating a color code system for patients who fit the criteria, those who did not, those who were not interested, and those who are waiting for determining whether they are eligible. ● Attended a site initiation meeting for the BI 205.477 trial with a guest monitor, Kathy, Sondra, and Dr. Burk. ● Aided in recruiting patients by entering their information in the database, faxing for records, and mailing clinical study packets. ● Thought up of more questions for the telephone survey and edited the telephone survey.

09/21/12	• Worked on finding ways to register for clinical research studies through pharmaceutical companies. • Continued updating the patient database and assisted in patient recruiting. • Went through EMRs to find patients that fit the criteria for the KaloBios asthma study, KB003-04. • Read *Strategies and Statistics in Clinical Trials* by Tal. • Began going over biostatistics in preparation for the practicum. • Filed patient documents, regulatory documents, and start up documents for the Novartis 2340 study.
Week 6 09/24/12	• Added patients to the database and took out the chart reviewed patients. • Went through patients in the EMR that fit the criteria for the KB003-04 study. • Edited the telephone survey to be used for the practicum. Also began creating a question bank to take note of questions that did not work or could be modified in the future after talking to Dr. Mallet, Dr. Burk, Dr. Gwirtz, Kathy, or Sondra.
09/25/12	• Went through patients in the EMR that fit the criteria for the KB003-04 study and the Forest ROF-MD-07 study. • Went with Sondra to a doctor's lunch meeting to see her present the new studies from Novartis and to explain to the doctors what each study was about. • Faxed and received medical records from several patients.
09/26/12	• Spent the whole day working on the ROF-07 study, learned the protocol, and went through the patient database to determine who would fit the criteria.
09/27/12	• Set up the committee meeting and began reviewing material in preparation for the meeting. • Started reading another book *A Manager's Guide to the Design and Conduct of Clinical Trials* by Phillip I. Good. • Finished going through the TPCCC research database for possible ROF-MD-07 participants.
09/28/12	• Received medical records from patients through fax and had to reorganize the files on that particular patient. • Went through the TPCCC research database and continued editing and refining it. • Reviewed over proposal and survey for the committee meeting.
Week 7 10/01/12	• Had the Committee meeting where the proposal and survey

	were critiqued by Dr. Burk, Dr. Mallet, Dr. Gwirtz, Kathy Kwaak, and Sondra Simpson. - Worked on developing hypotheses first then creating proper aims in order to gather more statistically significant data. - Talked with Dr. Burk about hypothesis ideas. - Received medical lab testing equipment, stored it, and recorded the occurrence.
10/02/12	- Continued working on hypotheses for proposal, then aims. - Changed the telephone survey to better suit the newly created aims. Began looking at wording the questions in a different format and creating branching questions. - Recorded patient recruiting and put patients in the TPCCC research database.
10/03/12	- Updated patient database and added new records to the TPCCC patient recruit binder. - Continued working on survey questions and hypotheses. - Went through LAC-MD-31, 32, and 36 files to determine if patient information had been entered correctly.
10/04/12	- Worked on creating a database for getting the phone numbers and demographic data of former patients in each trial. Created the template and made sure to avoid gathering information that required IRB approval. - Worked on the telephone survey and showed it to Sondra before sending it to Dr. Mallet. - Helped file and maintain patient records in the TPCCC research database.
10/05/12	- Helped file medical records into the patient recruiting binders. - Went to the library and researched over statistics and survey questions. Began creating a rough draft of a survey to give to patients at the research center.
Week 8 10/08/12	- Updated patient records on the TPCCC research database. - Finished creating a database for determining the number of patients to use for my practicum. - Identified suitable trials to use for the practicum report and incorporated it into the practicum database.
10/09/12	- Read through Novartis 2340 protocol and took notes to better understand the protocol and the treatment medication used. - Read through the Forest ROF-MD-07 protocol and went over the patient database to find any possible patients. - Researched other possible methods to be involved in more

