FACTORS THAT IMPACT PATIENT ENROLLMENT IN CLINICAL TRIALS

PRACTICUM REPORT

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By

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CHAPTER I

Introduction

Discussions of evidence-based medicine have been more increasingly urgent over the past few decades. Medical progress, now more than ever, demands clinicians to provide tangible proof over sound hypotheses[11]. This is where clinical research steps in as a combatant to the unknown provoked by logical theories and sound hypotheses. Clinical research trials are designed to propose an addition to medical knowledge regarding the prevention and retardation of diseases and conditions. They are the linking steps that enable basic research findings to emerge at patient bedsides and within examination rooms[5]. The eradication of polio in the western world was due in large part to a vaccine developed through clinical trials[19]. In 1954, Dr. Thomas Francis of The National Foundation for Infantile Paralysis implemented the first mass polio vaccine trial[19]. The scrutiny under which the research was carried out led to the distribution of the Salk vaccine in April 1955 and subsequently saw a dramatic decrease in the incidence of Polio in the decades to follow. The World Health Organization (WHO) estimates that Polio cases have decreased by more than 99% since 1988[19].

The value of clinical research is not strictly an altruistic endeavor. Clinical research trials provide an individual with the opportunity at improving their overall health. Not without drawbacks, clinical research trials present many risks. These include unpleasant or life-threatening side effects, as well as the possibility of a decreased therapeutic value[11]. Research participants must also invest a tremendous amount of time. Accounting for both the risks and

benefits, clinical research has had an undeniable influence on the modern world. The Food and Drug Administration (FDA) predicts that despite this influence there is a large disparity between adults living with common diseases and their participation in a clinical research study[20]. This parity contributes to the difficulties that stand against major scientific progress.

The process of clinical research begins well beyond the initial patient contact point. Research sites are responsible for ensuring the appropriate documents have been received, reviewed, and approved by the local Institutional Review Board (IRB). From this point, the trial site must undergo protocol training with a clinical research associate sent by the study sponsor. During this training, coordinators will receive an in depth overview of the study eligibility criteria, procedural protocol, and clinical end points the study wishes to achieve. Once the IRB has approved of the study and its respective documents, the research staff will begin the screening process for potential subjects. These subjects are provided from a list of either hospital or clinic patients that have ties to a physician authorized to conduct the respective research study.

Using the protocol procedures, the staff will review all of a subject's relevant medical history to determine if they are eligible for participation. Finding the "right patient" is critical for the continued success of a clinical trial. Poor patient selection can negatively impact a study's end point. Outlined within the eligibility protocol are inclusion and exclusion criteria. These criteria can include age, sex, race, and most importantly history of present illness. Inclusion criteria account for the essential attributes that qualify an individual for a particular study. Exclusion criteria disqualify an individual from a study given their possession of a particular condition. Without a given attribute, the subject will not meet appropriate measures for data standardization. Given a subject's possession of a particular exclusion criterion, their inclusion is deemed as a potential health detriment. Table 1.1 illustrates the distribution of inclusion and

exclusion criteria amongst four ongoing research studies at Plaza Medical Center of Fort Worth (PZMC). The distribution points to a heavier emphasis on exclusion criteria than inclusion criteria. In each of the four studies, the exclusion criteria outlines a vast array of medical conditions that are deemed to be unsuitable for participation.

Inclusion/Exclusion Criteria Distribution

Table 1.1	**Inclusion Criteria**	**Exclusion Criteria**
Study A	13	31
Study B	6	22
Study C	9	15
Study D	9	21

For example, in Study A, a subject must have been hospitalized for acute cardiac symptoms (ACS); this includes elevated cardiac biomarkers or resting electrocardiogram changes consistent with ischemia/infarction[7]. However, this subject cannot have a history of cancer within the past five years. Subjects are also required to have low-density lipoprotein cholesterol (LDL-C) of >70 mg/dL but cannot have a glomerular filtration rate (GFR) <30ml/min[7]. While Study A maintains that subjects must have an ACS event to be eligible for participation, Study C requires research staff to exclude subjects that have had an ACS event within the past 72 hours[4]. Of the four studies, three are categorized as clinical device trials. With these types of research trials, there are additional criteria that must be assessed. In addition to the general inclusion/exclusion criteria, Studies A, C, and D have angiographic criteria that are essential to device study participation. The angiographic criteria are assessed once the subject has consented to participate and the principal investigator is in the midst of performing the cardiac procedure. A common criteria between the four studies is the inclusion of principal investigator judgment. The studies conducted at PZMC have a number of interventional cardiologists under the delegation of

authority. The subjects enrolled are patients of these physicians; thus the physician's judgment is often more binding than inclusion-exclusion criteria. The physician-patient face to face interactions provide the physician with more access to a subject's life. This includes knowledge of lifestyle, habits, and any environmental factors that go beyond medical eligibility.

While subjects may possess all of the criteria necessary to qualify for a respective clinical trial, there are factors that can prevent the subject from actually enrolling in the study. These factors stem from an array of influences including, family, network of medical personnel, finances, and even personal beliefs. Despite the time and effort invested in the pre-screening process for potential subjects, there are still major issues that lie ahead. Recruitment is one of these major issues that can hinder the progress and even success of a clinical research study[11]. Recruitment for clinical research studies is a complex process by which researchers utilize a set of strategies to enroll study subjects[11].

Subject recruitment is a significant responsibility for clinical researchers. Without effective strategies implemented, there is cause for frustration, institutional concern, and even embarrassment[11]. The one constant in clinical research is that recruitment is always changing. It is up to researchers to adapt[11]. Analyzing factors that impact recruitment will effectively serve to improve the quality of clinical research conduction at PZMC.

CHAPTER II

Recruitment Background

Researchers collectively believe the most common reason for failure of a clinical research trial is recruitment, or lack thereof[11]. As a result of improper recruitment strategies, the National Institute of Health projects that more than 80% of clinical trials in the United States (US) fail to their meet desired timelines and subsequent abandonment of the trial[12]. This is a costly outcome that can harm the credibility of the investigator and their institution[11].

Data reports released by clinicaltrials.gov reportedly speculate that an ongoing trend in clinical research is outsourcing clinical trials to be conducted outside the United States (US) [21]. In 2013 the FDA approved only twenty-seven New Molecular Entities (NME) compared to the 88,854 current drugs or biologic studies that are registered, resulting in a 0.03% success rate in going from trial to market. It must be kept in mind, however, that of those 88,854 studies, an overwhelming majority are still in various phases of clinical trials[20]. In the same data report, it is estimated that only 40% of the clinical research is conducted in the US compared to the 45% of trials that are conducted elsewhere[20]. TIME magazine estimates that this rising trend in outsourcing clinical research is due in large part to deregulated markets that exist outside the US[17]. In other countries, subjects are willing to consent with less compensation, products are not tied up in rounds of clinical trials, and most alarmingly public health care is rather dismal[17]. These subjects do not have any alternative mode of access to healthcare other than participating in clinical trials. The reduced regulation and expedited modes of profit have led drug companies

to begin to reach into the pockets of developing countries to conduct their studies. Raisa Gul believes that any faults in recruiting can have "financial and [even] ethical implications" [9]. Gul also believes that recruitment is particularly crucial in randomized clinical trials (RCT) [9].

In order to more effectively combat the issue of insufficient recruitment, factors regulating this crucial step in clinical research have been stringently examined by clinical researchers. The first step required in conducting clinical trials effectively is recruitment. Without adequate numbers of subjects, how does a study expect to continue? Recruited subjects are pivotal in the development of a new drug or device that will eventually serve to improve healthcare of the directed population. It is through recruitment that the process of proactive medicine can begin to take shape. In analyzing factors that promote recruitment, researchers can incorporate a feasible strategy to improving the initial period of clinical research.

A study conducted by the NIH in 2004 on the attitude towards clinical trials found a number of rather disparaging concerns[13]. Approximately 1,013 US adults were questioned on their understanding of the nature of clinical trials[13]. Only 34% of the respondents had heard of clinical trials. Those who were aware of what clinical trials were had an overwhelming fear of being a "guinea pig" [13]. There is a fear of the unknown regarding potential side-effects and many did not feel inclined to be part of an experiment. There was also concern for the cost of the study among the surveyed. Many did not realize that participation in clinical trials conducted by the NIH were free of charge. The 2004 survey found that attitudes about clinical trials were more positive amongst households with higher incomes[13]. The study concluded by asking respondents to comment on any likely motivational factors that would enhance their participation in a clinical research study. Respondents felt that a doctor's recommendation would go a long way in their

decision as well as the opportunity of having the leading specialists involved in their care. The respondents also indicated their desire to contribute to the advancement of science[13].

In 2014 Kenneth Getz presented findings from a study conducted by the Center for Information & Study on Clinical Research Participation (CISCRP) to examine public perception of clinical trials[8]. The result of the survey conducted by CISCRP has shown public perception of clinical trials moving towards a more positive attitude than previously reported[8]. In 2005, 45% of individuals responded to a survey indicating they "did not trust research sponsors to inform the public quickly about safety concerns" compared to only 28% in 2013[8]. The decrease in percentage of public distrust seems to be attributed to the clinical research community's utilization of Clinical Trial Educators (CTE) [8].

Stewart H. Rosen, M.D., of medical affairs at Quintiles has seen successful patient recruitment when using CTE's in complex fields such as cardiovascular research[15]. Rosen goes further in advocating for the use of CTE's by reporting that a particular biopharma acute coronary syndrome case study saw patient recruitment reach more than 130% of projections [15]. These CTE's are crucial to research sites in that they work directly to help accelerate the clinical trial process. Some effective methods that CTE's have utilized included: patient education on therapy and compliance, linking patients to advocacy and support groups, as well as educating site staff on protocol and best practices[15].

In an attempt to address recruitment issues, the National Institute of Mental Health (NIMH) released a series of "points to consider" for research staff[14]. The suggestion calls for establishing a relationship with potential subjects. This includes engaging the subject's network of support to prevent communication and trust barriers[14]. The suggestions created by the NIMH emphasize the how pivotal of a role the research staff plays. It is up to the research to

appropriately communicate the study aims and improve a subject's understanding. They are also responsible for speaking with family members in answering any concerns regarding the study procedure. Spending time with the subject and their family to provide culturally and linguistically relevant education materials is the only way to deal with the trust problem[11].

