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**Introduction:** The Internet can be an efficient resource for research departments to utilize. Because of this, an Internet portal was created for the research department under the current Plaza Medical Center of Fort Worth's website. The portal is expected to educate current research patients and the general public, support patient involvement in their medical care, encourage patient communication, and improve the overall outcomes for the studies taking place. **Objective:** The main goal of this practicum project is to determine the effectiveness of the research portal in educating patients. **Method:** An online research portal and patient questionnaire was created in order to complete the project. The surveys were administered to current research patients, and the answers were analyzed using the chi-square method, including the Mantel-Haenszel chi-square test. **Results:** The data analysis determined that the research portal was effective in increasing patient knowledge, as well as patient involvement in their medical care and communication with others. It was also decided that the portal is viewed as an accurate source of information. Additionally, demographical factors were analyzed, and it was determined that estimated annual household income does effect the way some patients answered a few of the questions. **Conclusion:** The portal is an effective method for the research department to utilize, although there are a few improvements that can be made.

INCREASING KNOWLEDGE OF PATIENTS IN CLINICAL TRIALS  
THROUGH NEW MEANS OF COMMUNICATION

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INCREASING KNOWLEDGE OF PATIENTS IN CLINICAL TRIALS  
THROUGH NEW MEANS OF COMMUNICATION

INTERNSHIP PRACTICUM REPORT

*Presented to the Graduate Council of the  
Graduate School of Biomedical Sciences  
University of North Texas  
Health Science Center at Fort Worth  
in Partial Fulfillment of the Requirements*

For the Degree of

MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

Jordan Skrivanek, B.S.

Fort Worth, Texas

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## CHAPTER I

### *Introduction*

The main objective of this practicum is to analyze and determine the efficiency of an online portal in increasing the education of research patients at the Plaza Medical Center of Fort Worth. For the project, an education-based portal was created by the research staff and the student intern under the Plaza's current website. The portal will inform the public about the different clinical trials currently taking place at the Plaza Medical Center. For the purpose of the practicum project, the portal was used to educate current research subjects.

A goal of this project was to assist the current research patients in understanding the importance of clinical trials, as well as specific details about the studies in which they are enrolled. The Internet portal should have many positive impacts on the clinical research being completed at the Plaza Medical Center. The portal will offer additional education to patients by providing information on treatments that address the unmet need of their conditions. Additionally, the online portal will promote patient engagement in their medical care and encourage patient communication with the research physicians and staff. Because of this, shared decision-making based on medical evidence and clinical recommendations will increase, as well as patient preference, leading to improved patient care and better patient-staff relationships. In turn, loss to follow up should be reduced because of the better relationships and increased education. Loss to follow up is a constant

problem in trials, and reducing it leads to better outcomes in clinical research. Another importance of the online portal is that it will include accurate information about clinical trials, not leading patients astray. The Internet oftentimes misleads readers, discouraging them from partaking in clinical research trials. People have a tendency to present only their negative experiences, tarnishing the quality of research. The online portal is expected to have all of these positive influences, which are important for the success of clinical trials.

## CHAPTER II

### *Background*

With the increasing popularity of the Internet, it is important for research sites to keep up with the current technologies that can be used to inform the public about their clinical trials. It is especially important for lifelong learners, such as physicians, to embrace new techniques or available resources when they lead to improved patient care<sup>4</sup>. Utilizing the Internet can build highly engaged communities, reach more participants, develop more direct and personal relationships, and improve research reputation. According to Quorum Review IRB, “The Internet brings an entire new dimension to clinical research by offering a widely available medium in which the public, participants, and healthcare professionals can extend their research, exchange information, [and] build lasting highly engaged communities”<sup>9</sup>.

Internet sources have become increasingly important to patients throughout recent years. People now look to the Internet for more information after being diagnosed with a disease or even about family member illnesses. Moreover, the Internet has been proven as one of the first resources that people turn to after a cancer diagnoses<sup>23</sup>. However, just 3% of cancer patients partake in clinical trials<sup>19</sup>. With the high percentage of patients diagnosed with a disease turning to the Internet for information, including additional

information on websites about clinical trials could help recruit those patients. Table 2.1 contains a few statistics that reflect the importance of the Internet in today's society<sup>15</sup>.

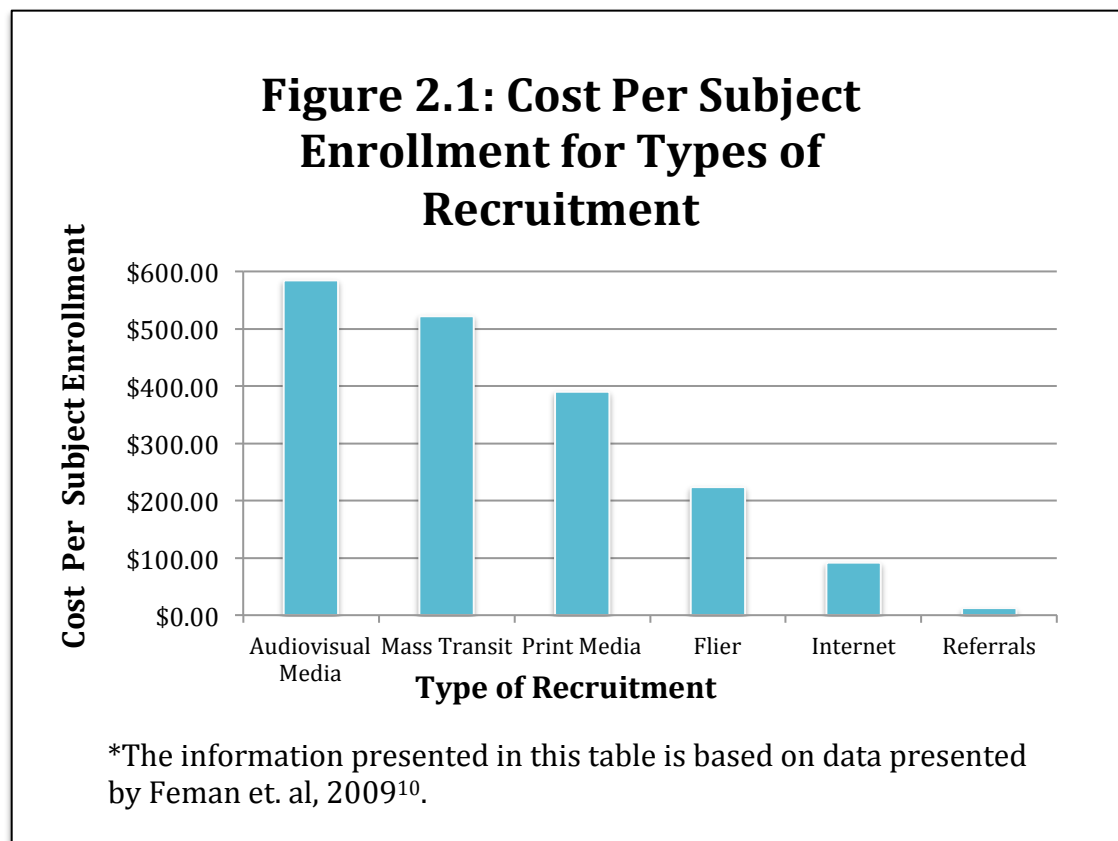
Table 2.1: Prevalence of Internet Use	
Topic	Statistic
General Internet Access	87% of U.S. adults use the Internet
	58% of U.S. adults own a smartphone
Health-related Internet Access	72% of Internet users say they looked online for health information within the past year
	77% of online health seekers say they began their last session at a search engine such as Google, Bing, or Yahoo
	13% of online health seekers say they began their last session at a sight that specializes in health information, such as WebMD
	50% of online health information research is on behalf of someone else
Health-related Mobile Internet Access	52% of smartphone owners have used their phone to look up health or medical information
	19% of smartphone owners have downloaded an app specifically to track or manage health
*The information presented in this table is based on data presented by the Pew Research Center <sup>15</sup> .	

The primary demographical factors that affect Internet usage are age, education level, and household income<sup>17</sup>. Although younger adults more commonly use the Internet, there have been significant findings that over half of individuals 50 years of age or older access the Internet and half of individuals in this age group use social networking sites frequently<sup>8</sup>. Many of the patients currently enrolled in research studies at the Plaza Medical Center Research Department are older, but according to these recent findings many of them will still access the Internet daily and can therefore benefit from the portal. The following table represents Internet use differences in America based on demographics<sup>17</sup>.

Table 2.2: Internet User Demographics in 2014		
Category	Subcategory	Percentage Who Use the Internet
Gender	Male	87
	Female	86
Race/Ethnicity	White	85
	African-American	81
	Hispanic	83
Age Group	18-29	97
	30-49	93
	50-64	88
	65+	57
Education Level	High school graduate or less	76
	Some college	91
	College+	97
Household Income	< \$30,000/year	77
	\$30,000-\$49,999	85
	\$50,000 - \$74,999	93
	\$75,000+	99
*The information presented in this table is based on data presented by the Pew Research Center <sup>17</sup> .		