	trials such as clinicalconnection.com, researchmatch.org, and other various websites.
10/10/12	Received LAC-MD-36 and LAC-MD-31 drug shipment and stored and labeled them. Updated TPCCC patient database with new patient information. Received patient files and faxed for medical records. Played around with the Sage Intergy EHR to better utilize it in the future for patient recruitment.
10/11/12	Received patient files and faxed for multiple medical records. Received more LAC-MD-36 supplies; stored and notified that they arrived. Began working on going through the old patient records located in the storage/drug room to determine how many participants were in each trial.
10/12/12	Received more LAC MD-32 and MD-31 drug shipment; stored and labeled that they arrived. Worked on more branching questions for the survey and settled on a desired amount of time the survey should be completed in. Worked on going through old patient source documents to determine how many participants were in each trial. This consisted of going through storage boxes located in the storage/drug room.
Week 9 10/15/12	Received patient packets in the mail, recorded the data on to the TPCCC database and faxed for their medical records. Read through the protocol for the Novartis 2340 study. Continued going through old clinical study boxes to gauge the number of patients needed for the practicum report.
10/16/12	Aided in recruiting patients by going through records and identifying drugs that could possibly knock them out from being a participant in the Novartis 2340 study. Received drug shipment and stored them. Also faxed confirmation and stored documents in the reference binder. Read up on statistics needed for conducting proper research.
10/17/12	Received equipment for the Novartis 2340 study, which consisted of a new spirometer, printer, and laptop. Set up all the equipment and stored extra supplies. Received patient packets in the mail, updated their info on the TPCCC research patient database, and faxed for MRs. Began prepping documents to match IRB requirements for pre-

	review.
10/18/12	Finished going through old source documents of previous clinical trial studies. Got an accurate number of patients involved in previous clinical studies and went through to determine the ones who had passed away. Gave rescue inhalers to a patient in the LAC-MD-31 study and took record of it. Received eDiaries for the Novartis 2340 study and stored them.
Week 10 10/22/12	Looked up new possible patients for the KB003-04 study. Went through patient MRs to determine if they met the criteria for the Novartis 2340 study. Focused on the medications they used and whether they would be able to washout of them for the Novartis study. Also looked over medical history to make sure there were no exclusions. Went through power analysis to determine a desired sample size for the practicum that fit the number of patients acquired from looking through old patient source documents.
10/23/12	Went to the Biostatistics department and received help and suggestions on how to best utilize the data necessary for the practicum. Updated and added patients into the TPCCC patient database. Went to the library and read *The Design and Conduct of Clinical Trials* by Phillip I. Good.
10/24/12	Began going through the practicum database and checking for repeat participants and participants who are now deceased. Tried to help set up the Novartis 2340 spirometer equipment and ERT device, but the ERT device did not work. Had to call the customer service hotline to request for a new ERT device.
10/25/12	Determined an accurate sample size from combing over the TPCCC database. Received equipment from Novartis for the 2340 study and set up the laptop, printer, and spirometer. Faxed for several medical records.
10/26/12	Went to the north Arlington office and discussed the status of several trials during a lunch meeting. Used pMDsoft a billing service that the doctors use, to find potential patients for the ROF-MD-07 study. Decided to begin using it for the, KB003-04, BI 205.477, and 205.478 studies.

	Filed and organized documents in the BI 205.452 regulatory binders.
Week 11 10/29/12 10/30/12 10/31/12 11/01/12 11/02/12	Worked on finding more patients for the Arlington office's research trials through Intergy. Began using Caregate for patients that fit the ROF-MD-07 study. Spent the full day going over patients' records and seeing if they fit the criteria for the ROF study. Received medical records for patients who had been contacted. Began learning how to review them to find criteria for exclusion. Went over ways to maximize the use of Caregate and pMDsoft to create a system for finding suitable patients for the Arlington office's research trials. Created a report from pMDsoft of all the patients who had been seen by the doctors in north Arlington and began finding their records on Intergy and Caregate. Received the wrong shipment of lab supplies for a BI study that had been closed for over a year. Had to dispose of all of the materials and record its disposal. Continued working on going through the list of patients from the day before and to find patients eligible or potentially eligible for studies in the north Arlington office. After compiling a list of possible patients that were eligible for the KB 003-04 asthma study and the Forest ROF-07 study, the process of weeding out each patient was started. The process started with first determining if they were in the TPCCC patient database on Intergy which showed the patient's medication and history. If there was no conclusive evidence to exclude or include the patient then Caregate was checked. With the list of patients who couldn't be weeded out through TPCCC's Intergy database, Caregate was used. Caregate's progress notes that are completed by all physicians involved provided a clear cut answer to patient medical history and diagnoses. Entered in Novartis 2340 drug and read The Monitor's issue on patient recruitment. Received the regulatory documents for the Novartis 2337 study. Began reading up on the protocol and set up the binder.
Week 12 11/05/12	The list of patients that could possibly qualify for the studies in the North Arlington office studies was sent to Heather. Recruitment letters and TPCCC medical release forms were