The strategies implemented through the use of CTE's and suggestions from the NIMH will certainly increase the success of recruitment in clinical research trials at the present time. More importantly these strategies create a path for future research studies. Building a positive relationship with the community of research subjects can facilitate the success of future studies. Identifying and preventing the barriers to recruitment is an ongoing process that has to be consistently researched. While clinical research trials require people to put themselves at risk, the evidence gained can provide undisputable certainty in medical decision making.

CHAPTER III

Hypothesis & Specific Aims

Hypothesis

The practicum project was designed to test the following hypothesis: Are there certain modalities in a subject's life that has influenced them to participate in a clinical research study? The hypothesis was tested to determine the significance of each question in regards to its impact. The use of Chi Square will provide an accurate and efficient method of significance testing.

Specific Aims

The following specific aims were addressed in a subject survey to provide a conclusion on how to successfully recruit study subjects. More importantly, analyzing the data from respondents will allow the local research staff to implement strategies to prevent hindrances to the recruitment process.

Aim I: Identify the barriers to subject recruitment:

The aim focuses on evaluating any barriers that are preventing subjects from enrolling in a research study. In order to successfully enroll a subject into a research study, the barriers or rather failures have to be acknowledged and corrected.

Aim II: Identify the factors that impact a subject's consent to a clinical study:

Analyzing the factors with the most significant impact, the local research staff can be provided with insight on what methods work well for future subject recruitment. The factors with

the greatest significance will be established as a continued standard of subject recruiting. This aim is in conjunction to Aim I.

Aim III: Analyzing the factors that establish relationships between the subject and site.

The role of the research staff is of crucial importance for the continuation of a research study. These staff members function as an extra safety net for a subject's health. Following enrollment, subjects will see the research staff annually and in some cases even as often as monthly. Questions regarding the efficacy of the site and site staff will be included in a survey in order to serve the needs of the research department at PZMC. Conclusions from those questions will be able to provide valuable insight on how current subjects feel about their time in the study. Subsequently these conclusions can also be utilized to prepare and accommodate future subjects.

CHAPTER IV

Design and Methodology

To address the specific aims of the practicum project, a fifteen-question survey was developed. With the assistance of the site mentor, the survey was formulated to resemble certain aspects of a survey created by the Center for Information & Study on Clinical Research Participation (CISCRP) [8]. The language of the survey was simplified to ensure that all subjects participating will easily understand the questions presented. In using a few of the top rated factors compiled by CISCRP, the survey utilized at PZMC distributed 13 of the 15 questions into 5 major domains:

a. Personal influence
    a. Questions 1, 2, and 3
b. Family influence
    a. Questions 4 and 5
c. Local Research Staff influence
    a. Questions 6, 7, 8, and 9
d. Financial influence
    a. Questions 10 and 11
e. Physician influence
    a. Questions 12 and 13

Illustration 4.2 provides a template of the questionnaire that subjects were responsible for completing. Question 14 was in place to measure subsequent attrition based on the subjects' responses. While the practicum steers away from the attrition argument, analyzing subject's likelihood of continued participation is a valued asset in the maintenance of patient satisfaction. The final question asks responders to recall on how they became involved in their research study. This question incorporates the idea of referral popularized by Clinical Trial Educators. Each question posed provided respondents with a possibility of five answer choices: strongly agree, agree, neutral, disagree, and strongly disagree. Following the data collection period, subject responses were then transcribed to a numerical value. Agree and strongly agree were to be deemed as "positive" responses eliciting a value of 4 and 5 respectively. Disagree and strongly disagree were designated as "negative" responses with a numerical value of 1 and 2. Neutral responses were treated as "no answer" and thus did not have an associative number transcribed to it. Before subjects were able to complete the survey, they were asked to read and sign an inform consent form (ICF) which detailed the study, the risks (or lack thereof) of the study, and the study's purpose. A series of previously approved ICF's were reviewed to provide a paradigm in which the survey study ICF was modeled after. Following their completion of the survey, subjects were given a copy of the ICF for their record. The ICF template approved by the IRB at PZMC can be seen from illustration 4.3. To maintain complete anonymity, the survey and ICF were kept separate from each other. While the survey was obtained through various methods, subjects were assured anonymity regardless of ascertainment method. Subjects who were available for in office follow-up visits were left in an examination room to fill out the survey. After completion of the survey, the subject placed the survey into a lock-box as further verification of anonymity. Subjects who returned the survey via mail were able to do so with an

unmarked envelope provided to them at the time their survey was sent. Although these subjects were also asked to return their ICF with the completed survey, the process of separating the ICF and placing the survey into a lock-box remained the same. The survey box and ICF envelope were kept separately and were not filed in any systematic order that would identify the ICF with its respective survey. The surveys were not viewed until closure of the study and the beginning of the data analysis process. The purpose of this anonymity was to encourage subjects to be honest in their responses without fear of how they would be perceived by the research staff. The survey was designed to include past-tense language to hopefully create a clearer picture of what/who/how a subject became involved in the study. Prior to the completion of the practicum, a Thank You letter was submitted to the IRB for expedited approval. Following approval, the letter and a copy of the respective subject's ICF was mailed to them. The letter and ICF copy were only mailed to subjects who did not complete the survey in the office. A template of the IRB approved "Thank You" letter can be seen below in figure 4.1.

Dear [Subject Name],

Thank you for taking part in the patient questionnaire.
Your responses are greatly appreciated and have tremendous value to this project.

Attached is a copy of your informed consent.

We thank you for your time and efforts,

CV Research Staff
Rubina Muzina
Brenda Tapia
Laura Rodriguez
Bhagawathy Sarma
Phong Duong

Figure 4.1

Subject Survey Template

1 I joined the study to get access to better medical care.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

2 I believed my participation made a contribution to science.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

3 By participating, I felt I was gambling with my health.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

4 My family was influential in my decision to participate in a research study.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

5 My family was involved when it came to office visits and other medical appointments.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

6 The staff at my site were knowledgeable about my study.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

7 The staff at my site was friendly during my visits.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

8 The research site I go to is easily accessible.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

9 I appreciated the reminder calls and letters I received from the staff.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

10 I participated in the study to receive free mediciation and treatment.

○ Strongly agree ○ Agree ○ Neutral ○ Disgagree ○ Strongly disagree

11 I joined the study to receive monetary compensation for my time and participation.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

12 My primary physician was supportive of my decision to join the study.

○ Strongly agree ○ Agree ○ Neutral ○ Disagree ○ Strongly disagree

13 I believed I have access to the best doctors.

○ Strongly agree ○ Agree ○ Neutral ○ Disgree ○ Strongly disagree

14 How likely are you to continue your participation in the study?

○ Very likely ○ Likely ○ Neutral ○ Unlikely ○ Very Unlikely

15 How did you first hear about the study?

○ Family member ○ Doctor ○ TV, radio, newspaper, internet ○ Other: _____

Figure 4.2

Patient Survey ICF Template

Introduction: You are cordially invited to participate in a research study. The study will be conducted by a student from UNTHSC interning with the Cardiovascular Research Department at Plaza Medical Center of Fort Worth. The student will be under the mentorship of Dr. Rubina Muzina, MD, MPH.

Study: The study will focus on factors in patient recruitment using answers given by patients already in a cardiovascular study. The study will be measured using questionnaires consisting of questions related to family influence, physician influence, personal health, financial incentives, and questions regarding site where care is received. The goal is to see which factors have a good influence on getting patients into clinical trials. In using the data the hope will be to improve the level of patient recruitment.

Method: After you have given consent, an anonymous survey about factors that have influenced you to participate in clinical research will be mailed to you to complete. You will be given two surveys to complete. The first one will be about why you decided to join a study; the second will be about what kept you in the study. You will be provided a postmarked envelope to mail back. The envelope will not include your return address to further assure your answers are completely anonymous.

Costs/Benefits: No additional costs will be required from you for your participation in the questionnaire. There will not be additional compensation other than the ones you are already receiving per your respective study. The envelopes that will be given to you to return the survey will already postmark.

Alternative: Regardless of your decision to participate, your care and treatment will remain the same.

Participation: Your participation is completely voluntary. You may refuse participation at any time without penalty.

Confidentiality: As part of the method, your return envelope will not include any information that would exclude you individually. Your responses in the questionnaire will be combined in a database with other responses.

Questions: You have the right to any questions regarding the study. If you have any such questions or comments you can contact, Phong Duong or Rubina Muzina, MD, MPH in the CV Research Department.

You will receive a signed copy of this consent document

I, _____ understand and am completely satisfied with the information provided in the above document and acknowledge that I have received a copy of the consent form.

_____ _____

Patient Signature Date

_____ _____

Student Signature Date

_____ _____

Mentor Signature Date

Figure 4.3

CHAPTER V

Sample Demographic

In obtaining a normalized sample size, subjects were surveyed from four ongoing clinical trials at PZMC. The studies are designated by letters A-D to avoid any undue disclosure and identification of study protocol and materials. The subjects from Study A, C, and D have all had cardiac catheter procedures and stent placement. Study B subjects are currently enrolled in a cholesterol lowering medication study. There were 50 subjects from the four studies who were eligible to be surveyed. The eligible subjects were between the ages of 46 years and 92 years with an average age of 71.9 years. There were a total of 35 males and 15 females that were eligible for participation. Study A provided the majority of eligible subjects (70%). In contrast, Study D had only one subject eligible during the period of survey administration. Table 6.1 illustrates a complete distribution of subjects who were eligible to complete the survey. The distribution includes maximum/minimum age, male to female ratio, average age of eligible respondents.

Table 6.1: **Eligible Subjects for Survey Participation**

	Study A	Study B	Study C	Study D	Total
Male	25	6	3	1	35
Female	10	4	1	0	15
Average Age	74 Years	63.6 Years	79.3 Years	51 Years	71.9 Years
Range	41 Years	25 Years	23 Years	0 Years	46 Years
Max	92 Years	71 Years	87 Years	51 Years	92 Years
Min	51 Years	46 Years	64 Years	51 Years	46 Years

Additional inclusionary/exclusionary criteria were not included in the survey study. Subject participation hinged on three things: first the subjects must be enrolled in an open research trial at PZMC; second, the studies must be in the stages of enrollment or follow-ups; and lastly the subjects must complete an ICF before responding to the survey. Table 6.2 displays the distribution of 31 subjects who completed the survey. Average subject age from this distribution pool was 72.7 years with a majority of the respondents being male (71%).