Patient retention and recruitment is immensely important to the clinical trial process, and researchers must learn to adapt to the new tools that are available. Research staff members have decided that patient recruitment is the most difficult and time-consuming process during clinical trials because patients do not want to participate<sup>24</sup>. Unfortunately, what worked just five years ago probably is not working as efficiently anymore<sup>20</sup>. The Internet can be an excellent resource to help increase patient recruitment and retention. As a matter of fact, a recent study determined that enrollment rates were highest from Internet source recruiting, followed by multi-source recruiting and referrals from physicians<sup>10</sup>. Another important result from the study was that using the Internet to recruit patients was the second lowest cost recruitment strategy. The only approach that was less costly was physician referrals. Table 2.1 reflects the cost of enrollment for different recruitment types<sup>10</sup>.



Successful clinical trials must achieve an acceptable sample size via retention and recruitment in order to have statistically satisfactory results. Disappointingly, “86% of all U.S. clinical studies fail to recruit the required number of subjects on time”<sup>21</sup>. Even in those trials that do recruit enough patients, low retention rates will negatively impact the study. One of the main consequences is longer study duration, which in turn leads to more expenses dedicated to the trial than originally expected. Some of these expenses will be from enforcing new recruitment strategies<sup>21</sup>. Social media, including Facebook, has become a recent source of trial recruitment because it is widely used and freely available. Another benefit of social media platforms is that the variety of people it reaches is a powerful representation of the population. Unsurprisingly, the only significant demographical gap is age<sup>3</sup>. Facebook in particular is a good source of recruitment because it is the most common social media platform<sup>3</sup>. Even though there is an age difference among users, studies show that 71% of adults who have Internet access use this social media site<sup>3</sup>.

Another successful use of the Internet is creating a clinical research section on the hospital or private site’s website. This allows Internet users to put a “human face” to the recruitment efforts, especially when biographies and pictures of the research staff are used. Successful sites should have a section of their website completely dedicated to the research taking place, and it should be easily recognized by the public. Making this information available to the public will allow those patients that research their diseases or recent diagnosis on the Internet to learn about trials and find one that fits into their schedule and their needs<sup>2</sup>. Internet sources are expanding. It only makes sense that researchers should use these tools to their benefit and increase their patient recruiting and retention for their clinical studies.

An additional benefit of the online portal is that it can clear up misconceptions about clinical trials across populations. Subject availability has been affected because clinical trials are not well understood in some communities. There are perceptions that participation is risky and that they take a lot of time and effort<sup>8</sup>. The portal can be a reliable and dependable source of information that can alleviate some of these misconceptions. Physicians should not leave their patients to fend for themselves, and medical personnel need to have trustworthy sources of information where they can send their patients. Although the Internet can provide helpful information, sometimes it will not be in the top Google searches. Because of this, physicians and medical staff need to be able to point their patients in the right direction. “Medicine has to adapt to and address” the Internet<sup>1</sup>.

The Internet can help people understand the actual trial process. Once a drug or device is involved in human clinical trials, it has already undergone vigorous testing and research. This sometimes involves studying medications similar in characteristic to the one in question or animal trials. Most of the time, medications are first tested in healthy individuals in order to assess unforeseen consequences. For the devices and medications that cannot be tested in healthy individuals, the trial will be conducted in hospital-like settings with professionals so that the safety of the patient can be continuously monitored<sup>24</sup>.

Participants in clinical trials are necessary for improvement of current technologies, procedures, and knowledge. While healthy volunteers will not directly benefit from a research study they are participating in, they are important for determining the safety of the drug or device or they can be used as controls. Healthy volunteers who serve as controls are used to compare the patient group to the healthy group<sup>22</sup>. Both healthy

volunteers and patients are imperative for advancements in medicine, and there are ethical and regulatory parameters that are in place to protect their safety throughout the trial process.

While many people may think that their safety is in jeopardy by partaking in clinical trials, there are many guidelines and regulatory organizations set in place to protect human rights and safety. The International Conference on Harmonisation (ICH) released many guidelines regarding clinical research that are used worldwide by researchers. The ICH E6 document, titled Good Clinical Practice, in particular provides ethical guidelines and quality standards for researchers. ICH E6 2.3 states that the rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society<sup>14</sup>.

The FDA, a regulatory body present in the United States, regulates all clinical trials taking place, making sure that patient safety is secure and protected<sup>25</sup>. The FDA will perform inspections at clinical trial sites throughout the duration of research trials. There are also regulatory authorities called Institutional Review Boards (IRBs). Each clinical trial has an IRB that reviews and approves the trial before it begins, reviews the study throughout the process, and ensures the safety, rights, and welfare of the participants are always being protected<sup>25</sup>. For example, if a study has unnecessary or elevated risks to the patients, the IRB will not approve the trial. Sometimes the IRB will suggest changes for the trial. If those are made, the trial can then be approved by the IRB<sup>25</sup>. The IRBs are also responsible for approving informed consent forms, which are used to inform the potential participants of a study about the risks, compensation, and other details of the trial they can partake in. The informed consent form is necessary to protect the patient's rights. Data

safety monitoring committees are also used as an additional safeguard to protect participants. The committees, which are used more commonly for multicenter trials, monitor the data throughout the study in order to increase the protection of the study subjects<sup>27</sup>.

Despite the many benefits of using the Internet to connect with the public, research departments have been slow to adopt the available technologies. Unfortunately, only eleven percent of clinical trials used social media for advertising in 2014<sup>12</sup>. While many aspects of human research are highly regulated, the FDA only has a few regulations set about the Internet and social media. In fact, the FDA did not release any guidance about the use of social media until 2014. Some research departments are unsure about the review and approval processes regarding Internet platforms because of this lack of regulation. Departments also feel that the lack of FDA enforcement when using the Internet could potentially jeopardize study integrity<sup>9</sup>. Study integrity and professionalism should be a priority, and even physicians have made mistakes when posting to social media. For instance, a recent study involving a group of physicians determined that 10% of the physician postings were unprofessional<sup>11</sup>. Some researchers also do not understand current technologies that are available and do not believe the return in investment is worth it<sup>9</sup>. However, there have been many findings that the use of the Internet has significant impacts and is well worth the cost.

The guidance documents the FDA released in 2014 include some information about forming research online portals and communicating via social media<sup>9</sup>. Reviewable subject matter includes social media communication involving specific trials that is directed to the public, current trial participants, or potential patients. These types of communications are

usually advertisements and should direct viewers to more complete information about trials, such as clinical trial websites<sup>9</sup>. IRB review is unnecessary for material posted on a website that is purely educational or provides general information<sup>11</sup>. Unlike drug and device advertising, trial information does not need to include risks because they will be outlined in the informed consent documents. Trial information does need to be accurate, non-misleading, and should communicate information about eligibility and interest. Also, advertisements must not improperly enhance certain information<sup>18</sup>.

A few important guidelines to consider when reaching out to the public about medicine and clinical trials with the Internet are listed below in Table 2.3<sup>7</sup>.

<b>Table 2.3: Internet Guidelines</b>	
<b>Who owns the page (you, sponsor, or institution)?</b>	The creator of the trial page is responsible for the content.
<b>Is your institution aware the page will exist?</b>	Engage your institution's media department so you are aware of the guidelines.
<b>Is IRB review required?</b>	Consult local research administration to determine whether the page needs review.
<b>Are you placing content that is consistent with the trial?</b>	Refrain from providing significant details of any trial. Only basic study information should be available.
<b>Is there a potential for liability or claims of false advertising?</b>	Avoid making claims of treatment efficacy or side effects. Use disclaimers to reduce risk.
*The information presented in this table is based on data presented by Dizon et. al, 2012 <sup>7</sup> .	

In conclusion, the Internet provides researchers with various opportunities. With the increasing prominence of the Internet in society, the Internet is a wonderful outlet that can expand the information available to online health seekers, as well as patients. It has been shown that a majority of the U.S. population accesses the Internet regularly and a large proportion of those users have looked for health information online<sup>15</sup>. Although there are some demographical differences related to Internet use, the Internet is an asset that can be used to inform the general public about research and possible clinical trials that they could partake in. Patient retention and recruitment should improve through including trial information online, lessening the burden on researchers to meet their goals.

Misconceptions about clinical trials will be cleared up, as well as the belief that researchers are not dedicated to patient safety. Research workers should use the guidelines posted by the FDA to create their online websites and social media platforms in order to increase the efficiency of their research site. Because of these advantages, the Plaza Medical Center of Fort Worth's research team has decided an Internet portal will be constructive for their many clinical trials. The Plaza's research portal is projected to provide numerous benefits to the hospital and staff involved with research.

## CHAPTER III

### *Hypothesis & Specific Aims*

This practicum project is designed to test the following hypothesis: Does the new online portal increase the overall research knowledge of the patients enrolled at the Plaza Medical Center Research Department? This hypothesis was tested using patient surveys to determine how effective the portal is at increasing patient knowledge about the study they are participating in, promoting patient involvement in their study and medical care, and interest in communicating with healthcare workers and friends or family. The survey also asks patients about their demographics in order to evaluate differences in patient responses related to their background. To evaluate these important topics, the following specific aims were addressed in the patient questionnaires.