	mailed to the potential candidates as well. • These patients were updated in the TPCCC research database, and categorization of the database was started. Complete color coding was created in which yellow was a potential candidate, green was for a candidate who fit the criteria of a study, red was for patients who did not fit the criteria at the time, purple was for patients who would not be able to fit the criteria for any study, and light blue was for patients involved in asthma studies.
11/06/12	• Decided on slowly color coding the database and also eliminating patients that were simply taken from the TPCCC Intergy database. Because Kathy and Sondra wanted to remove any chance of "cold calls" to patients that have not been approached by research before. • Learned where the rescue inhalers and additional inhalers such as Advair and Combivent were stored in case patients needed them. • Checked in more Forest LAC-36 drug and had to reorganize the entire storage system to accommodate the increased amount of research drug.
11/07/12	• Began following how Sondra enters information electronically for patients in Forest's research studies. For each segment of the visit, from the initial check through, to the PFT test, and finally the lab work, everything was to be recorded in a clear and concise manner. Any new medical diagnoses or concomitant medication was recorded as well. • After entering the information in Forest's electronic data site, the annotated notes were completed. Each of these notes is a brief overview of the visit and if anything out of the ordinary occurred during the visit. These notes are then read and signed by the PI, Dr. Burk to document he is involved and aware of the visit.
11/08/12	• Received LAC-32 research drug and LAC-32 rescue inhalers, entered their arrival, printed records of the shipment, and stored it. • Began observing how Sondra enters information for Novartis electronically. Novartis's electronic documentation is much different from Forest's and the process took a considerably longer amount of time. Because each medication entered needed a breakdown of its properties for example Advair's two components (Fluticasone a corticosteroid and Salmeterol a long acting beta-2 agonist), this was quite a tedious process. • After this information was entered queries showed up that had

	to be addressed. Queries from Data Control were easily taken care of, but some queries required clarification and therefore emails were sent to find out the best possible way to answer them. - Queries from Forest were also taken note of and were addressed. Any difficult queries could be addressed by calling the monitor of the study, Dennis.
Week 13 11/12/12	- Heather emailed back about the patients who were interested and who weren't interested in the North Arlington studies. Their information was updated and coded to red, green, yellow, purple, or blue. Continued cleanup of the TPCCC research database continued. - Additional queries from the Novartis study popped up and they had to be dealt with. Because most of the queries involved errors on the Data Control's part, emails were sent to explain why the data was entered in the way it was. - Added five potential recruits into the TPCCC research database for COPD studies that had seen the advertisements from the Senior News.
11/13/12	- Received the computer, modem, printer, Masterscope, and ERT devices for the Novartis 2337 study. Because the patient room already has LAC 31/36, LAC 32, and Novartis 2340 equipment, there was considerable rearrangement in order to set up everything properly. After everything was assembled and labeled, the startup of the Novartis 2337 equipment began. - The ERT devices did not work; so much of the day was spent contacting the Novartis Help Desk to figure a way to fix the problem. Once the equipment was deemed unfixable, measures were taken to quickly ship out the product and to ensure replacement ERT devices would arrive as soon as possible. - Continued working on reorganizing the TPCCC research database and eliminating unnecessary patient recruits.
11/14/12	- Focused on finding patients for the Novartis 2340 study. Many of these patients were simply recruits in the database that had seen the ad from the Senior News and were interested in COPD research so the only things necessary was for them to fill out a waiver for their medical records. - Roughly eight of the patients in the LAC-31 study were interested in the Novartis 2340 study and prescreening visits were scheduled to determine if they would qualify for the Novartis study.