Table 6.2: **Subjects Who Completed the Survey**

	Study A	Study B	Study C	Study D	Total
Male	14	5	2	1	22
Female	5	3	1	0	9
Average Age	75.9 Years	63.6 Years	84.3 Years	51 Years	72.7 Years
Range	30 Years	25 Years	4 Years	0 Years	46 Years
Max	92 Years	78 Years	87 Years	51 Years	92 Years
Min	62 Years	46 Years	83 Years	51 Years	46 Years

Subjects were included in the survey study regardless of race and gender. There were a total of 28 Caucasians, 2 African Americans, and 1 Hispanic that completed the survey. Figure 6.1 depicts a breakdown of the 31 respondents by race and gender.

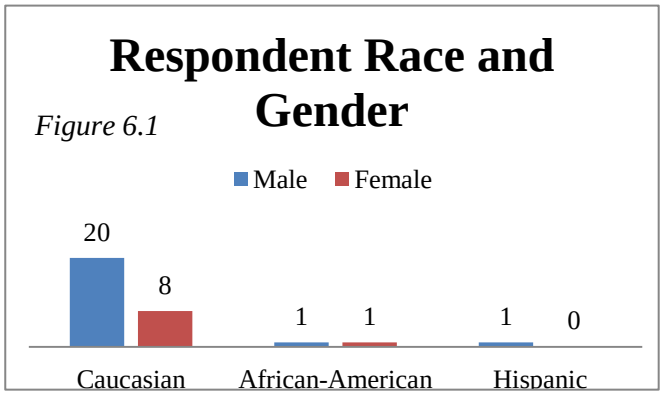

Figure 6.1

The subjects were approached beginning July 18, 2014, following PZMC's IRB approval of the survey study. The period of survey administration lasted until the October 17, 2014. Subjects who were contacted and have signed ICF's during this period were included in the final data analysis. The final sample size to analyze from was 31 subjects.

CHAPTER VI

Data Analysis & Results

Following IRB approval of the survey study, contact information and visit window dates were collected to prepare for data collection. Of the 50 eligible subjects, 36 received a survey either in office or by mail (72% of eligible). There were 3 subjects who declined to participate, all three with varying reasons. One subject felt that being a screen-failure would not have yielded appropriate data. Another subject felt the survey would be too time-consuming. The final subject to decline, did so due to a recent move out of state. One of the eligible subjects was in critical condition and was currently in a nursing care facility during the period of survey administration and contact was not made. Another subject passed away earlier in the year and thus contact was not made. Subjects were given a survey only after initial interest was expressed. Subjects who did not have a window visit date during the eligible administration period were contacted by phone. In total 26 subjects were contacted by phone, with nine unreturned messages despite multiple contact attempts. All of the subjects (15) who had in office follow-up visits completed a survey. As illustrated by table 4.1, the survey return rate across all four studies was quite outstanding.

Survey Distribution

Table 7.1	Study A	Study B	Study C	Study D	Total
Eligible Subjects	35	10	4	1	50
Surveys Administered	23	8	4	1	36
Surveys Returned	19	8	3	1	31
Unreturned Surveys	4	0	1	0	5
Declined	2	1	0	0	3
Unable to Reach	8	1	0	0	9
Critical Care/Decease	2	0	0	0	2

Study B and D had all of the administered surveys returned. The 100% return rate for Study B and D was perhaps a result of the small sample size (n= 11). Although Study C had a small enrollment number, a majority of the subjects (75%) returned the survey. Subjects in Study A (n=19) managed a high return rate (83%) despite the sheer number participants. The overall return rate amongst the four studies was slightly below (86%) the initial goal (90%). Subjects who refused to participate were contacted prior to administration of the survey therefore never received a survey. Every subject who was seen in office for a follow-up visit agreed and completed a survey. The three refusals were done via phone at time of initial subject contact. Two of the subjects who refused are no longer participating in their respective study at PZMC; the third has a pending visit window in 2015. The method of ascertainment was scrutinized to determine if a discrepancy existed. Subjects who completed the survey in office had similar responses to those who had the survey mailed to them. There were slight variations in the overall data between the two groups. Utilizing the associative number outlined in "Design & Methodology", the distribution of subject survey score is illustrated in figure 7.1. The 16 respondents who returned their surveys via mail had a mean score of 47.9 with a standard deviation of 9.5. The maximum score given to any subject in this subset was 62 and the minimum score given was 31. The 15 in-office respondents had a mean of 49.8 with a standard deviation of 7.5. The maximum score for these subjects was 64 and the minimum score was 36. The 31 subjects overall had a mean score (48.9) and standard deviation (8.5) that fell between the values of the separated groups.

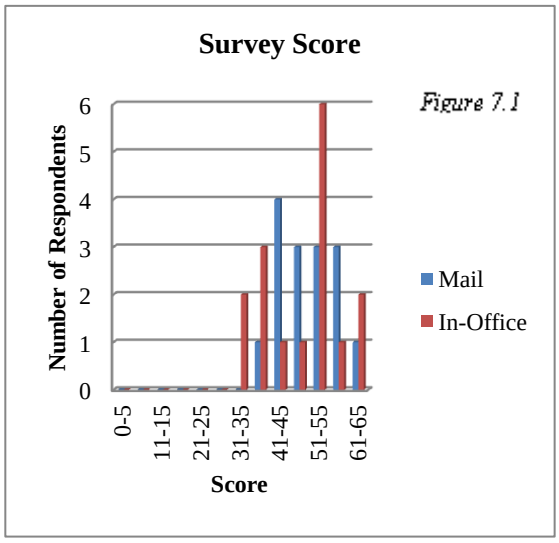

Figure 7.1

Personal Influence

Questions 1, 2, and 3 directed the subjects to respond to how they viewed their participation in a clinical research study. Responses indicated that a majority (74%) of the subjects joined a research study to get access to better medical care (Question 1). An overwhelming majority (87%) disagreed and even strongly disagreed with the idea that by participating in a study, they were gambling with their health (Question 3). Subjects responded rather positively to their role as a contributor to science (90%), with zero respondents in disagreement to this sentiment (Question 2). Neutrality was only present in a small minority (12%) of the overall responses for the three questions posed regarding the personal domain.

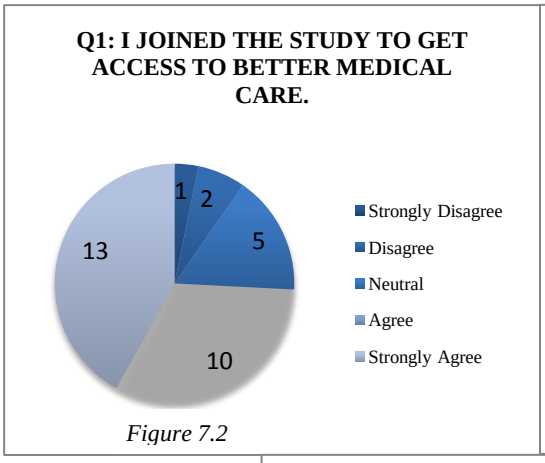

Figure 7.2

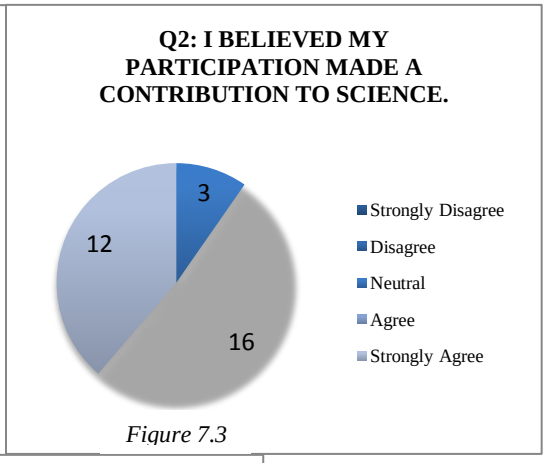

Figure 7.3

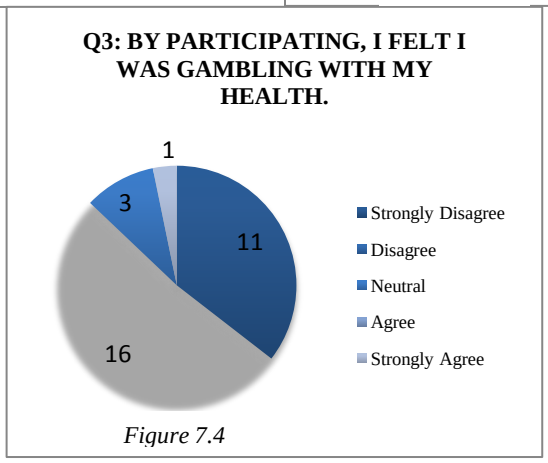

Figure 7.4

Family Influence

When asked about family influence and involvement respondents were seemingly ambivalent. Responses about how impactful family influence was in a subject's decision to join a research study were almost evenly split with only a few neutral responses (19%). There were more patients (42%) who believed their family contributed to their decision compared those who did not believe (39%) that family influence was a factor (Question 4). Family involvement invoked a slightly more skewed distribution (Question 5). Respondents more frequently claimed (68%) that their family was present and involved when they came to the research office for follow-up visits as well as other medical appointments. Of the five domains into which the questions were designated, the family domain had the most "neutral" responses. Between the two questions that were posed to subjects, 16% of the responses did not have patients choosing agree or disagree. In comparing the family influence domain, responses distributed quite evenly among the 5 available response options. The highest majority for any given response between the two questions was only 42%, compared to a majority of 77% in questions regarding the research staff. While family members are not quite as influential in a subject's decision to participate in a research study, many of the subjects have been observed bringing a spouse or child during their office visit.