**Specific Aim I: Determine if the research online portal enhances patient knowledge about their study and their importance to the study they are participating in.**

This aim is important because the main objective of the online portal is to increase patient knowledge. Patients who understand more details about their study are more likely to be satisfied with their medical care during their clinical trial. Moreover, patients who realize the significance of their study tend to also be more pleased with their additional medical care.



**Specific Aim II: Determine if the research online portal increases patient involvement and investment in their medical care.**

Patient involvement and investment is an added benefit of increasing patient knowledge about their respective study. Many of the trials taking place at the Plaza Medical Center of Fort Worth's Research Department involve physical exams, EKGs, or ultrasounds. These are free of charge to the patient. The online portal reminds patients of their more intensive monitoring while participating in their trial. This free and additional healthcare could notice a problem before the patient's primary care physician would. The added patient investment would benefit the research department by increasing patient retention.

**Specific Aim III: Determine if the research online portal encourages patients to communicate with the research doctors and staff, as well as friends and family about the study they are enrolled in.**

This aim is directed at communication because it can also lead to higher retention for the research department. When patients are more likely to communicate with the doctors or healthcare workers assisting with their medical care, they increase their understanding and willingness to participate. Additionally, patient communication with friends and family is encouraged because of the same reasons. The research department wants its patients to be comfortable talking about their clinical trial.

**Specific Aim IV: Determine if the research online portal is viewed as an accurate source for information regarding the studies.**

The online portal was designed to be an accurate and professional source of information for the research patients, as well as the general public. This aim was included in the survey in order to gauge how the patients perceive the online portal.

**Specific Aim V: Identify the demographical characteristics that affect the different responses from the patients.**

As mentioned in the background section, age, education, and household income affect Internet usage differences the most. This aim is directed towards testing this information and discovering other demographical factors that significantly affect the answers given in the surveys.

## CHAPTER IV

### *Research Design & Methodology*

The research design involved creating an online portal in the new redesigned Plaza website and a patient questionnaire. The portal, created by the research staff and student intern, includes an overview of the research department and their collaboration with the University of North Texas Health Science Center, information about each study being conducted at the Plaza Medical Center Research Department, and the names of the physicians involved with the research. Patients were asked to access the website and view the information about the study they are enrolled in.

The following figures were taken from the Plaza Medical Center's website and include the information the research patients were asked to access. Figure 4.1 is the main portal page that each patient viewed. Figures 4.2 through 4.11 contain the information about each study. For example, if a patient was enrolled in the Odyssey Trial, they would view Figure 4.6 and Figure 4.7 to read about their study. The six studies incorporated into the website include patients that were approached for this practicum project.

**Figure 4.1: Primary Research Portal Page**

## Research

### Plaza Medical Center of Fort Worth Research

#### Clinical Trials: Partnering with you today to benefit medicine tomorrow

The Plaza Research team is dedicated to helping find prevention therapies and treatments for diseases and illnesses. We participate in a number of clinical trials and scientific studies that test new drugs and devices. Our research is focused mainly on cardiovascular, electrophysiology and neurological medicine.

The Plaza Research Office also collaborates with the [University of North Texas \(UNT\)](#) master of science program in clinical management. As part of their curriculum, students in this program have a six-month practicum with the Plaza Research team, culminating in a scientific thesis. A Plaza representative is part of the faculty advisory committee for the student.

By taking part in a clinical trial, you can:

- Play a more active role in your own health care
- Help others by contributing to medical research

To see if you qualify for enrollment in one of our clinical trials, call (817) 347-6058.

#### Active clinic trials at Plaza Medical Center

Plaza is currently seeking volunteers for these studies:

- [COBRA](#) - Participants will help study doctors learn whether the investigational COBRA PzF coronary (heart) stent works for opening up the blocked or narrowed blood vessels in the hearts of patients with coronary artery disease (CAD).
- [Dance](#) - Studies whether dexamethasone, an FDA-approved anti-inflammatory drug, can be delivered safely into the tissue around the blood vessel at the time of angioplasty or atherectomy and prevent re-narrowing of the blood vessel.
- [Odyssey](#) - The study hopes to prevent future heart events by using an injectable investigational drug to lower bad cholesterol (LDL) in people with a history of heart disease. This medication is used with statins. The study is being conducted worldwide and has passed through early phases of clinical trials.
- [Platinum](#) - Gathers information (i.e. medical history, demographics) from women and minorities with coronary artery disease who have been treated with the Promus PREMIER coronary (heart) stent. This is an observational study and no investigational medications or medical devices will be administered as part of this study.

Enrollment is Closed for these Active Clinical Trials

- [CANOPY study](#) - Purpose is to continue evaluating the safety and effectiveness of the RX Acculink Carotid Stent System.
- [SuperNova](#) - Studies whether the investigational INNOVA stent works for opening up the blocked or narrowed blood vessels in the upper legs of patients with peripheral artery disease (PAD).

Research Office Supervisor: Dr. Rubina Muzina

Principal Research Investigator: [Dr. Amir Malik](#)

Sub-investigators: [Dr. Farhan Ali](#), [Dr. Dennis Doan](#), [Dr. Giri Mundluru](#), Dr. Ashesh Parikh and physicians in Plaza's cardiology fellowship program.

*"The only way of discovering the limits of the possible is to venture a little way past them into the impossible" – Arthur (Charles) Clarke*

[Main Services](#)

#### Contact Us

(817) 347-6058

## Figure 4.2: COBRA Study Information Page 1

### About the COBRA Study

#### What is the purpose of this study?

Participants are very important to this study. By participating in this study, participants will help study doctors learn whether the investigational COBRA PzF coronary (heart) stent works for opening up the blocked or narrowed blood vessels in the hearts of patients with coronary artery disease (CAD).

#### Am I eligible?

Do you meet the following criteria?

- Age 18 or older
- Have been diagnosed with coronary artery disease and/or have had symptoms (i.e. chest pain, shortness of breath) for which your doctor has decided to investigate by scheduling a cardiac catheterization procedure.

#### What does taking part in this study involve?

- Participants will undergo a procedure to open up the blood vessels in the heart using the COBRA PzF stent.
- The study will last for 5 years. Participants will return to the study doctor's office for follow-up visits and medical testing (i.e. ECG, physical exam) at 1 month and 9 months following the stent procedure. They will also be contacted by the research staff by phone at 6 months and annually until the end of the study.

#### Where will participants have study visits?

Study visits will take place at the Plaza Research Office located in the medical professional building next to the Plaza Medical Center ER entrance. Parking is available in the parking garage and parking tickets will be validated.

#### Could participants receive a placebo?

This study does not include a placebo group. Patients with coronary artery disease requiring intervention which satisfies the study criteria will receive the COBRA PzF stent during the procedure.

#### What happens during study visits?

During study visits at the research office, patients will have a physical exam done by the doctor. An electrocardiogram (ECG) of their heart will be completed at the 9-month visit. During study phone calls, patients will be asked questions about their health and any medications they may be taking. With flexible office hours, these visits/phone calls can be scheduled at a convenient time with minimum interruption to daily life. All of our staff are well trained in this study and are available for questions.

#### Do I have to take part?

Being part of the research study is voluntary. For patients who do not want to be a part of the study, or who decide to stop the study before completing the follow-up visits, this decision will have no negative impact on current or future treatment.

- What are other choices for patients who choose not to participate?  
Patients do not have to be in this study to have arteries in their hearts treated. Their doctor will explain to the other possible treatments, as well as their benefits and risks.

**Figure 4.3: COBRA Study Information Page 2**

### **About the COBRA Study**

#### **Can I talk to other people about the study?**

We encourage patients to talk with other people about participating in this study. They are also welcome to bring anyone with whom they'd like to share information to the study visits.

#### **What are the benefits of participating in this study?**

As a study participant, health will be monitored closely through physical exams with the doctors, medical testing (i.e. ECG) and study phone calls. All study-related medical testing performed during the follow-up visits is provided at no cost. Participation in this study will also help gather information that could benefit future patients with similar symptoms of coronary artery disease.

#### **Where else can I find information about this study?**

Please follow the links below to find more information about this study.

<https://clinicaltrials.gov/ct2/show/NCT01925794?term=cobra&rank=5>

<http://celonova.com/portal/physician/ous/physician-type-ous/cardiovascular-ous/catania-coronary-stent/cobra-pzf-stent/>

## **Figure 4.4: Dance Study Information Page 1**

### **About the Dance Study**

#### **What is the purpose of this study?**

Participants are very important to this study. The study hopes that the delivery of dexamethasone, an anti-inflammatory drug approved by the U.S. Food and Drug Administration can be delivered safely into the tissue around the blood vessel at the time of angioplasty or atherectomy and prevent re-narrowing of the blood vessel.

#### **Am I eligible?**

Do you meet the following criteria?