	Received lab supplies for Novartis 2337 study, which being a 12 hour study had a different numbering system. To make sure everything was included in the kits, the kits were opened up and the items inside were counted to make sure everything was included.
11/15/12	Learned exactly how and what to print and fill out for a prescreening visit. Observed how Sondra and Kathy asked questions regarding medical histories, concomitant medication, possibilities of drug use, and if they are involved in other studies. Saw how successful prescreen patients were entered into Novartis's EDC (electronic documentation) system. Each medical event had to be properly dated with when the event occurred and whether it was ongoing. As for medication, dosage, drug type, and classification were all necessary. Aided Sondra in going over all these requirements for medical events and concomitant medication. Continued reorganizing the TPCCC research database, and switched the database over to the TPCCC server so that everyone could have access to it.
11/16/12	Because Kathy would be away for the coming week, learned how to set up patient documents before a visit and on how to handle the items in a lab kit. Received Novartis 2340 drug, entered the information and printed the necessary documents, then stored it.
Week 14 11/19/12	Began writing the IRB pre review documents. Determined if the practicum would be an exempt review or an expedited review. Once it was determined to be an expedited review, the expedited review application form was filled. After this, the protocol synopsis was worked on. Finished reorganizing the TPCCC research database and removing any extraneous information such as unwanted patients or patients with missing information. Helped set up the patient documents needed for the two visits the next day.
11/20/12	Arrived early to help set up the Masterscope and lab kits for the visits. Was able to read the urine dipstick results, centrifuge the blood, and properly ship the lab documents for each patient. Helped enter in the information through Forest's EDC program and aided in entering the information necessary for the annotated notes.

	Worked on the HIPAA Research Waivers and Conflict of Interest forms for the IRB pre-review.
11/21/12	Arrived early to help set up the Masterscope and lab kits for the two visits again. Was able to read the urine dipstick results, centrifuge the blood, and ship the necessary documents for each patient to Quintiles. Had to complete the correct CITI training in order for IRB pre-review. Since this was the day before Thanksgiving, just finished up the Informed Consent document needed for the IRB pre-review and submitted the necessary documents for IRB pre-review.
Week 15 11/26/12	With Acurian being involved with the KB003-04 and Novartis 2340 studies, there was going to be a much greater influx of potential patient recruits. Therefore, we watched the introductory video on how Acurian would work for us and the necessary steps we needed to do to ensure a consistent number of possible patients were sent our way. Looked into more potential ROF-07 patients. This time the focus was more so on Caregate and pMDsoft as opposed to using the TPCCC Intergy database.
11/27/12	Began receiving patients from Acurian for both the KB003-04 and Novartis 2340 studies. With each potential patient, they were given a call and a voice mail was left. If they did not return then a patient recruitment packet was mailed to them regardless, since by signing up for Acurian, they were ok with having clinical trial information sent to them. Each of these patients was entered into the TPCCC research database as well. Continued looking up patients for the ROF-07 study. The few potential patients were emailed to Heather for her to contact and notify. Read up on biostatistics in order to talk to Dr. Aryaal or anyone in his biostats lab about ways to manipulate and present the data to be collected in the practicum.
11/28/12	The Novartis 2337 printer and ERT devices were not working, so worked on fixing the printer and notifying the Novartis Help Desk of the ERT device malfunctions. Received more potential patients from Acurian and began calling and mailing patient registration packets to them. Went to the UNTHSC campus to talk to the Stats lab about ways to collect and present data for the practicum report.
11/29/12	Received the corrections from the IRB pre-review and spent