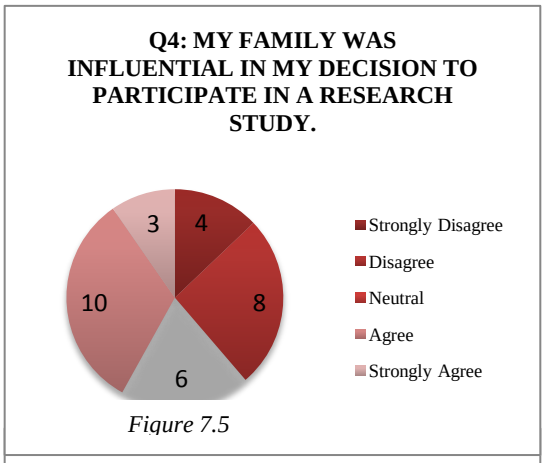

Figure 7.5

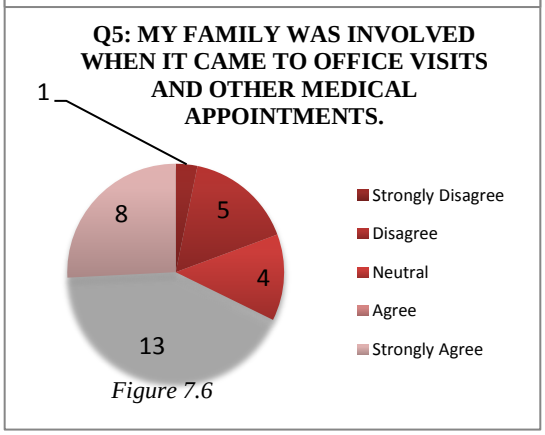

Figure 7.6

Local Research Staff Influence

Inquired about their experiences with the local research staff, respondents were overwhelmingly positive with almost all (98%) of the responders agreeing or strongly agreeing to statements. Of the four questions posed, only 3 of the responders provided a neutral answer. Those three neutral responses were in regards to the accessibility of the research office site (Question 8). Overall the responders did not feel negatively towards any of the 4 questions that were directed at them.

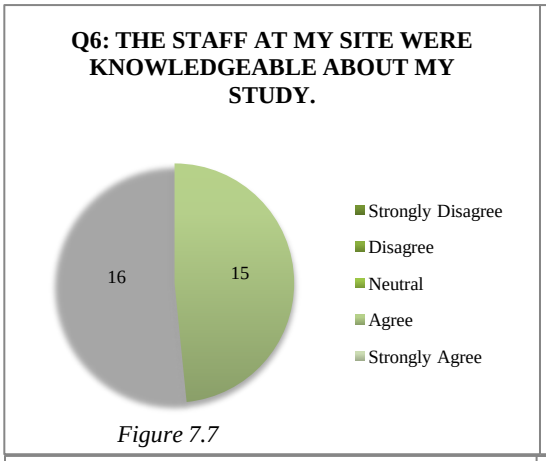

Figure 7.7

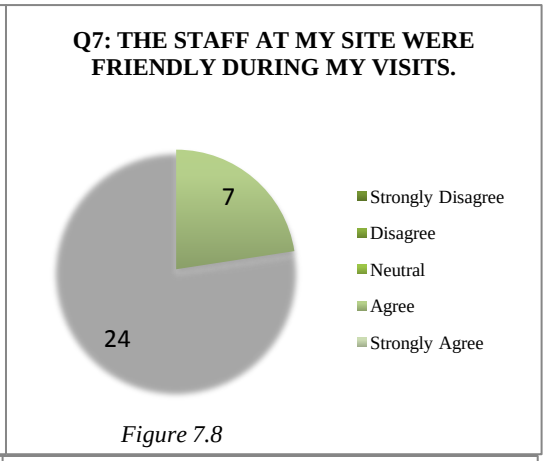

Figure 7.8

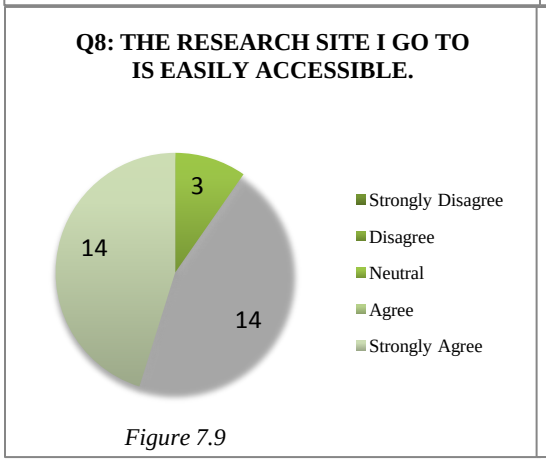

Figure 7.9

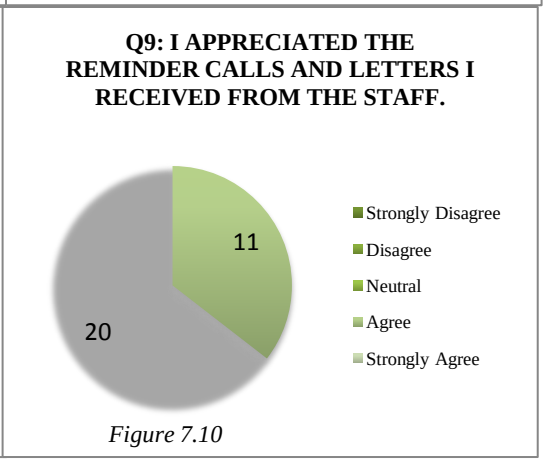

Figure 7.10

All of the respondents were in agreement that the research staff is knowledgeable about the studies (Question 8); more than half (52%) of the respondents strongly agreed to the statement and the remainder (48%) agreeing. A little less than three-quarters (74%) of respondents strongly felt that the research staff is friendly and inviting during follow-up visits in the office

space. One of the duties of a research coordinator consists of calling and sending out reminder letters to a subject when their follow-up visit window is near. Subjects are mailed a letter one week before their target window date to remind them of their follow-up visit. Once the subject calls to coordinate a date and time when they are able to follow-up, it is up to the coordinator to ensure these subjects are reminded by phone one day before their visit date. All of the responders (100%) were in agreement that the reminder calls and letters they receive from the research staff is greatly appreciated. More than half (65%) of the subjects strongly agreed when asked about their appreciation of reminders and the remaining 35% simply agreed. Compared to the other four domains, questions about research staff were the only ones to elicit all positive responses. None of the responders strongly disagreed or even disagreed with statements about the research staff. Each of the three respondents who selected neutral when asked about site accessibility associated their response with an explanation. All three believed that their lack of transportation to the research site for follow-up visits contributed to their neutrality on the matter. Although the attitude was generally positive regarding the research site, a little less than half (45%) of the respondents felt strongly about site access. Unlike other domains, two of the four questions pertained more to subject satisfaction. Question 8 and question 9 were in place to gauge the subject's subsequent contentment after successful recruitment and enrollment in their clinical trial. The responses from this domain have tremendous implications for the research staff. The number one goal for a research site is to enroll as many subjects as possible for a particular study. In keeping subjects satisfied, the line of communication stays open and a level of trust can be established to encourage continued participation. Since the staff becomes the primary safeguard for a subject's overall health during their time in the study, any acknowledged faults can be amended and any praises can be utilized in interactions with future research subjects.

Financial Influence

Contrary to the positive responses regarding the research staff, questions targeted at financial incentives were met rather negatively. A majority of the respondents (71%) disagreed that their participation in a research study were motivated by free medication and treatment (Question 10). Even more subjects (81%) disagreed with the idea that monetary compensation contributed to their decision to join a clinical trial (Question 11).

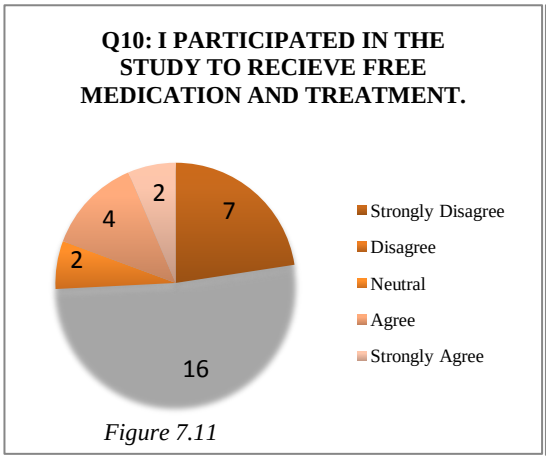

Figure 7.11

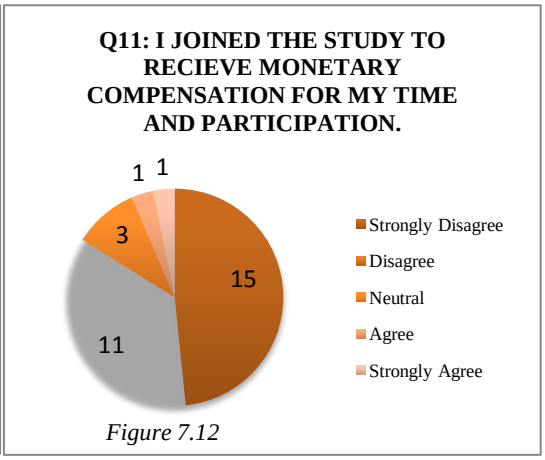

Figure 7.12

Between the four different studies in which data was collected from, only one study (Study B) offered subjects compensation for their time and travel expenses. Study B also provided subjects with vouchers to cover the expenses of the medication associated with their study. Although Study A, C, and D lack monetary incentives, subjects had the cost of their device excluded from the final bill. Subjects in those three studies also had less frequent office visits than those who are participating in Study B. Following hospital discharge, subjects in Study A, C, and D are only required to follow-up annually in office. Any other visits are done via phone. For Study B, subjects are required to attend office follow-ups monthly for the first 6 visits. Following this period, subjects are then limited to bi-monthly visits, then ultimately subjects will only be required to follow-up annually.