- ≥ 18 years
- Clinical diagnosis of PAD requiring intervention

#### **What does taking part in this study involve?**

- During the interventional procedure for PAD of the patient's legs, the anti-inflammatory dexamethasone will be injected in the tissue around the blood vessel wall of the arteries of the leg. The dexamethasone is already approved by the FDA for injecting in blood, skin and joints. It will be delivered through a Bullfrog infusion device, which is FDA cleared for infusing medications into tissues around the blood vessels.
- The study period is for 2 years. Participating in the study would mean that the patient receives the dexamethasone injection during the procedure. There are follow-up visits at 30 days and every 6 months thereafter until 2 years from the procedure.

#### **Where will study visits take place?**

Study visits will take place in the Research Office located in the medical professional building next to the Plaza Medical Center ER entrance. Parking is available in the parking garage and parking tickets will be validated.

#### **Could I receive a placebo?**

This study does not include a placebo group. Patients who have PVD of their legs requiring intervention which satisfy the study criteria will receive the medication during the procedure.

#### **What happens during study visits?**

During study visits, an ultrasound and physical examination will be done. The study staff will take blood pressures of both of arms and legs and the patient will also be asked to complete health questionnaires.

**Figure 4.5: Dance Study Information Page 2**

## **About the Dance Study**

### **Do patients have to take part?**

Participation in the study is voluntary. Refusal to participate or withdrawing from the study will not interfere with a patient's standard of care.

- What are other choices for those who choose not to participate?  
Patients who choose not to participate in the study will receive the routine standard of care. During the procedure, these patients will receive an angioplasty or atherectomy without the dexamethasone being injected to the blood vessel.

### **Can patients talk to other people about the study?**

We encourage patients to talk with other people about participating in this study. Patients are welcome to bring anyone with whom they'd like to share information to the study visits.

### **What are the benefits of participating in this study?**

As a study participant, health will be monitored closely through physical exams with the doctor and medical tests. Participation in this study will also help gather information that could benefit future patients with similar symptoms of PAD.

### **Where else can I find information about this study?**

Please follow the links below to find more information about this study.

<https://clinicaltrials.gov/ct2/show/NCT01983449>

[http://www.mercatormed.com/pressreleases/071612-DANCE\\_Pilot.html](http://www.mercatormed.com/pressreleases/071612-DANCE_Pilot.html)



## **Figure 4.6: Odyssey Study Information Page 1**

### **About the Odyssey Study**

#### **What is the purpose of this study?**

Participants are very important to the purpose of this study. The study hopes to prevent future heart events by using this injectable investigational drug to lower bad cholesterol (LDL) in people with a history of heart disease. This medication is used with statins. The study is being conducted worldwide and has passed through early phases of clinical trials.

#### **Am I eligible?**

Do you meet the following criteria?

- ≥ 40 years old
- History of a recent heart event (within the past 1 year)
- Elevated LDL (bad cholesterol) with statins.

#### **What does taking part in this study involve?**

- Participants in the study will have a qualifying visit to screen lipid levels. Those who qualify will receive the investigational drug/placebo once every 2 weeks.
- The study duration is 2-3 years. It involves monthly visits in the first 4 months followed by quarterly visits thereafter in the first 2 years and half yearly until the end of the study.
- Each visit will be scheduled at a time convenient, as our office hours are very flexible. All our staff can be contacted anytime regarding the study.

#### **Where will study visits take place?**

Study visits will take place in the Research Office located in the medical professional building next to the Plaza Medical Center ER entrance. Parking is available in the parking garage and parking tickets will be validated.

#### **Could the patient receive a placebo?**

Yes, the patient may receive a placebo. Patients who qualify to participate in the study will be randomized into either the study drug group or the placebo group. Both groups will be monitored medically by the study sponsor.

#### **What happens during study visits?**

During the visits the following will be done

- Initial and annual visits will have a physical performed by a doctor.
- A review of routine and study medications.
- Labs will be drawn to monitor cholesterol levels.
- Review of medical history and EKG in the initial visits.

**Figure 4.7: Odyssey Study Information Page 2**

## **About the Odyssey Study**

- Review of any hospital or Emergency room visits.
- A short health questionnaire

### **Do patients have to take part?**

Participation in the study is voluntary. Refusal to participate or withdrawing from the study will not interfere with a patient's standard of care or medical treatment.

- What are other choices if a patient chooses not to participate?  
Those who chose not to participate in the study will receive routine cholesterol medication and possible other alternative treatments, as advised by their physician.

### **Can participants talk to other people about the study?**

We encourage patients to talk with other people about participating in this study. Patients are welcome to bring anyone with whom they'd like to share information to the study visits.

### **What are the benefits of participating in this study?**

The study participant's health will be monitored closely through with annual physical examinations and blood tests to review their complete metabolic profile. The study values the participant's time by paying for the study visits and statin medication. Participation in this study will also help gather information that could benefit future patients with similar symptoms of heart disease and prevent heart events in people with high cholesterol.

### **Where else can I find information about this study?**

Please follow the links below to find more information about this study.

[http://www.odysseytrials.com/web/about\\_odyssey\\_program](http://www.odysseytrials.com/web/about_odyssey_program)

<http://newsroom.regeneron.com/releasedetail.cfm?ReleaseID=901604>

<https://clinicaltrials.gov/ct2/show/NCT01507831>

<http://www.medpagetoday.com/Endocrinology/GeneralEndocrinology/47462>

<http://www.modernhealthcare.com/article/20150411/MAGAZINE/304119937>

## Figure 4.8: Platinum-Diversity Study Information Page 1

### About the Platinum-Diversity Study

#### What is the purpose of this study?

Participants are very important to this study. By participating in this study, patients will help the study sponsor gather information (i.e. medical history, demographics) from women and minorities with coronary artery disease who have been treated with the Promus PREMIER coronary (heart) stent. This is an observational study and no investigational medications or medical devices will be administered as part of participation in this study.

#### Am I eligible?

Do you meet the following criteria?

- Age 18 or older
- Have been diagnosed with coronary artery disease
- Self-identify as one or more of the following: Female, Black of African Heritage, Hispanic/Latino, and/or American Indian or Alaska Native.

#### What does taking part in this study involve?

- Patient will undergo a procedure to open up the blood vessels in the heart using the Promus PREMIER coronary (heart) stent.
- The study will last for 1 year. Patient will be contacted by the research staff by phone at 30 days, 6 months, and 12 months after enrollment in this study.

#### Where will study visits take place?

All study visits are conducted over the phone. No visits to the research office are required.

#### Could I receive a placebo?

This study does not include a placebo group. Patients who have coronary artery disease requiring intervention which satisfies the study criteria will receive the Promus PREMIER stent during the procedure.

#### What happens during study visits?

During the study phone calls, the patient will be asked questions about their health and any medications they may be taking. With flexible office hours, these phone calls can be scheduled at a convenient time with minimum interruption to daily life. All of our staff are well trained in this study and are available for any questions.

#### Do patients have to take part?

Being part of the research study is voluntary. For patients who do not want to be a part of the study, or who decide to stop the study before completing the follow-up visits, this decision will have no negative impact on current or future treatment.

- What are other choices for patients who choose not to participate?  
Patients do not have to be in this study to have the arteries in their heart treated. The patient's doctor will explain the other possible treatments, benefits and risks.

**Figure 4.9: Platinum-Diversity Study Information Page 2**

## **About the Platinum-Diversity Study**

### **Can the patient talk to other people about the study?**

We encourage patients to talk with other people about participating in this study. They are also welcome to bring anyone with whom they'd like to share information to the study visits.

### **What are the benefits of participating in this study?**

Health will be monitored closely through the study phone calls. Participation in this study will also help gather information that could benefit future patients with similar symptoms of coronary artery disease.

### **Where else can I find information about this study?**

Please follow the links below to find more information about this study.

<https://clinicaltrials.gov/ct2/show/NCT02240810?term=platinum+diversity&rank=1>

<http://www.bostonscientific.com/en-US/medical-specialties/interventional-cardiology/clinical-spotlight/platinum-diversity-trial.html>

## Figure 4.10: CANOPY Study Information

### About the CANOPY Study

#### **Purpose**

Participants are very important to this study. The purpose of the CANOPY study is to continue to evaluate the safety and effectiveness of the RX Acculink Carotid Stent System, manufactured by Abbott Vascular, in patients at standard risk for complications from carotid endarterectomy in the commercial setting. The CANOPY study is a post-approval study, in which the FDA approved the RX Acculink Carotid Stent System and it was used for the treatment of the study subjects.

#### **Eligibility criteria at the beginning of the study**

- Participants must be  $\geq 18$  years of age
- Participants must have been diagnosed with carotid artery disease

#### **Study activities**

- Participant underwent a procedure to open up the blood vessels in their carotid using the RX Acculink Carotid Stent System.
- Participants in this study were followed up 24 hours post-procedure; 30 days, 1 year and annually for a total of 3 years. All visits were conducted in the research office.
- Study staff conducted neurological examinations which included the National Institutes of Health Stroke Scale (NIHSS) and modified Rankin Scale (mRS). The NIHSS is used as a clinical stroke assessment tool to evaluate and document neurological status in acute stroke patients. The mRS is a commonly used scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability. All study staff are NIHSS-certified. With flexible office hours, these office visits were scheduled at a convenient time with minimum interruption to daily life. All staff members are well-trained in this study and are available for to answer questions.