	the whole day working on the necessary corrections.
11/30/12	Continued working on the corrections that the OPHS committee advised for the documents that needed to be submitted for IRB approval.
Week 16 12/03/12	• Worked with Sondra to help her prepare for a 2340 study visit by seeing how and what to do in a visit after the initial screening visit. Saw how to prepare patient files for the next day and the correct way to organize everything. • Realized that the proposal was not submitted yet, so went to campus to get the necessary signatures and to submit it. • Kept editing the documents for IRB approval and emailed back and forth with Itzel Pena for further clarifications. Thought about possibly altering how the demographic data would be collected by perhaps scrapping the idea of asking the patients their zip code and other basic info. • Began compiling a list for BI 205.477 and 205.478 potential patients. Planned on reviewing over each patient later on in the week.
12/04/12	• Had a busy morning with two patients coming in and starting on going through potential patients for the BI 205.477 and 205.478 studies. By starting through pMDsoft to determine what they were hospitalized for and continuing through CareGate to find any potential exclusionary criteria. • In the afternoon, worked on entering possible recruits for the Novartis 2340 study in the patient database and also faxing for medical records. • After debating about how to attain the demographic data for the practicum, the decision was made to both attain the data from the patient database and confirm these findings with the patient while performing the survey.
12/05/12	• Continued reviewing through patients for the BI 205.477 and 205.478 studies, any potentials found were marked and given to Sondra or Kathy to double check to make sure they fit the criteria. • Any potential patients with severe exacerbations that did not fit the BI studies were looked at again to see if they fit the ROF-MD-07 study. If they met the criteria, the patient information was forwarded to Heather for approval. • Faxed and sent for medical records from potential patients for the Novartis 2340 study. Sondra started calling more patients that came from Acurian for the KB Asthma study so started looking through these patients to see if they fit the criteria.
12/06/12	

12/07/12	• Was sick for the day and did not go in. • Was sick for the day and did not go in.
Week 17 12/10/12 12/11/12 12/12/12 12/13/12 12/14/12	• Was sick for the day and did not go in. • Was sick for the day and did not go in. • Was sick for the day and did not go in. • Came back and tried to catch up on what needed to be done. Went through the telephone screening sheets and updated the TPCCC research database. • Began searching for the fax numbers of several medical offices for patients who had returned their registration packet. Faxed all the medical requests by the end of the day. • Spent the day putting signed documents in the source documents and regulatory binders. Because of the sick days taken, there was a considerable amount of paper work that needed to be put in. • Read through issues of The Monitor and read journal articles regarding research recruitment to see if anything could be added to the practicum defense.
Week 18 12/17/12 12/18/12	• Entered roughly 20 candidates into the TPCCC research patient database which consisted mainly of possible candidates for the KB003-04 asthma study. Since all were from Acurian, even the eliminated candidates had to be recorded to ensure they are not recycled. • Received drug for the Novartis 2340 study and proceeded to enter and store it. • Updated the regulatory binders of the Novartis 2340 and the BI 205.477 studies. • Continued adding new patients to the TPCCC database from Acurian contacts. These were potential recruits for the KB003-04 and Novartis 2340 studies. • Went to the Arlington North office to get the 1572s from Heather since she had resigned from her position. Had a walkthrough of the office to see where everything was located and then made copies of all the 1572s to remove Heather's name and get signatures from the other involved in the studies. • Put together and mailed several patient registration packets to

	Acurian candidates who we have not been able to contact.
12/19/12	Received drug for the Novartis 2337 study. Entered and stored the drugs for the new trial, and read over the protocol for the 2337 study. Faxed for the medical records of several candidates that had returned the registration packets mailed out to them. Set up documents and made new folders for two patients that were going to sign their informed letter of consent for the Novartis 2340 study.
12/20/12	• Observed how Kathy goes about a visit in which the patient signs informed consent. Made copies for the patients who signed consent and saw how to enter the new patients electronically. • Went through the daily activities log for editing purposes. • Received patient packets and entered their information in the TPCCC research database. Faxed for their medical records after.
12/21/12	• Received lab kits from Quintiles for the Novartis 2340 and 2337 studies. Recorded the arrival and stored them safely. • Learned from Kathy how to go through medical records and to highlight pertinent information so that she, Sondra, and Dr. Burk can check to make sure the patient is eligible. Spent the rest of the day going over medical records and highlighting information that would be useful in determining whether or not the potential patient has no exclusionary criteria. • Took some time off for Christmas and New Year's since there were no patients scheduled for the upcoming week.
Week 19 01/02/13	Added possible patients to the research database from the Acurian recruiting service for the KaloBios asthma study and the Novartis 2340 study. Faxed for several medical records and began reviewing a couple to determine if they are eligible for trial participation.
01/03/13	Received IRB approval, began printing out the necessary documents and forming a clear cut plan for who and when to contact. Went to the Arlington North office to gather demographic data of the research patients in that office and to go over source documents to make sure there were no errors or missing documents. Added the Arlington North schedule in order to further coordinate when to exactly go to the office to give surveys in