Physician Influence

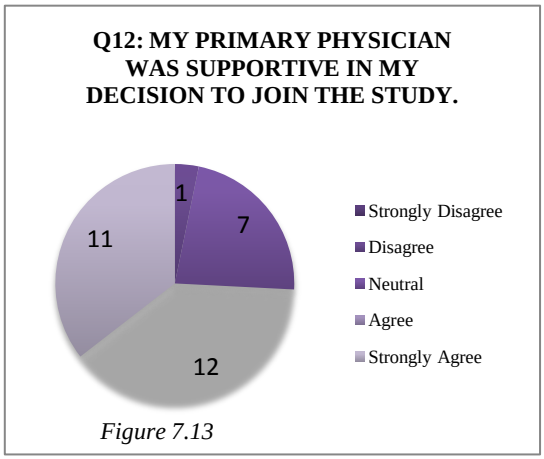

Figure 7.13

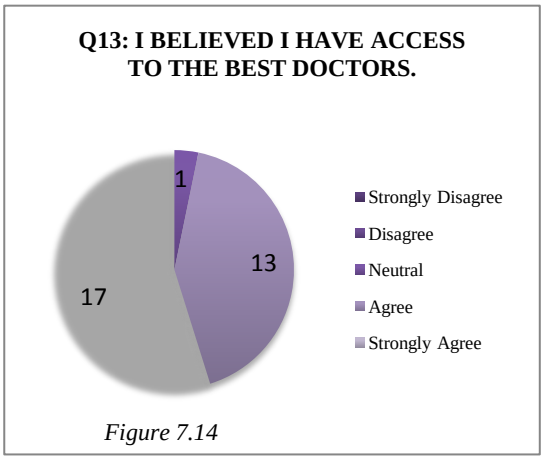

Figure 7.14

Prior to participating in a clinical research study, subjects have previously built a rapport and relationship with PZMC credentialed cardiologists. One of the leading factors that prevent subject enrollment in clinical studies is the distrust of physicians and the research community. In evaluating how subjects feel about their physicians, it becomes of great relevance in preventing laymen distrust of medical personnel. It seems that while distrust remains a major hindrance, the PZMC research staff and team of physicians have successfully combated this. All 31 respondents indicated that they heard about their respective research study from either a physician or by a research coordinator. Questions regarding a subject's network of physicians elicited overall positive responses, similar to that of the local research staff. According to the 31 subjects, almost all of them (97%) believed that by participating in the research study, they have access to the best physicians. The statement did not elicit any negative responses from responders and only one subject felt neutral about the matter. It should be noted that while the subject felt neutral about the superiority of his/her cardiologist, the subject did not feel the research study was a health gamble. A majority of responders (74%) felt their primary care physicians supported their decision to participate in a research study. One subject disagreed with the sentiment while the remaining subjects (23%) provided a neutral response.

Continued Participation

The final aspect of the subject survey also yielded strongly positive responses. With yet another overwhelming majority (90%), respondents indicated they were likely to continue their participation in their respective research study. Although a small minority (7%) responded negatively to the inquiry, the two responses was merely an "unlikely" to continue participation. None of the subjects felt strongly negative about the question. More than 60% of the positive responders indicated a very strongly likelihood of continued participation. The results from the question yielded a distribution similar to that of statements regarding the local research staff. While the ultimate goal of any research study is to retain 100% of their subjects, the respondents who did not respond positively to the question provided an explanation. The subject who remained neutral indicated that transportation could prevent future follow-up visits. The two subjects who responded negatively to the question implicated their advancing age as the issue in preventing continued participation. The subjects felt that the inconvenience of travel associated with physical immobility warranted discontinuation of their participation. Despite the subjects' knowledge regarding the anonymity of the survey, their unsolicited explanation is a great asset to be utilized for future research subjects. A few subjects who managed to respond positively to the question stipulated that their continued participation was dependent on if they survived the next year. While it is difficult to ascertain the level seriousness these subjects' displayed, their advanced age and innumerable health conditions make the statement a serious cause for concern.

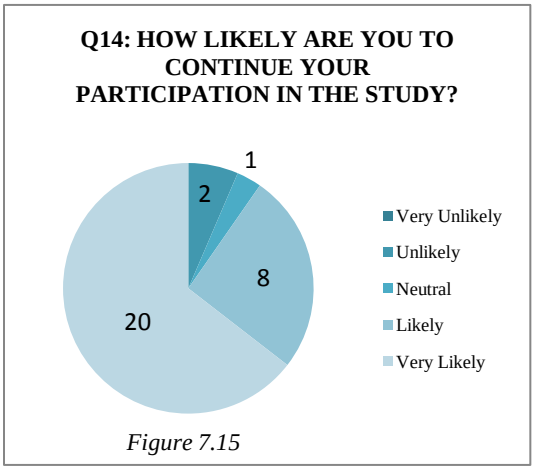

Figure 7.15

Q1: I joined the study to get access to better medical care.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	13	41.94	13	41.94
Agree	10	32.26	23	74.20
Neutral	5	16.13	28	90.33
Disagree	2	6.45	30	96.78
Strongly Disagree	1	3.23	31	100.01

Table 7.2

Chi Square	17.226
DF	4
Pr> ChiSq	0.0017

The relatively small p-value indicates that more subjects than expected responded positively to the sentiment. This implies that the accessibility to better medical care is significantly influences in a subject's decision to join a research study.

Q2: I believed my participation made a contribution to science.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	12	38.71	12	38.71
Agree	16	51.61	28	90.32
Neutral	3	9.68	31	100.00
Disagree	0	0.00	31	100.00
Strongly Disagree	0	0.00	31	100.00

Table 7.3

Chi Square	34.968
DF	4
Pr> ChiSq	<0.0001

According to table 7.3 the idea that a contribution to science was being made has strong impact on a subject's decision to join a research study. The frequency distribution and very small p-value illustrates extreme statistical significance.

Q3: By participating, I felt I was gambling with my health.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	1	3.23	1	3.23
Agree	0	0.00	1	3.23
Neutral	3	9.68	4	12.91
Disagree	16	51.61	20	64.52
Strongly Disagree	11	35.48	31	100.00

Table 7.4

Chi Square	31.419
DF	4
Pr> ChiSq	<0.0001

Similar to the previous question, Question #3 yielded similar significance. The distribution leaned more negatively than expected. While the subjects did not believe that they experienced a health gamble, the small p-value indicates that the sentiment has an impactful influence on participating in a clinical trial

Q4: My family was influential in my decision to participate in a research study.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	3	9.68	3	9.68
Agree	10	32.26	13	41.94
Neutral	6	19.35	19	61.29
Disagree	8	25.81	27	87.10
Strongly Disagree	4	12.90	31	100.00

Table 7.5

Chi Square	5.290
DF	4
Pr> ChiSq	0.2588

Of the 14 questions subjected to chi-square testing, Question #4 yielded the only "not statistically significant". For the most part the distribution frequency yielded similar values to what is expected. There is not enough evidence to suggest that family influence as having any sway on a subject's decision making process.

Q5: My family was involved when it came to office visits and other medical appointments.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	8	25.81	8	25.81
Agree	13	41.94	21	67.75
Neutral	4	12.90	25	80.65
Disagree	5	16.13	30	96.78
Strongly Disagree	1	3.23	31	100.00

Table 7.6

Chi Square	13.355
DF	4
Pr> ChiSq	0.0097

While Question #5 was statistically significant, the strength of significance was not as strong. The rather small p-value implies that unlike family influence, family involvement had a significant influence on a subject's decision to participate in a clinical research study.

Q6: The staff at my site was knowledgeable about my study.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	16	51.61	16	51.61
Agree	15	48.39	31	100.00
Neutral	0	0.00	0	100.00
Disagree	0	0.00	0	100.00
Strongly Disagree	0	0.00	0	100.00

Table 7.7

Chi Square	46.581
DF	4
Pr> ChiSq	<0.0001

Staff knowledge of the subject's research study was extremely significant. The positive responses and very small p-value indicates staff knowledge is quite influential in a subject's decision to participate in a clinical research trial.

Q7: The staff at my site was friendly during my visits.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	24	77.42	24	77.42
Agree	7	22.58	31	100.00
Neutral	0	0.00	0	100.00
Disagree	0	0.00	0	100.00
Strongly Disagree	0	0.00	0	100.00

Table 7.8

Chi Square	69.806
DF	4
Pr> ChiSq	<0.0001

With the largest Chi-Square values and an extremely small p-value, the staff's positive attitude has significant implications in a subject's decision. The p-value is also indicative that the distribution was dramatically more positive than expected.

Q8: The research site I go to is easily accessible.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	14	45.16	14	45.16
Agree	14	45.16	28	90.32
Neutral	3	9.68	31	100.00
Disagree	0	0.00	0	100.00
Strongly Disagree	0	0.00	0	100.00

Table 7.9

Chi Square	33.677
DF	4
Pr> ChiSq	<0.0001

Site accessibility plays a pivotal role in a subject's decision. This is most evident by the small p-value indicating extreme statistical significance. It should also be noted that subjects who provide explanations with their responses mention transportation and accessibility rather vehemently as a hindrance to their participation in a clinical trial.

Q9: I appreciated the reminder calls and letters I received from the staff.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	20	64.52	20	64.52
Agree	11	35.48	31	100.00
Neutral	0	0.00	0	100.00
Disagree	0	0.00	0	100.00
Strongly Disagree	0	0.00	0	100.00

Table 7.10

Chi Square	53.032
DF	4
Pr> ChiSq	<0.0001

Similar to Question #7, the large Chi-Square value and extremely small p-value indicates an extreme level of statistical significance. The staff's reminder calls and letters are of great influence in a subject's continued participation.

Q10: I participated in the study to receive free medication and treatment.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	2	6.45	2	6.45
Agree	4	12.90	6	19.35
Neutral	2	6.45	8	25.80
Disagree	16	51.61	24	77.41
Strongly Disagree	7	22.58	31	99.99

Table 7.11

Chi Square	22.065
DF	4
Pr> ChiSq	0.0002

With one of the higher p-values, Question #10 still possesses an extreme statistical significance. The unexpected distribution heavily favors negative responses. This data favors the majority of the subjects and suggests that free medication and treatment are reasons for participation.

Q11: I joined the study to receive monetary compensation for my time and participation.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	1	3.23	1	3.23
Agree	1	3.23	2	6.46
Neutral	3	9.68	5	16.14
Disagree	11	35.48	16	51.62
Strongly Disagree	15	48.39	31	100.01

Table 7.12

Chi Square	26.581
DF	4
Pr> ChiSq	<0.0001

Much like Question #10, the level of statistical significance indicates that subjects viewed monetary compensation rather negatively. It is with great certainty that the data suggests that monetary compensation is not influential in a subject's clinical trial participation.