#### **Location of the Research office**

Study visits take place at the research office located in the medical professional building next to the Plaza Medical Center ER entrance. Parking is available in the parking garage and parking tickets will be validated.

#### **Nature of the study**

This study did not include a placebo group. Participants who had carotid artery disease requiring intervention which satisfied the study criteria received the RX Acculink Carotid Stent System during the procedure.

#### **Questions patients might have during follow-up visits**

Being part of the research study was voluntary. If a patient decides to stop the study before completing follow-up visits, this decision will have no negative impact on current or future treatment.

#### **Discussing the study follow-up visits with family/friends/social circles**

Participants are encouraged to talk with other people about their participation in this study. They are welcome to bring anyone with whom they'd like to share information to study visits.

#### **Benefits**

As a study participant, the patient's health will be monitored closely through physical exams with the doctor and via neurological testing. All study-related medical testing performed during the follow-up visits is provided at no cost. Participation in this study will also help gather information that could benefit future patients with similar symptoms of carotid artery disease

#### **Information**

Please follow the links below to find more information about this study.

<https://clinicaltrials.gov/ct2/show/NCT01445613?term=CANOPY&rank=1>

<http://evtoday.com/2014/11/06/canopy-supports-cas-as-an-alternative-to-cea-for-stroke-prevention-in-standard-risk-patients>

## Figure 4.11: SuperNova Study Information

### About the SuperNova Study

#### Purpose

Participants are very important to the purpose of this study. Participation in this study helped the study doctors learn whether the investigational INNOVA stent works for opening up the blocked or narrowed blood vessels in the upper legs of patients with peripheral artery disease (PAD).

#### Eligibility criteria at the beginning of the study

- Age 18 or older
- Have been diagnosed with peripheral artery disease

#### Study activities

- Participants underwent a procedure to open up the blood vessels in their upper leg using the INNOVA stent.
- The study duration is 3 years. Participants return to the study doctor's office for follow-up visits and medical testing (i.e. ultrasound, X-ray) at 1 month, 6 months, 12 months, 2 years and 3 years following the stent procedure.
- During study visits, participants will have an ultrasound and an X-ray done of the part of the leg where the stent was implanted. The study staff will take blood pressures of both of arms and legs and the participant will be asked to complete a six-minute walking test. Participants will also be asked to complete questionnaires regarding their health. With flexible office hours, visits and phone calls can be scheduled at a convenient time with minimum interruption to daily life. All of our staff are well trained in this study and are available for questions.

#### Location of the Research office

Study visits will take place at the Research Office located in the medical professional building next to the Plaza Medical Center ER entrance. Participants may park in the parking garage, with parking ticket validation.

#### Nature of the study

This study does not include a placebo group. Participants who had peripheral artery disease requiring intervention which satisfied the study criteria received the INNOVA stent during the procedure.

#### Questions for follow-up visits

Being part of the research study is voluntary. For patients who decide to stop the study before completing the follow-up visits, this decision will have no negative impact on current or future treatment.

#### Discussing the study follow-up visits with family/friends/social circles

Patients are encouraged to talk with other people about their participation in this study. They are also welcome to bring anyone with whom they'd like to share information to the study visits.

#### Benefits for staying in the study

As a study participant, health will be monitored closely through medical testing (i.e. ultrasound, X-ray). All study-related medical testing performed during the follow-up visits is provided at no cost. Participation in this study will also help gather information that could benefit future patients with similar symptoms of peripheral artery disease.

#### Information participants might need during participation in the study

Please follow the links below to find more information about this study.

<https://clinicaltrials.gov/ct2/show/NCT01292928?term=supernova&rank=2>

<http://news.bostonscientific.com/2013-08-19-Boston-Scientific-Completes-Enrollment-In-SuperNOVA-Trial-Evaluating-Innova-Self-Expanding-Stent-System>

A fifteen-question survey was created in order to evaluate the specific aims of the practicum project. The language used in the questionnaire was simplified to guarantee that all patients understood the questions they were asked. The questions were divided into two separate sections, Study Related Questions and General Information. The Study Related Questions portion includes eight questions corresponding to specific aims one through four. The General Information section includes seven questions relating to specific aim five. The outline below reflects the division of the survey into each specific aim.

### **Study Related Questions**

- I. Specific Aim I: Questions 1 and 7
- II. Specific Aim II: Question 2, 3, and 4
- III. Specific Aim III: Questions 5 and 6
- IV. Specific Aim IV: Question 8

### **General Information**

- I. Specific Aim V: Questions 1, 2, 3, 4, 5, 6, and 7

The survey, shown in Figure 4.17 and Figure 4.18, was Institution Review Board approved by both the local Plaza IRB and the University of North Texas Health Science Center IRB. An IRB-approved informed consent form (ICF) was also produced and can be seen in Figure 4.15 and Figure 4.16. Before each patient completed the survey given to him or her, they were asked to read and sign the ICF. The project start date for consenting patients was August 5<sup>th</sup>, 2015. The ICF, modeled after previous ICFs, introduced the study,

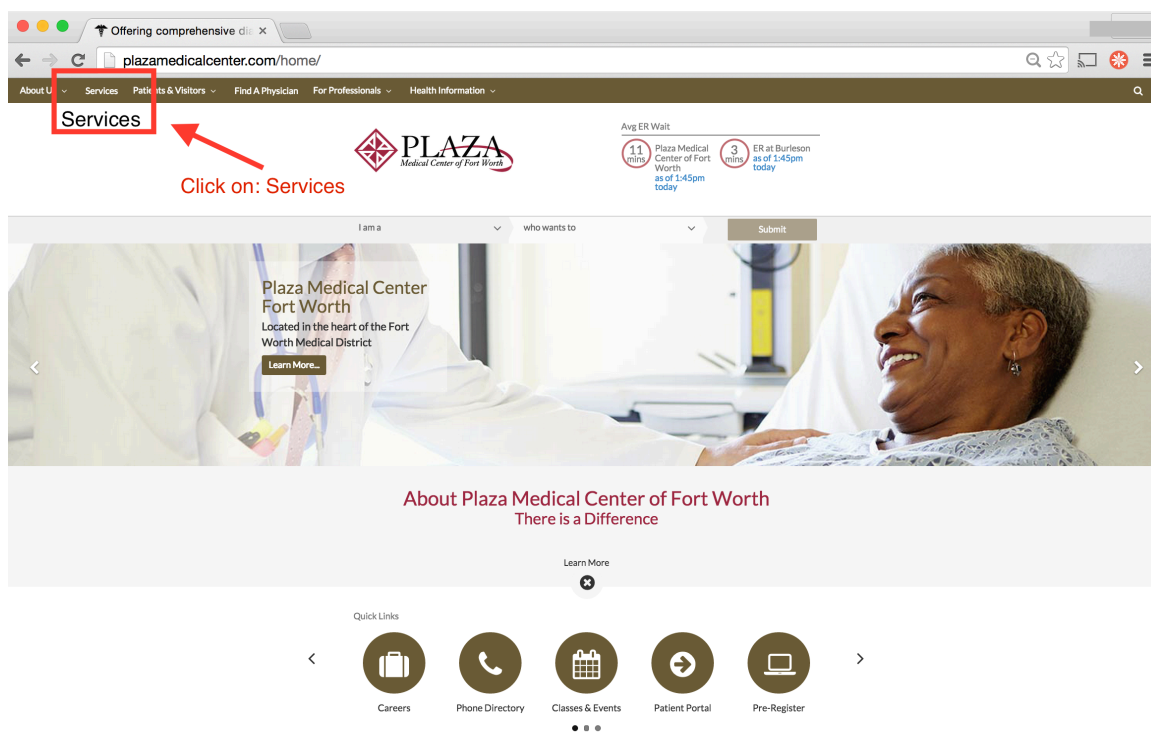
its importance, the method utilized during the study, costs and benefits of participation, notice that the medical care they are receiving will remain the same, the voluntary nature of the study, confidentiality, and who to contact for further information.