	person as opposed to simply calling them.
01/04/13	Created a checklist to ensure all patients would be accounted for. Went through the list to make sure all numbers are up to date and finished working on a schedule for calls and in person surveys. Two patients in the research center agreed to fill out the survey and their data was collected. Also began preparing for next week's patients coming in.
Week 20 01/07/13	• 1 patient in the research center agreed to participate in the survey and the data was recorded. Worked on finding the numbers of participants past and present. Also ensured that all patients who were to be called were not screen failures off the initial visit. • Began thinking of ways to put the data sheet to use, researched the positives and negatives of different statistical software to use. • Received Novartis 2340 drug, marked as received, and put it in storage.
01/08/13	• Was sick for the day and did not go in.
01/09/13	• Was sick for the day and did not go in.
01/10/13	• Was sick for the day and did not go in.
01/11/13	• Was sick for the day and did not go in.
Week 21 01/14/13	• Returned back and gave 1 patient the printed survey to complete. Patient agreed, completed the survey, and the data was recorded on the data sheet. • Because Acurian has started assisting with the Novartis 2340 study along with the KaloBios asthma study there was an enormous number of patients who had been contacted. Each patient that was telephone screened was entered into the research database. Any patient that showed interest in either trial was mailed a patient registration packet. Spent the rest of the day getting up to date since every patient called had to be reported as contacted to Acurian. If not then Acurian would stop sending potential patients to be screened.
01/15/13	• Kathy and Sondra had Dennis, the Forest Monitor arrive at the Arlington site for his visit. Because Heather had left, Kathy and Sondra both went there fix up the site for the next three

	days. Therefore I had to open and close the Fort Worth site for the next three days. • Went through and called several patients from the checklist. 15 patients were given the telephone survey and their information was entered onto separate data sheets. • Received patient registration packets in the mail. Entered the data into the TPCCC research database and faxed for patients' medical records.
01/16/13	• Talked to two patients who called and were interested in research. Took their information and mailed them registration packets. • Continued going through the checklist and had 10 patients agree to conduct the survey over the telephone. Their answers were then transferred to the data sheet.
01/17/13	• Went through several patients in the checklist but only 3 patients agreed to take part in the survey. Patients who were not able to be reached were marked for notice and will be called at a future time. The 3 patients' data was transferred to data sheets. • Received more patient registration packets in the mail. Entered the patient information in the research database and faxed for the patients' medical records. • Received Novartis 2340 drug. Marked the drugs as received and stored the drug in the drug supply room.
01/18/13	• Because I opened and closed the last three days, Kathy and Sondra were ok with me staying in and doing my work for my practicum at home. Read biostatistics books to make sure the information I collected was relevant.
Week 22 01/21/13	• Went in the morning and two of the scheduled patients completed the survey. Entered their information onto the data sheets. • Went to Arlington to help with moving the office stuff around and also got talked to two more patients during their consent visit who agreed to do the survey on their initial visits.
01/22/13	• Received patient packets and faxed for their medical records. Also entered in the patient information for the patients who had been contacted the last few days. • Kathy left for a dentist appointment, so the rest of the day was spent making phone calls to patients. 10 patients agreed to the survey and completed them.