Q12: My primary physician was supportive of my decision to join the study.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	11	35.48	11	35.48
Agree	12	38.71	23	74.19
Neutral	7	22.58	30	96.77
Disagree	1	3.23	31	100.00
Strongly Disagree	0	0.00	31	100.00

Table 7.13

Chi Square	19.806
DF	4
Pr> ChiSq	0.0005

The small p-value indicates that a subject's primary care physician's support was statistically significant enough to influence their decision.

Q13: I believed I have access to the best doctors.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	17	54.84	17	54.84
Agree	13	41.94	30	96.78
Neutral	1	3.23	31	100.01
Disagree	0	0.00	31	100.01
Strongly Disagree	0	0.00	31	100.01

Figure 7.14

Chi Square	43.032
DF	4
Pr> ChiSq	<0.0001

With overwhelmingly positive responses, subjects felt that they had access to the best doctors. The very small p-value indicates that the data is statistically significant enough to attribute as an influence in the subject decision making process.

Q14: How likely are you to continue your participation in the study?				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	20	64.52	20	64.52
Agree	8	25.81	28	90.33
Neutral	1	3.23	29	93.56
Disagree	2	6.45	31	100.01
Strongly Disagree	0	0.00	31	100.01

Figure 7.15

Chi Square	44.645
DF	4
Pr> ChiSq	<0.0001

The results from Question 14 were of extreme statistical significance. The data implies that a subject's decision to continue participation was made retroactively when they agreed to enroll in a research study.

Tables 7.2-7.15 provide a frequency distribution of the responses with respect to each individual statement/question posed. The tables utilized the Chi-square method for testing the appropriate influence of each statement. With the exception of Question # 4, all of the results were found to be either very statistically significant or extremely statistically significant. In stratifying the questions by their respective domain, an overall Chi-Square test was performed. The data yielded Chi-Square values of 11.355 (Personal Influence), 14.129 (Family Influence), 186.242 (Research Staff influence), 40.581 (Financial Influence), and 56.871(Physician Influence). The values were tested under the following parameters: **α=0.05** with **four** degrees of freedom.

CHAPTER VII

Significance of the Practicum Project

The National Vital Statistics Reports presented final mortality data in 2010 that implicates diseases of the heart as the leading cause of death in the US[3]. The Center for Disease Control and Prevention (CDC) strengthened this finding with reports that 1 in every 3 deaths in the US is attributed to cardiovascular disease (CVD) [3]. It is estimated that the lifetime risk for a forty-year old developing CVD is approximately 50% in men and 32% in women[1]. To further emphasize the brevity of CVD, the CDC reported that this leading cause of mortality in Americans have had historical significance since 1935[3].

Not only are those statistics alarming, the economic impact heart disease has on the nation is quite extravagant. CVD has been implicated as the mostly disease in the US[10]. It is estimated that the annual direct and overall costs resulting from CVD are estimated to be between $273 billion and $444 billion[3]. The American Heart Association (AHA) predicts that within the next 20 years, CVD costs are estimated to triple[1].

CVD diagnoses and admissions have become the leading listed diagnosis in emergency rooms, with an increase of more than 30% since 1979[1]. Although advancing age has been suspected of contributing to CVD, there have been dramatic declines in age-related mortality from CVD[1]. This certainly bodes well for reducing the burden of CVD; however, costly prevention procedures and diagnostics continue to unravel the achievements made towards CVD management. It was estimated that from 1979-2003 total inpatient operations and procedures

increased by more than 470%[1]. Cardiac catheterization procedures alone saw a spike of more than 370%[1].

The growing burden of CVD creates a demand for the relevance of cardiovascular clinical research. The International Classification of Diseases considers the following conditions as components of CVD: ischemic heart diseases, pulmonary heart disease, strokes, and diseases of arteries, arterioles and capillaries[10]. One of the leading causes of CVD stems from uncontrolled LDL-C. The American Heart Association describes LDL-C as the "bad" form of cholesterol. It is a major contributor to the development and growth of atherosclerotic plaques on arteries and can subsequently lead to myocardial ischemia and infarcts. Uncontrolled LDL-C levels were established by the National Cholesterol Education Program (NCEP) as being low (<100mg/dL), intermediate (<130mg/dL), and high risk (<160mg/dL) [3]. The NCEP also deemed this designation useful as LDL-C was the main target of lipid-lowering therapy. The Lipid Research Clinics Prevalence Study found that CVD death rates increased with higher plasma concentrations of total and LDL-C[16]. In combating this ailment, a number of clinical trials involving LDL-lowering therapies have had resounding benefits[16]. These therapies lower LDL-C and raise high-density lipoprotein (HDL)[16]. In evaluating a patient's lipid profile, it was also noted that there was a dramatic improvement in the LDL phenotype from the more atherogenic small dense LDL particles to the more buoyant, less atherogenic particles[16].

As of October 13, 2013 PZMC began enrolling subjects for a drug study that aims to examine the efficacy of an LDL lowering medication on top of a current Statin regiment. The study drug works by blocking the action of the PCSK9 protein[7]. PCSK9 is involved in the body's natural process of controlling the amount of cholesterol that circulates in the blood[7]. The PCSK9 protein achieves this goal by decreasing the rate at which cholesterol, specifically LDL-C, is

removed from the bloodstream. Individuals with hypercholesteremia have been seen to have excessive PCSK9 activity[7]. In blocking its activity, research has found that more LDL-C can be removed from the bloodstream, benefitting those with high cholesterol[7]. The study is currently still in the process of subject enrollment. This study was designated as Study A for the purpose of the practicum report. The subjects enrolled at PZMC will add to existing data that can assist clinicians in providing effective therapies for controlling LDL-C. The study has approximately 5,000 patients that have been enrolled and randomized worldwide. These patients will be closely monitored for five years, beginning with monthly visits and ending with a period of annual visits. The subjects from this study will only be enrolled in the study following an ACS event that led to their hospitalization.

Another study currently in its enrollment stage is a bare-metal stent study (Study D). The stent system is indicated for improving coronary obstructions in patients with ischemic heart disease. The study enrolls subjects who have very small atherosclerotic lesions (between 2.5-4.0mm in diameter) [4]. The bare-metal stent utilizes a state of the art polymer blend that hopes to prevent vessel damage and future plaque build-up. Subjects from this study will also be monitored for five years. The Cardiovascular Research Institute at the University of California in San Francisco states "the best opportunities for scientific progress lie in understanding the detailed mechanisms of cardiovascular disease at the molecular level and applying this understanding to develop and implement new strategies for its prevention and treatment."[2]

As of October 2014, there were more than 2700 ongoing clinical research studies dealing with CVD in the US. This is not accounting for the recently closed studies or studies that are in the pending approval stage[21]. The significance of the practicum report was to examine and correlate the subject survey with factors that will improve recruitment in clinical trials. The

primary endpoint of administering the questionnaire is to examine which factors have a positive influence on recruiting subjects to participate in clinical trials. The goal of the project is to improve the level of subject recruitment and analyze factors that will subsequently impact attrition. Subjects in clinical trials are still treated by an interventional cardiologist, but the research staff also plays a central role in safeguarding the subject's health. It is the research staff that these subjects communicate with regularly. Subject office visits are conducted in the confines of the office, reminder phone calls for follow-ups are done by the office staff, and medication dispensations are completed in the office.

Important feedback on the performance of the research staff is necessary in order to better serve the research subjects and improve the conduction of clinical research trials. In away, portions of the survey can even be viewed as a satisfaction questionnaire. The survey study conducted within the research department at PZMC is the first of its kind. In the previous year, a research study was conducted to evaluate the retention process of research subjects at PZMC. The project implemented a system of reminder letters and phone calls that have proved to be quite successful in retention efforts. Subjects have insisted that the calls and letters have been very appreciative. So while research retention studies are pivotal to the overall health of clinical research trials at the later stages, analysis of recruitment issues are much more pressing.

Many clinical research proponents have implicated recruitment as the leading cause of failed clinical research. Recruitment provides clinical research with subjects to monitor and retain. There is substantial revenue available to PZMC and its physicians from conducting clinical research trials. More importantly, the value of a study can have resounding effects on subject's life. They have access to the newest available care, they are afforded an extra set of eyes in the research staff to closely monitor their health, and they are at the forefront as pioneers

of science. Proper recruitment has provided the subjects with theses amenities. Proper recruitment has provided PZMC and its cardiologists with the highest of recognition. The practicum has value in evaluating the steps necessary to continue this excellence.

CHAPTER VIII

Limitations of the Study

Limitation Due to Time

Due to the short length of the internship, time was a major hindrance to the data collection process. There was only three months available to administer the survey to study subjects. Some of the subjects had to be contacted via phone multiple times before a survey was returned. There were a total of 15 eligible subjects that did not have surveys administered to them. With more time, more contact attempts could be made. While there were a few refusals, all of the subjects who appeared in the office for their follow-up visit completed the survey. Many of the 15 eligible subjects will not have their office visits until much later in the year and even the beginning of 2015. The IRB approval process did not allow survey administration until one month into the internship. PZMC's IRB constitutes that any patient contact must be subjected to a full board review. The full board reviews are scheduled to be held monthly, given that quorum is met. Contact with the research subjects did not begin until after July 18th, 2014. At this point many of the subjects have already had their follow-up visit.

Limitation Due to Methodology

Subjects who were contacted via phone to participate in the study were mailed a survey and ICF to complete. After two weeks, the subjects received a follow-up phone call, many of these subjects indicated that they did not receive a survey or had misplaced their previous one.

Two subjects returned surveys but did not include their ICF. Subsequent contact to obtain the ICF's were unsuccessful and their surveys to had to be disposed.

Limitation Due to Sample Demographic

Eligible subjects' advanced age made contact quite difficult. There were a total of eight unreturned messages; all eight messages were left with the subjects' family member. Following the initial contact, contact was unsuccessful in subsequent attempts. During an attempt to contact one subject, a family member informed the study coordinator that the subject had passed away months ago. Another subject was being cared for at critical care facility and unable to participate.

Limitation Due to Design

While the PZMC research department has seven ongoing studies, only four were considered open studies. To allow for a standardize sample, surveys were only made available to those who currently in an open study. This meant the study must either be enrolling or in the follow-up phases of the clinical trial process.