Confidentiality was an important factor when conducting the study. To assure the anonymity of patient responses, two methods were utilized. For those patients who completed the survey within the research office, hospital, or Heart Center of North Texas during a follow-up visit, a drop box was provided for them to return their survey. These patients completed the surveys alone in their examination room and placed their surveys within the drop box on their own. Patients who were not scheduled for a follow-up visit received the ICF, survey, directions about how to access the website, and a prepaid envelope via the mail. The directions included pictures of the web pages in order to simplify the process for each patient. The pictures informed each patient to first access the website at [www.plazamedicalcenter.com](http://www.plazamedicalcenter.com), click on “Services” in the top left corner, click on “Research”, and lastly click on their respective study. The directions can be seen in Figures 4.12 through 4.14. Although these patients returned both their ICF and survey within the same unmarked, prepaid envelope, the process of collecting their surveys remained the same. The ICF and survey were separated immediately when received. Anonymity was ensured because the ICF only included the patient name and signature on the second page, which was not viewed when placing the received survey into the same drop box as the one used by the in-office patients. It was important for responses to be entirely anonymous so that each patient felt as if they could be completely honest when answering. Honesty was an invaluable characteristic for the accuracy of the practicum project. As required, each patient received a copy of their ICF with all signatures, including their own, the student

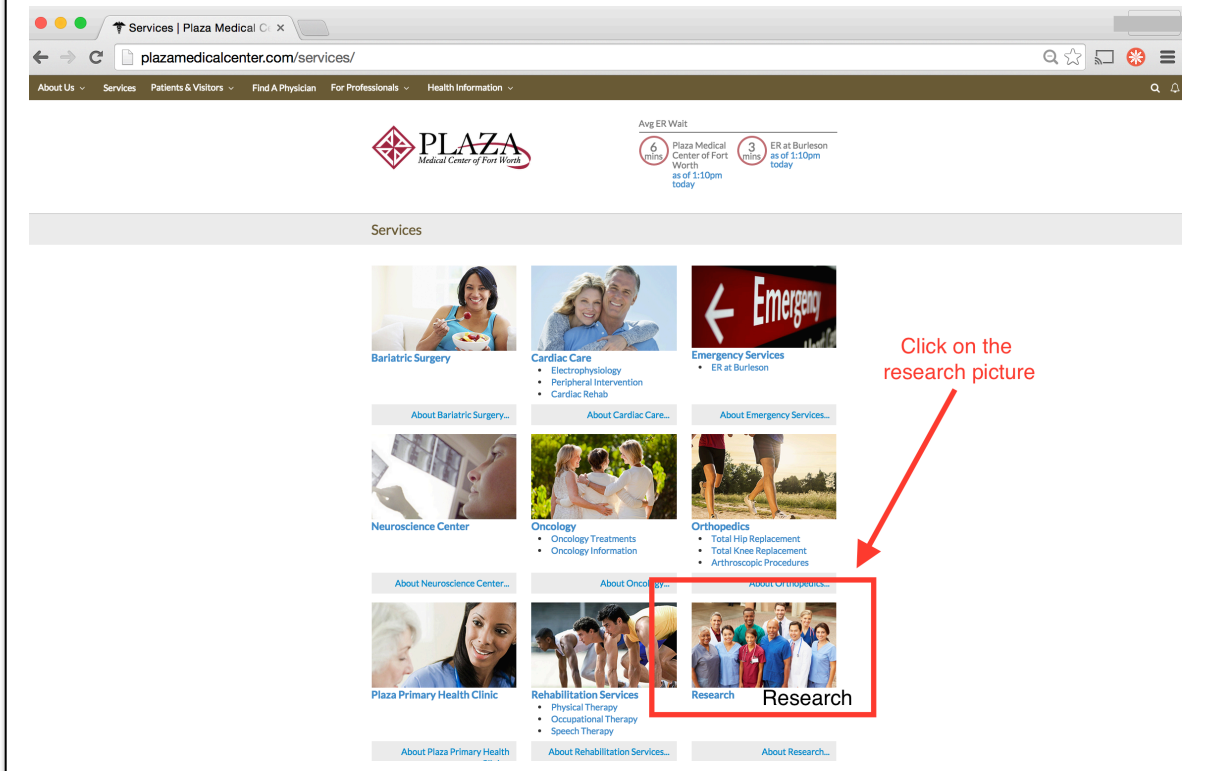


intern, and the site mentor. For those patients who returned their ICF in the mail, a copy was mailed to their home. Data was collected when twenty surveys were received and again when all surveys were received. Each survey was given a random number and their answers recorded in Excel. The answers for all surveys were then tallied together to achieve percentages for each answer choice within their respective question. Surveys were collected until October 6, 2015.

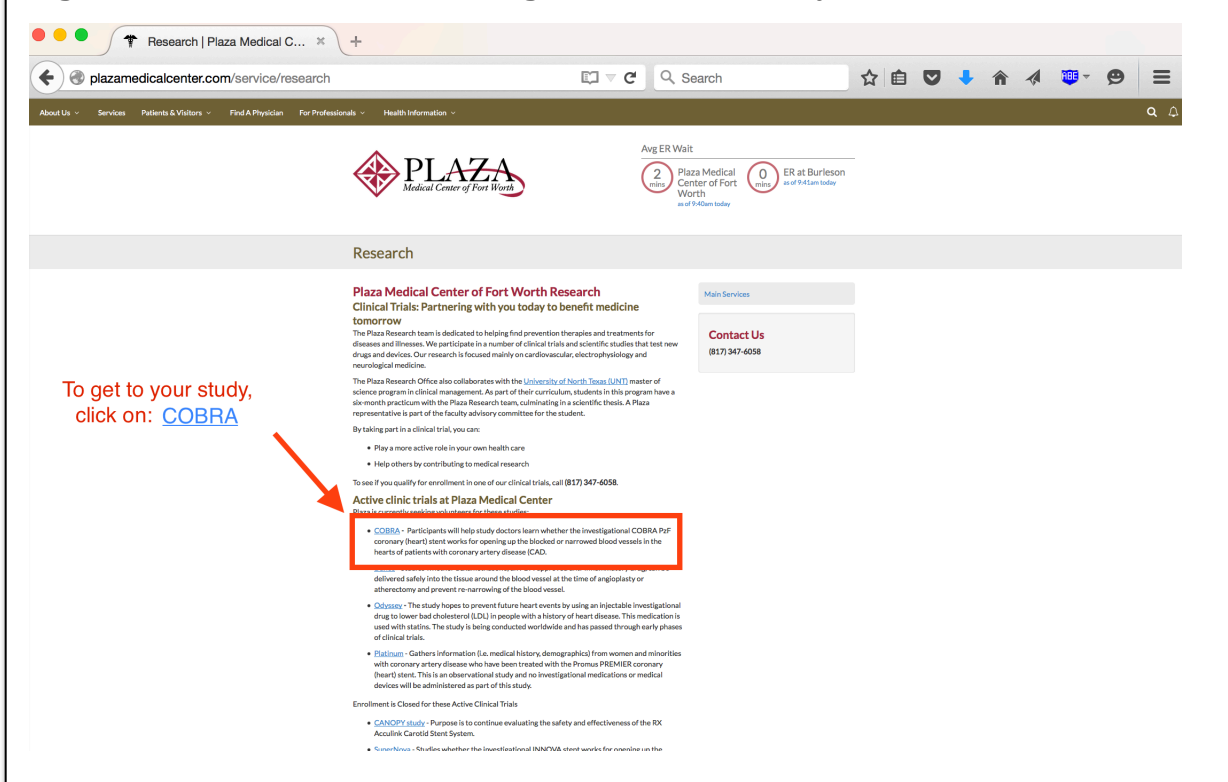
**Figure 4.12: Patient Directions Page 1**



**Figure 4.13: Patient Directions Page 2**



**Figure 4.14: Patient Directions Page 3 for COBRA Study Enrolled Patients**



**Figure 4.15: Informed Consent Page 1**

**Increasing Knowledge of Patients in Clinical Trials Through New Means of Communication – Informed Consent Form**

**Introduction:** You are invited to participate in a research study survey. The survey will be conducted by a student from the University of North Texas Health Science Center interning with the Research Department at the Plaza Medical Center of Fort Worth. The student will be under the mentorship of Dr. Rubina Muzina, MD, MPH, ~~CCRC~~.

**Study:** The study will focus on the efficiency of an education-based online portal for the Plaza Medical Center's Research Department. The study will be measured using a survey consisting of questions related to demographics and the effectiveness of the information provided on the online portal. The goal is to determine the effectiveness of the online portal in increasing patient knowledge about their patient care, retention in studies, communications with research physicians and staff, and willingness to spread the information learned to others.

**Method:** After you have given consent, an anonymous survey will be given to you. You will only complete the survey after you have viewed the online portal during your appointment or at home at your pace. You will have the option to complete the survey while you are still at the Plaza Medical Center or take the survey home to complete. If you choose to complete the survey on site, there will be a box to anonymously place your survey. If you choose to complete the survey at home, you will be given a prepaid envelope to mail back the survey to the Research Department. The envelope will not include your return address or information to further assure your answers are completely anonymous.

**Costs/Benefits:** No additional costs will be required from you for your participation in the survey. There will not be any additional compensation other than the ones you are already receiving per your respective study. The prepaid envelopes that will be given to you to return the survey if you do not complete it during your appointment will already be postmarked.

**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, you will return your survey in an anonymous box or return the survey via mail. The return envelope will not include any information that could be used to identify you. Your responses in the survey 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 Jordan Skrivaneck or Rubina Muzina, MD, MPH, CCRC in the Research Department.