01/23/13	• Two more patients in the morning agreed to complete the survey. Worked on entering all the patient information onto the data sheets. • Spent most of the day updating and working on the TPCCC research database. Moved it out of the sleep server so it would be easier to update and save information. • Began writing down the zip codes and ages of all the survey participants for statistical analysis.
01/24/13	• Received Novartis 2340 drug, entered the drug shipment information and stored the drug. Helped Kathy with setting up the lab work that needed to be shipped and called FedEx to schedule a pickup. • Filed documents that had been signed by Dr. Burk for the regulatory binders. • At night went to help Sondra with cleaning up the Arlington office. Moved and packed up several ROF medications and also stored the shipping supplies.
01/25/13	• Got one patient to complete the survey. Went to the Cooper Street office to store up on supplies needed to patient recruitment. • Entered patient information from the telephone screen sheets that Sondra was filling out while calling potential patients.
Week 23 01/28/13	• Sondra was out on vacation and Kathy went to Arlington to help with getting the research center in shape. Opened the research center, filled out the temperature logs, and called a couple of potential recruits who had called during the weekend. Entered their information and mailed out their packets. • Began writing thesis for the practicum defense. Read through previous TPCCC interns' works to see what they did and did not do. • Called 15 patients who agreed to complete the survey. Entered their information onto data sheets and began looking up the best methods for testing this information.
01/29/13	• Opened the research center today because Sondra was on vacation and Kathy was in Arlington for the day. Spent most of the day outlining and brainstorming ideas and methods to write the thesis. • Received patient packets in the mail, updated their information on the research database, and faxed for their medical records. • Called one patient who agreed to participate in the survey.

01/30/13   01/31/13

	• Received patient packets in the mail, entered their data into the TPCCC database, and faxed for their medical records. • Planned on calling more patients but was not able to due to personal reasons. Decided to call tomorrow.
02/07/13	• Helped Kathy and Sondra with looking up file cabinets for the Arlington office. • Filed several documents for the regulatory binders and source documents. • Got a hold of 21 patients to complete the survey. Personal record!
02/08/13	• Office was closed.
Week 25 02/11/13	• Read what was needed to understand ANOVA and other statistical programs to get the best possible results for the practicum project. • Went through the database checklist and came up with a plan of who to call and when to call them in the coming few weeks. • Received patient registration packets, faxed for medical records, and updated information on the TPCCC research database.
02/12/13	• Continued reading and taking notes on what type of statistical tests were needed to ensure clarity and as little error as possible for the data collected. • Successfully called 14 patients today that participated in the telephone survey. Two other patients requested not to participate and voice mails were left for 4 others.
02/13/13	• Had a flat tire so came in late to the clinic, transferred all the survey information from the previous day to the data sheets, took note of all the zip codes in hopes of creating a zip code map, and continued reading about ways to statistically represent the data collected. Left early to fix flat tire.
02/14/13	• Broke up survey questions to associate with specific aims. For each aim and group of questions, the proper test was looked at and assessed. • Finished reading up statistical information for the data collected. Reached out to 13 patients today that completed the survey and transferred all the data onto the data sheets. • Received patient registration packets and faxed for medical records.
02/15/13	

	• Sondra and Kathy both came back from Arlington and therefore today was mostly just catching up with office work. Put up papers that belonged in the regulatory binders and source documents. • Mailed, faxed for records, and updated numerous patients that Sondra had talked to this week. Also updated the patient recruitment binder and made sure everything was organized by date. • Went through the first ten weeks of the journal to make sure grammar and punctuation was correct. Also went to make sure descriptions were accurate and detail oriented rather than short and bland.
Week 26 02/18/13	• Opened the clinic, and began working on the Power Point presentation portion of the practicum. Searched for design templates and made an outline of what the Power Point would have for the practicum. • Set up the biological specimens for shipment and scheduled the pickup for the specimens. Faxed for a few medical records, and updated the patient database. • Outlined what data was necessary for the practicum and began to create an outline for everything needed.
02/19/13	• Started working on the initial basic Power Point slides for the presentation and began working on transition effects needed for each slide. • Dr. Burk came by to see how the practicum defense work was going. Entered all the demographic data collected from the data sheets into Excel since he suggested it would be easier for statistical programs to take data from a program like Excel. • Called 8 patients today but received no response so marked them down to call at a later time and proceeded to continue working on the Power Point presentation.
02/20/13	• Received patient medical records and registration packets from potential patients. Faxed for the desired medical records. Also got a call from a potential recruit who was interested in research, and therefore set up and mailed the TPCCC research registration packet to him. • Helped Kathy by setting up and scheduling the pickup of lab work from patients who had visited that day. Also received 2340 drug shipment so had to enter it in manually and electronically. • Sondra was in the Arlington office for the day and had forgotten some keys for the Arlington office so had to go drop them off to her.