CHAPTER IX

Discussion & Conclusion

The Chi-Square values lead to a rejection of the null hypothesis (There is no association between factors and their influence on clinical trial participation). Data collected during the project indicates that there are indeed influences that impact a subject's decision to participate in a research study. While the strength of these influences cannot be statistically determined, the subjects' agreement and disagreement can provide some conclusions. The modalities that seem to have the most impact seem to be that of the local research staff. This seems rather counterintuitive; however, because the research staff has had contact with a subject prior to the ICF process, it would seem to make complete sense. Prior to signing the ICF and agreeing to participate in the study, subjects are given a complete and in-depth breakdown of the study. The research staff is also made available to answer any questions or concerns. This process seems to be of great influence, given that every respondent answered positively to the question regarding the staff's knowledge of their research study. This can lead to the formation of a trusting relationship that eases the subjects into making that decision to participate. On the contrary, influences of a family member was not at all significant in the decision making process. However, when associated with the presence of a family member during office visits and other medical appointments, the data revealed statistical significance.

CHAPTER X

General Internship Experience

This internship was conducted in the CV research department at Plaza Medical Center of Fort Worth The office is located in the medical professional building adjacent to the main hospital. While a majority of the time is spent in the office, there are studies that require the research staff to conduct their work in the hospital catheter lab. There are currently three research coordinators (Laura, Brenda and Bhagawathy) working under the tutelage of Dr. Rubina Muzina. Along with her many years of research experience, Dr. Muzina brings an array of clinical knowledge from her time as an infectious disease physician in Europe. The experiences of the internship began with getting accustomed to the intricacies of the office space. Following the first few days of orientation, an in-depth review of study protocols was required. From there, meetings were set with the local IRB coordinator to provide an exposure to federal regulations pertaining to clinical research. The time was also utilized to provide an introduction to local IRB policies regarding new and current studies. Reviewing the IRB process was not only crucial in assisting the research staff with their duties but it was pivotal for the success and subsequent approval of the practicum project. Other important tasks required training in current and new study protocols, inclusion/exclusion criteria, adverse events (AE)/serious adverse events (SAE), and electronic databases. The day-to-day tasks included assisting study coordinators with the screening and enrollment process for the open studies. Most weeks included multiple patient follow-up visits. Depending on the study, follow-up visits usually consisted of a physical exam

performed by a cardiology fellow, a blood draw, medication list updates, and discussion of overall health. As previously mentioned, the subjects that are entering clinical research studies are current patients of a group of interventional cardiologists at the Heart Center of North Texas. In assisting the coordinators with screening theses patients, regular correspondence was made with the medical records department to obtain relevant medical history. During the internship period beginning in June of 2014, two new studies had been approved by the local IRB and one study was preparing for final site closure. This provided valuable insight to virtually the entire process a clinical research study, from its opening, to its enrollment process, to the follow-up phase, and finally to its close-out. A number of the studies in the department had regular monitor visits which provided an overview into the corporate aspect of a clinical research study. While performing the daily duties assigned by the Dr. Muzina and the research coordinators, survey preparation and administration during the early parts of the internship experience was extremely pertinent to the success of the project. Although the regulatory protocols require Dr. Muzina and staff to spend a majority of their days under piles of documents and data entry, the most important task performed is the safeguarding of the research patient's health. The experience has been an invaluable educational journey since day one. Through the work performed with the research staff at PZMC, a paradigm of proper clinical trial conduction has certainly been shaped.

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Appendix A

June 2-12, 2014

a. Plaza Medical Center HR orientation.
b. Preparing for the required NIH Human Subject Protection Certificate required by Plaza IRB.
c. Brain storming for research ideas regarding the topic of the internship.

June 13, 2014

a. Overview of Improve-It study protocol, inclusion-exclusion criteria, AE/SAE, study follow-up visits, medications with research supervisor.
b. Assisted in answering queries regarding three subjects in Improve-It study.
c. Overview of Supernova study protocol and the visits.
d. Assisted in updating a patient's AE description in Supernova study.
e. Worked on researching background literature for thesis proposal.
f. Worked on IRB approval for project.
g. Observed first patient encounter in Odyssey study.
    a. Training for proper injection method;
    b. Observed medication's injection method;
h. Worked on project proposal for submission to Plaza IRB
i. Discussed plan for following week.

Student _____ Date _____

Mentor_____ Date_____

June 16, 2014

a. Completed entering the Odyssey study window dates in Excel through the completion of study.
b. Entered the reminder call dates for Odyssey and Canopy study into the shared calendar.
c. Researched sources for proposal.
d. Read and outlined sources for proposal.
e. Continued to work on proposal.

June 17, 2014

a. Filed screening pages 1-4 for subject binder 8-22 in the Odyssey study.
b. Assisted in screening patients for Odyssey study from cath lab schedule.
c. Assisted on performing follow-up phone calls for Improve-It:
    a. Updated all paperwork related to it.
d. Typed out letter reminder letters for patient visits.
e. Mailed out 2 year visit reminders for Canopy study.
f. Observed SAE submission process to IRB
g. Updated calendar for the completed visits.
h. Worked on proposal.

June 18, 2014

a. Updated CV's and Medical Licenses for the physicians in the preparation for the monitor visits.
b. Assisted on preparation of the submission of a patient's AE for Improve-It study.
c. Assisted in screening patients for Odyssey study from cath lab schedule.
d. Miscellaneous filing.
e. Organized desk and shelf.
f. Made a unified physician directory.
g. Brainstormed for proposal.

June 19, 2014

a. Assisted in screening cath lab schedule for the possible subjects for different studies.
b. Assisted in screening patients for Odyssey study from cath lab schedule.
c. Assisted IRB coordinator with binders and delivery for upcoming IRB meeting.
d. Researched more details for proposal.
e. Removed Patient Identified Information for a patient in First Study.

June 20, 2014

a. Assisted on screening cath lab schedule for possible subjects for different studies.
b. Assisted in screening patients for Odyssey study from cath lab schedule.
c. Researched proposal.
d. Assisted on follow-up calls for Improve-It.
e. Assisted in entered data on Inform for the final follow-up of two Improve-It patients.
f. Worked on proposal.

Student _____ Date_____
Mentor_____ Date _____

June 23, 2014

a. Discussed the committee meeting and created a general plan of attack.
b. Assisted in screening patients for Odyssey study using cath lab schedule.
c. Assisted in reminder phone calls for patient 001 and 002 in the Canopy study
d. Assisted in coordinating UPS/DHL pick-ups for the office.

June 24, 2014

a. Worked on proposal
b. Finalized plans for the committee meeting
c. Assisted in screening patients for Odyssey study using cath lab schedule.

June 25, 2014

a. Discussed local IRB protocol for new and ongoing studies with IRB Coordinator.
b. Prepared folders and presentation for committee meeting,
c. Observed the initial qualifying visit for a new patient in the Odyssey study.
d. Coordinated committee scheduled to set up a defense date

June 26, 2014

a. Finished preparation for committee meeting.
b. Assisted in general tech support for the office.
c. Discussed ways to improve employee and subject satisfaction.
d. Committee meeting.
e. Discussed the general outline of the patient survey with Dr. Muzina.
f. Reviewed the studies and created a timeline for data collection.

June 27, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Retrieved patient information from the Heart Center for visit scheduling phone calls.
c. Assisted in updating patient medication dispensation database
d. Assisted in documenting protocol deviation to sponsor and local IRB
e. Updated the local Odyssey screen fail database.
f. Updated the sponsor screen fail database.
g. Worked on revamping patient questionnaire for research project.

Student _____ Date _____

Mentor_____ Date_____

June 30, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule
b. Assisted in updating sponsor screen fail database for Odyssey study
c. Worked on patient questionnaire using peer reviews and other literature
d. Retrieved patient information from Heart Center for possible inclusion in Odyssey study Assisted in a patient follow up for First study
e. Assisted in requesting patient information following patient follow up

July 3, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule
b. Assisted in updating sponsor screen fail database for Odyssey study
c. Called Harris-Cleburne to request normal lab values for spreadsheet
d. Compiled and updated normal lab values for other facilities
e. Finalized project proposal and completed all required documents to submit to IRB coordinator
f. Office Party!

Student _____ Date_____

Mentor _____Date_____

July 7, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in entering patient AEs for First study.
d. Assisted in entering patient medications for First study.
e. Assisted in scheduling patient's 2yr office visits for Canopy study.
f. Created a spreadsheet to determine data collection dates for patients in Odyssey and Canopy study.

July 8, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in entering new data for Improve-It study provided by CRO.
d. Observed a patient 2yr follow-up visit.
e. Called Texas Health Harris Cleburne to request medical records for a patient AE who is in the Canopy study.
f. Requested medical records from Heart Center for a patient AE.

July 9, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Observed a patient screening visit.
d. Assisted in centrifuging and collecting blood serum for a potential patient in Odyssey study.
e. Arranged for UPS pick-up to return serum to Covance headquarters.
f. Assisted in creating a new SUSAR cover letter for Odyssey study.
g. Assisted in updating IRB SUSAR submission log.
h. Assisted in reporting a Canopy patient's AE to local IRB.

July 10, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Created an updated spreadsheet for screen-fail for Dr. Doan from HCNT-Weatherford.
d. Called to retrieve medical records for patients that potentially qualify for the Odyssey study.
e. Assisted in documenting medications that were to be quarantined following a deviation of temperature in fridge storage.
f. Assisted in verifying that a new shipment of stents was correct.

July 11, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Worked on thesis proposal for review by committee.
d. Assisted in verifying treatment numbers for quarantined medication.
e. Reviewed and completed a SUSAR memo for local IRB

Student _____ Date_____
Mentor_____ Date _____

July 14, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Created an IRB cover letter for a SUSAR from the Odyssey study.
d. Observed a patient's screening visit.
e. Assisted in entering a patient's screening visit into Odyssey database

July 15, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Requested medical records from Baylor All Saints to complete a patient's screening visit data entry.
d. Observed a patient visit for possible inclusion in the Odyssey study.
e. Assisted in preparing the required documents for a site initiation visit regarding a new stent study.