## Figure 4.16: Informed Consent Page 2

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 4.17: Survey Page 1 – General Information**

## Increasing Knowledge of Patients in Clinical Trials Through New Means of Communication

### General Information

#### 1. Gender

Female	Male	Prefer not to say
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 2. Age

Under 19	20 to 29	30 to 39	40 to 49	50 to 59	60 to 69	70 to 79	80 to 89	90 and above	Prefer not to say
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 3. Race

American Indian or Alaska Native	Asian	Black or African American	Hispanic or Latino	Native Hawaiian or Pacific Islander	White	Multi-Race or Unknown	Prefer not to say
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 4. Estimated annual household income

Under \$25,000	\$25,000 to \$49,000	\$50,000 to \$99,000	\$100,000 or above	Prefer not to say
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 5. Highest educational level

Less than high school graduate	High School Graduate/GED	Some College/Technical Certification Program	4-Year College Degree	More than 4 years of College	Prefer not to say
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 6. Do you have access to the Internet at home?

Yes	No
<input type="radio"/>	<input type="radio"/>

#### 7. How often do you use the Internet?

At least daily	At least weekly	At least monthly	Rarely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Figure 4.18: Survey Page 2 – Study Related Questions**

Increasing Knowledge of Patients in Clinical Trials Through New Means of Communication				
Study Related Questions				
1. The research online portal increased my knowledge about the study I am enrolled in.				
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. The research online portal made me feel more involved in my medical care.				
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. The research online portal made me feel more invested in my study.				
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. The research online portal increased my motivation to continue participating in my study.				
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. The research online portal increased my willingness to communicate with the research doctors and staff.				
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. The research online portal encouraged me to talk more about my study with friends and family.				
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. The research online portal helped me feel more knowledgeable about my important role in the study.				
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. I feel confident that the research online portal is one of the best Internet sources for accurate medical information regarding my study.				
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## CHAPTER V

### *Data Analysis & Results*

The practicum project utilized patients from six different clinical trials that are ongoing at the Plaza Medical Center of Fort Worth's Research Department. Although the research department is beginning a few more trials, they were not openly enrolling during the entire survey collection period. There were 68 patients who were candidates to complete the survey with an average age of 70 years old. This excludes expired, withdrawn, or loss to follow-up patients that belong to the research department.

Of the 68 possible patients, 54 were approached about completing the survey (79% of the eligible patients). The 14 eligible patients who were not approached were all from Study B. Table 5.1 demonstrates the average age, the number of surveys received during the collection period, the possible number of patients, and the percentage of patients who completed the survey within each study. Although there were 24 eligible patients in study B, only 10 of them were approached about completing the project. It was decided not to contact the other patients because of lack of follow-up visits or follow-up phone calls per the study protocol during the internship period. The patients in this study only have office visits with the research department once a year. Notably, the study with the lowest average age, Study A, had the highest completion rate.

**Table 5.1: Study Average Age and Completion Rate for All Possible Patients**

<b>Study</b>	<b>Average Age</b>	<b>Number of Surveys Completed</b>	<b>Number of Possible Patients</b>	<b>Completion Rate</b>
<b>A</b>	62	14	14	100%
<b>B</b>	75	8	10	80%
<b>C</b>	68	6	8	75%
<b>D</b>	69	9	12	75%
<b>E</b>	66	4	7	57%
<b>F</b>	79	1	3	33%

Within the survey collection period, 42 of the 54 approached patients returned the survey, meaning that 78% of those approached completed the requirements for this project. The average age of the patients who returned the survey was 68 years old, which is lower than the age of all of the patients (70 years). There were various reasons for the lack of response from the 12 patients who were approached and did not complete the requirements of the project. Four patients could not be contacted via the phone during the entire survey period, and three patients stated over the phone that they would complete the survey, but they never did. One patient who was contacted via the phone sent the survey in after the survey collection cutoff. Additionally, two patients did not have access to the Internet and therefore could not return the survey. Only two of the patients who could be contacted declined to complete the survey. Both of these patients declined to participate because of the time requirements of the project. These results can be seen in Table 5.2.



**Table 5.2: Reasons Surveys Were Not Returned During Collection Period**

<b>Reason</b>	Could not be contacted during survey period	Stated they would complete the survey but never did	Sent the survey but missed the survey cutoff	No Internet access and no future visit	Declined
<b>Number of Surveys</b>	4	3	1	2	2

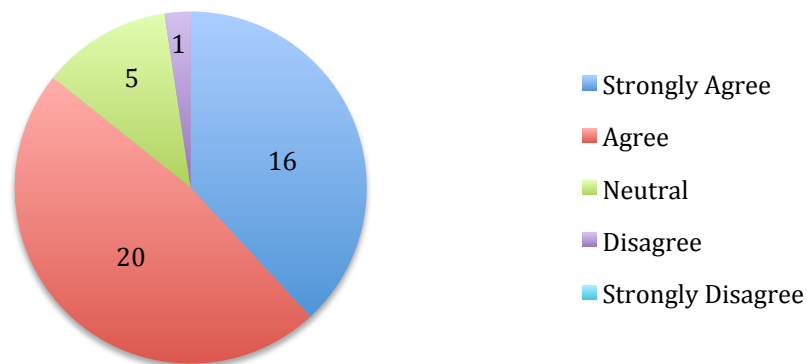
The following paragraphs will analyze the results of the surveys received by the 42 patients of the Plaza Medical Center's Research Department. Pie charts were created in order to easily visualize the results of the survey questions, and the chi-square method was used to statistically analyze the results. Distribution frequencies can be seen, along with the chi-square results, in Tables 5.3 – 5.10 for the first four specific aims. The chi-square method was utilized using  $\alpha=0.05$  and a degree of freedom of three. Specific aims I through IV comprise the study related questions, and specific aim V includes the general information. A modified chi-square test, the Mantel-Haenszel chi-square, was used for specific aim V with  $\alpha=0.05$  and a degree of freedom of one. Tables 5.12 – 5.23 are all related to this aim.

### **Specific Aim I**

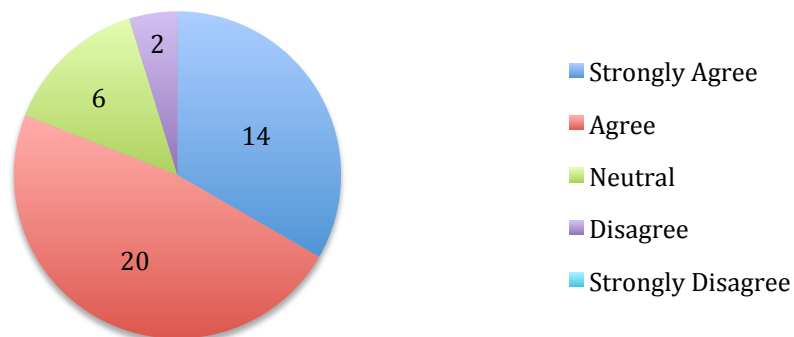
Survey questions 1 and 7 are directed at specific aim I, which determines if the research portal is effective in increasing patient knowledge and understanding of their importance in their study. A vast majority of the patients, 86%, indicated that the online portal did increase their knowledge about their study (Question 1). Additionally, most of the subjects, 81%, stated that the online portal increased their awareness of their

important role in their study (Question 7). The main goal of this practicum project was to increase patient knowledge, and the percentage of subjects that agreed with the statement in question 1 was the highest of all the questions.

**Figure 5.1: Q1 - The research online portal increased my knowledge about the study I am enrolled in.**



**Figure 5.2: Q7 – The research online portal helped me feel more knowledgeable about my important role in the study.**



**Table 5.3: Q1 – The research online portal increased my knowledge about the study I am enrolled in.**

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
<b>Disagree</b>	1	2.38	1	2.38
<b>Neutral</b>	5	11.90	6	14.29
<b>Agree</b>	20	47.62	26	61.90
<b>Strongly Agree</b>	16	38.10	42	100.00

<b>Chi-Square</b>	22.9524
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<b>DF</b>	3
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<b>Pr &gt; ChiSq</b>	< .0001
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The exceptionally small p-value (< .0001) reflects the outstanding results of the research portal. The p-value indicates that the portal increases patient knowledge about their study and that this question has high statistical significance.

**Table 5.4: Q7 – The research online portal helped me feel more knowledgeable about my important role in the study.**

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
<b>Disagree</b>	2	4.76	2	4.76
<b>Neutral</b>	6	14.29	8	19.05
<b>Agree</b>	20	47.62	28	66.67
<b>Strongly Agree</b>	14	33.33	42	100.00

<b>Chi-Square</b>	18.5714
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<b>DF</b>	3
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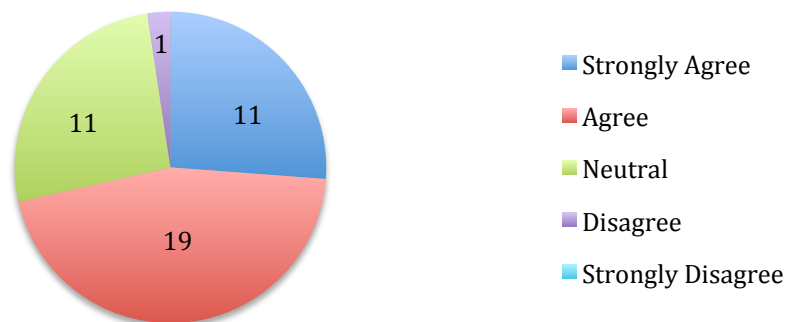
<b>Pr &gt; ChiSq</b>	0.0003
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Question 7 also has a low p-value (0.0003), signifying that the online portal also educates patients on their importance to the study they are enrolled in. Although this value isn't as low as question 1, it is still extremely significant because it is less than or equal to 0.05.