02/21/13	• Waited to make phone calls for the practicum but the Sleep Lab had a meeting around 5 so there was too many distractions to make calls for the day. • Drove to the Arlington office to drop off a rescue inhaler Sondra needed. Came back and continued working on thesis paper for the practicum defense. Created a deadline for when to be done with the thesis paper by the end of next week. • Received a patient registration packet with an extensive number of medical record request forms. Talked to the patient to ensure which records were necessary and to answer any research questions the potential patient had. Faxed for the MRs after talking to the potential patient. • Successfully called and got a hold of 8 patients who completed the survey. Missed calling two patients, but will call them later.
Week 27 02/25/13 02/26/13 02/27/13	• Called the two people from Thursday. Collected the majority of the data but realized that with so many patients being screen-fails, there had to be a better way to interpret the data without the bias of having never been truly involved in TPCCC's research. Therefore the criteria of having had completed at least 1 visit was made. Began sorting through all the data and weeding out patients who had screen failed in their initial visit. • Received patient packets and faxed for medical records. • Called the final person that needed to be called for the telephone survey. Using the sample size calculator, determined that of the 102 people that fit the criteria for the practicum, a sample population of 87 was needed. With upcoming visits at the research center, the total number of participants in the survey would be 90. • Set up all the data onto a spreadsheet and began analyzing the data. Decided to meet with Dr. Mallet for questions regarding the statistics. • Helped Sondra with setting up a patient's lab work for shipment. Scheduled a pickup through FedEx. • Went to Dr. Mallet and discussed the best method to analyze the data. • Worked on thesis and started reading a book given by Dr. Mallet to aid in data analysis. • Collected a completed survey from 1 patient during their visit. • Went to campus to attend a workshop involving RefWorks for easier paper writing.

02/28/13 03/01/13	• Worked on statistical analysis and thesis writing. • Collected a completed survey from 1 patient during their visit. • Helped Sondra go through several patients through Acurian. Entered their information in the TPCCC database, and mailed their patient registration packets. • Worked on statistical analysis and thesis writing.
Week 28 03/04/13 03/05/13 03/06/13 03/07/13 03/08/13	• Worked on statistical analysis and thesis writing. • Worked on statistical analysis and thesis writing. • Collected the last patient's completed survey and had the number of participants in the survey at 90. • Received patient packets in the mail, entered their data in the TPCCC research database, and faxed for their medical records. • Worked on statistical analysis and thesis writing. • Worked on statistical analysis and thesis writing. • Worked on statistical analysis and thesis writing.
Week 29 03/11/13 03/12/13 03/13/13 03/14/13 03/15/13	• Entered all the patients that Sondra had contacted through Acurian in the TPCCC research database. • Helped Kathy with the shipment of lab work for the patients that had come in. • Went through the TPCCC research database and created a guide for easy use. • Worked on statistical analysis and thesis writing. • Helped the new Arlington CRC Marcia with using the TPCCC research database. • Went to see Dr. Mallet to discuss the data collected and other ways to analyze the data. • Worked on statistical analysis and thesis writing. • Worked on statistical analysis and thesis writing. • Finished statistical work and began putting the data in the power point presentation. Also worked on thesis writing. • Helped Kathy find Novartis 2340 drug that wasn't recorded correctly by Novartis. Also discovered one of the patients got

	the wrong labeled drug and had to contact the patient to get the drug back. • Received patient packets in the mail, entered their information in the research database, and faxed for their medical records. • Worked on statistical analysis and thesis writing.
Week 30 03/18/13 03/19/13	• Worked on thesis writing and the power point presentation. • Worked on thesis writing and the power point presentation.

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