July 16, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in centrifuging and collecting blood serum for a patient's lab work.
d. Arranged a UPS pick-up for lab work.
e. Followed-up on a medical records request from the previous day

July 17, 2104

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in completing a 2-year visit data entry after receiving medical records.
d. Assisted in completing an Appendix 9: Annual Review for IRB submission

July 18, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in completing an Appendix 7 for IRB submission.
d. Observed a site initiation visit and training.
e. Assisted in preparing area for new study coordinator.

Student _____ Date_____
Mentor_____ Date _____

July 21, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Received confirmation from IRB coordinator regarding project approval.
d. Organized IRB approved informed consent and patient survey to be sent out to interested subjects.
e. Observed a Canopy patient's 2 year visit.
f. Assisted in centrifuging and transfering blood work to be sent to sponsor.
g. Coordinated a UPS pick up.

July 22, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Observed an Odyssey subject's 4 month visit.
d. Discussed details of project with subject.
e. Obtained informed consent from subject.
f. Assisted in centrifuging and transfering blood work to be sent to sponsor.
g. Coordinated a UPS pick up.
h. Entered "injection phone call reminders" for Odyssey patients into research calendar up to end of study.

July 23, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Observed an Odyssey subject's randomization visit
d. Assisted in centrifuging and transferring blood work to be sent to sponsor.
e. Coordinated a UPS pick up.
f. Assisted in calling Canopy patients to regarding the patient survey.
g. Organized and sent out survey and informed consent to subjects who have expressed interest in participating.
h. Observed an Odyssey subject's 4 month visit

July 24, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Observed a patient's initial visit for the Odyssey study.
d. Organized Odyssey subject binders to include source documents up to 1 year.
e. Created labels for Odyssey patients regarding future blood pressure measurements.
f. Assisted in creating an appendix 7 and 10 for IRB review regarding a Spanish translated informed consent.

July 25, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.

Student _____ Date_____
Mentor_____ Date _____

July 28, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Observed an Odyssey patient's randomization visit.
d. Explained and administered patient questionnaire.
e. Received and organized completed patient surveys

July 29, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in calling Supernova patients regarding patient survey.
d. Prepared and mailed questionnaire and ICF to Supernova patients
e. Prepared and mailed reminder letters to Canopy patients with upcoming 2 year visit windows.

July 30, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in retrieving and filing updated IRB correspondence for Cobra Study.
d. Briefly reviewed Dance study protocol.

July 31, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Observed an Odyssey patient's screening visit.
d. Assisted in screening patients for CMS coverage using cath lab schedule.
e. Further reviewed carotid screening process with study coordinator.

August 1, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Reviewed submission process of a new study protocol with research supervisor.
d. Assisted in filing Board Action documents into their respective study binders.

Student _____ Date_____
Mentor_____ Date _____

August 4, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in scheduling a UPS pick up for serum return to central labs.
d. Redacted PHI from a patient's source documents for SAE documentation.

August 5, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Redacted PHI from a patient's source documents for SAE documentation.
d. Assisted in organizing patient binders for the Odyssey study.

August 6, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in retrieving and filing updated IRB correspondence for Cobra Study.
d. Assisted in preparing SAE for a patient in the Odyssey study.

August 7, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Redacted PHI from a patient's source documents for SAE documentation

August 8, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in preparing source documents for two upcoming studies.
d. Created a new filing cabinet for screen-failed patients in the Odyssey study.

Student _____ Date_____
Mentor_____ Date _____

August 11, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Scheduled a UPS pick up for serum return to central lab.
d. Assisted in creating source documents for the Cobra study.

August 12, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Continued assisting with source documents for the Cobra study.
d. Scheduled a UPS pick up for serum return to central lab.

August 13, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Organized study shelves to make room for new study binders.
d. Assisted in logging injection kits into the regulatory binder for Odyssey.
e. Discussed and administered project questionnaire to an Odyssey patient.

August 14, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Discussed and administered project questionnaire to an Odyssey patient.
d. Prepared boxes for storing closed studies.
e. Reviewed storage protocol with supervisor and coordinators.

August 15, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Documented and prepped study binders to be sent to storage.

Student _____ Date_____
Mentor_____ Date _____

August 18, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Scheduled a UPS pick up for serum return to central lab.
d. Assisted in loading storage boxes for materials department.
e. Administered patient questionnaires for two patients.
f. Prepared a certified letter following 2 phone call attempts for a Canopy 2 year follow up.

August 19, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Scheduled a UPS pick up for serum return to central lab.
d. Assisted in following-up with 2 patients from Supernova study regarding patient questionnaire.

August 20, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted study coordinator in reviewing an Odyssey patient's medication list.
d. Assisted in entering a month 1 visit in the EDC.

August 21, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in finalizing subject binders for the Cobra study.

August 22, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Reviewed inclusion/exclusion criteria for Cobra study with study coordinator
d. Assisted in screening patients for Cobra study using cath lab schedule
e. Completed subject binders for Cobra study in preparation of patient enrollment.

Student _____ Date_____
Mentor_____ Date _____

August 25, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Assisted in the informed consent process for Cobra.
e. Observed procedures in the cath lab with principal investigator.

August 26, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Scheduled a UPS pick up for serum return to central lab.
d. Assisted in screening process for potential Cobra patients.
e. Prepared index event lab work and EKG folder for physician signatures.

August 27, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Requested medical records from local hospitals for patient SAE's.
d. Followed up on medical record requests.

August 28, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Assisted in the informed consent process for Cobra.
e. Observed procedures in the cath lab with principal investigator.

August 29, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Observed procedures in the cath lab with principal investigator.

Student _____ Date_____
Mentor_____ Date _____

September 2, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Logged IRB submissions and submitted all pertinent documents to IRB coordinator.

September 3, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Requested medical records from the Heart Center of North Texas, regarding potential patients for the Cobra study.

September 4, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Redacted patient PHI for a patient in the Cobra study.
d. Falls Prevention education with site mentor and study coordinators.

September 5, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening patients for Cobra using cath lab schedule.
d. Reviewed Cobra's online data entry process with study coordinator.
e. Created a patient thank you letter for IRB approval (Questionnaire project).

Student _____ Date_____
Mentor_____ Date _____

September 8, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Logged IRB submissions and submitted all pertinent documents to IRB coordinator.

September 9, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Logged IRB submissions and submitted all pertinent documents to IRB coordinator.

September 11, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening patients for Cobra using cath lab schedule.
d. Administered patient questionnaire.

September 12, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening patients for Cobra using cath lab schedule.
d. Observed procedures in the cath lab
e. Assisted in calling additional patients in the canopy study for questionnaire.
f. Prepared questionnaires to be mailed out.

Student _____ Date_____
Mentor_____ Date _____

September 15, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Prepared questionnaire to be mailed out.
e. Scheduled a UPS pick-up to be returned to central lab.

September 16, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Requested medical records from the Heart Center of North Texas, regarding potential patients for the Cobra study.
d. Attended cath lab nurse's in-service training for Cobra.

September 17, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Redacted patient PHI for a patient in the Cobra study.
d. Requested medical records for potential Cora patients.
e. Prepared documents for a monitor visit from Cobra study's CRA.

September 18, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening patients for Cobra using cath lab schedule.
d. Observed a Cobra consultation with a potential patient.
e. Observed procedure in the cath lab.

September 19, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening patients for Cobra using cath lab schedule.
d. Observed procedure in the cath lab.

Student _____ Date_____
Mentor_____ Date _____

September 22, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Scheduled a UPS pick-up to be returned to central lab.
e. Assisted in follow-up phone calls regarding questionnaire.

September 23, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Requested medical records from the Heart Center of North Texas, regarding potential patients for the Cobra study.
d. Updated data collection spreadsheet.
e. Assisted in organizing office space.
f. Updated patient binders with source documents from Odyssey study.
g. Redacted patient PHI for a patient in the Cobra study.

September 24, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Requested medical records for potential Odyssey patients from the Heart Center.
d. Restocked and completed all patient binders with source documents from the Cobra study.
e. Observed a conference call from Odyssey Sponsors.

September 25, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening patients for Cobra using cath lab schedule.

September 26, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Attended IRB meeting with IRB coordinator.

Student _____ Date_____
Mentor_____ Date _____

September 29, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.

September 30, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Requested medical records from the Heart Center of North Texas, regarding potential patients for the Cobra study.
d. Acquired final patient questionnaire

October 1, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assessed computers for encryption technology.
d. Assisted supervisor in encrypting and burning CMS files for carotid patients.

October 2, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening patients for Cobra using cath lab schedule.
d. Attended IRB meeting with IRB coordinator.

October 3, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.

Student _____ Date_____
Mentor_____ Date _____

October 6, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Observed a procedure in the Cath lab.
e. Began assembling sections for thesis.

October 7, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Worked on practicum report introduction

October 8, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Began data analysis process.
d. Reviewed significance testing with research mentor.

October 9, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening patients for Cobra using cath lab schedule.
d. Assisted in Cobra enrollment process with study coordinators.
e. Assisted in entering mandatory lab work for Cobra patient.

October 10, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Met with major professor to discuss data analysis
d. Worked on practicum report.

Student _____ Date_____
Mentor_____ Date _____

October 13, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted in screening process for potential Cobra patients.
d. Worked on "Design and Methodology" section of practicum report.

October 14, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Worked on "Data Analysis" section of practicum report.
d. Discussed infection control within the office space with coordinators and mentor.
e. Verified receipt of IRB documents.

October 15, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Worked on "Sample Profile" and "Design & Methodology" section of practicum.
d. Observed monthly research meeting with Director.

October 16, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Assisted coordinators and supervisor in locating and organizing regulatory binders for a monitor visit.

October 17, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Met with major professor to discuss the progress of the practicum report
d. Worked on practicum report.

Student _____ Date_____
Mentor_____ Date _____

October 20, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Worked on practicum report.

October 21, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Worked on practicum report.

October 22, 2014

a. Worked on practicum report
b. Discussed edits with major professor and site mentor.

October 23, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Began editing practicum report.

October 24, 2014

a. Assisted in screening patients for Odyssey study using cath lab schedule.
b. Assisted in updating sponsor screen fail database for Odyssey study.
c. Worked on editing practicum report.

Student _____ Date_____
Mentor_____ Date _____