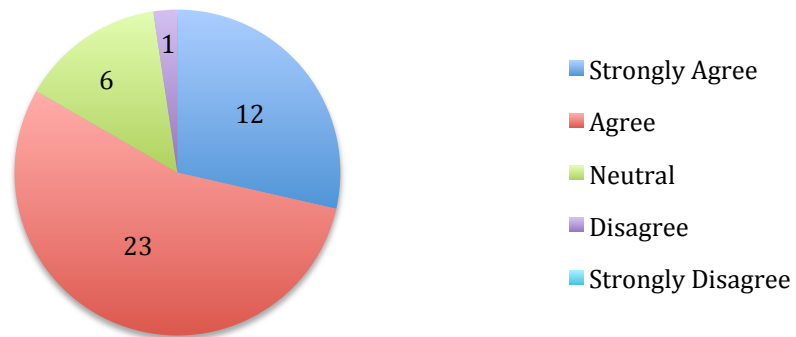
## Specific Aim II

This aim and questions 2, 3, and 4 are dedicated to determining if the portal encourages patients involvement and investment in their study. As with the questions for specific aim I, a majority of the subjects responded favorably. Moreover, 71% of the subjects stated they felt more involved in their medical care after accessing the portal (Question 2). The online portal had a more significant impact on increasing patient investment in their study with 83% of subjects answering positively (Question 3). Furthermore, the online portal is more effective at increasing study investment when compared to medical care involvement. Lastly, 74% of patients stated that they had an increased motivation to continue participating in their study after visiting the portal (Question 4). Although this is not the lowest percentage obtained for a question, question 4 did have three people who disagreed with the statement, which was the most in disagreement out of all of the statements in the survey. Some patients, although they answered positively for question 2 and 3, did not think their motivation was increased because of the portal.

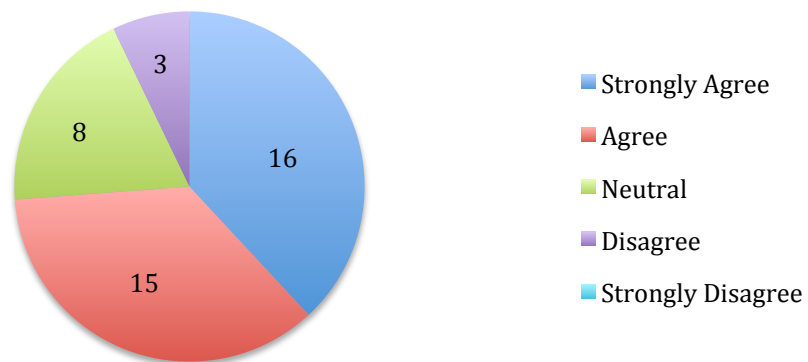
**Figure 5.3: Q2 – The research online portal made me feel more involved in my medical care.**



**Figure 5.4: Q3 – The research online portal made me feel more invested in my study.**



**Figure 5.5: Q4 – The research online portal increased my motivation to continue participating in my study.**



**Table 5.5: Q2 – The research online portal made me feel more involved in my medical care.**

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Disagree	1	2.38	1	2.38
Neutral	11	26.19	12	28.57
Agree	19	45.24	31	73.81
Strongly Agree	11	26.19	42	100.00

<b>Chi-Square</b>	15.5238
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<b>DF</b>	3
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<b>Pr &gt; ChiSq</b>	0.0014
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The p-value in Table 5.5 (0.0014) represents statistically significant data since it is less than or equal to 0.05. Patient participation and involvement is heightened by the portal, which is expected to also increase study retention rates.

**Table 5.6: Q3 – The research online portal made me feel more invested in my study.**

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Disagree	1	2.38	1	2.38
Neutral	6	14.29	7	16.67
Agree	23	54.76	30	71.43
Strongly Agree	12	28.57	42	100.00

<b>Chi-Square</b>	25.6190
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<b>DF</b>	3
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<b>Pr &gt; ChiSq</b>	< .0001
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Question 3 is another example of extreme statistical significance because of the low p-value (< .0001). As reflected in the data, the research portal increases patient investment. This is expected to increase study retention rates also. Like the other questions, more patients responded positively to question 3 than expected.

**Table 5.7: Q4 – The research online portal increased my motivation to continue participating in my study.**

<b>Group</b>	<b>Frequency</b>	<b>Percent</b>	<b>Cumulative Frequency</b>	<b>Cumulative Percent</b>
<b>Disagree</b>	3	7.14	3	7.14
<b>Neutral</b>	8	19.05	11	26.19
<b>Agree</b>	15	35.71	26	61.90
<b>Strongly Agree</b>	16	38.10	42	100.00

<b>Chi-Square</b>	10.7619
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<b>DF</b>	3
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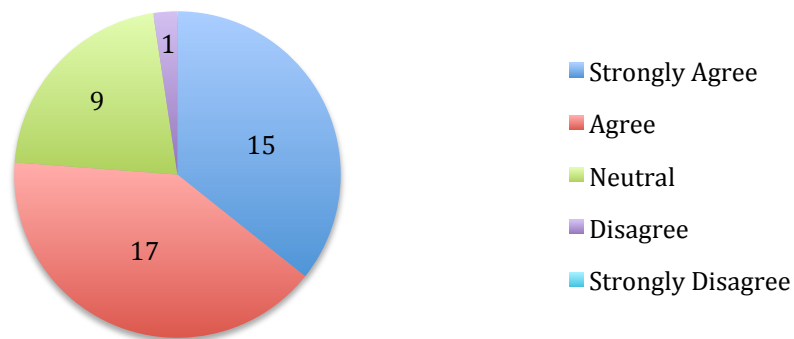
<b>Pr &gt; ChiSq</b>	0.0131
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The p-value (0.0131), although not as small as the previous p-values, is still significant. The online portal does increase patient motivation to continue participating in their study.

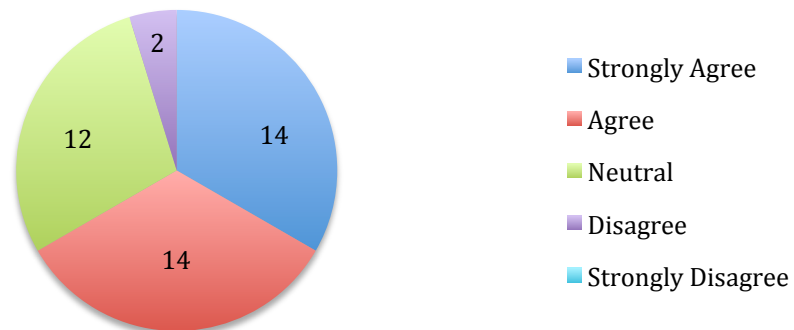
### **Specific Aim III**

This aim was directed at increasing patient communication with others and includes questions 5 and 6. While the majority of subjects responded positively, the percentage for question 6 was considerably lower. Seventy-six percent of patients agreed that the portal increased their interest in communicating with the research staff and physicians (Question 5). Unfortunately, only 67% of the subjects responded favorably to an increased interest in discussing their study with friends and family (Question 6). This is the lowest percentage for any of the questions in the survey. A large proportion of people responded “neutral” for question 6, making the percentage of patients agreeing lower.

**Figure 5.6: Q5 – The research online portal increased my willingness to communicate with the research doctors and staff.**



**Figure 5.7: Q6 – The research online portal encouraged me to talk more about my study with friends and family.**





**Table 5.8: Q5 – The research online portal increased my willingness to communicate with the research doctors and staff.**

<b>Group</b>	<b>Frequency</b>	<b>Percent</b>	<b>Cumulative Frequency</b>	<b>Cumulative Percent</b>
<b>Disagree</b>	1	2.38	1	2.38
<b>Neutral</b>	9	21.43	10	23.81
<b>Agree</b>	17	40.48	27	64.29
<b>Strongly Agree</b>	15	35.71	42	100.00

<b>Chi-Square</b>	14.7619
<b>DF</b>	3
<b>Pr &gt; ChiSq</b>	0.0020

As seen in Table 5.8, the p-value (0.0020) implies that the research portal encourages patient communication with the medical staff involved in the study they are enrolled in. The p-value is significant, with more subjects responding positively than expected to question 5.

**Table 5.9: Q6 – The research online portal encouraged me to talk more about my study with friends and family.**

<b>Group</b>	<b>Frequency</b>	<b>Percent</b>	<b>Cumulative Frequency</b>	<b>Cumulative Percent</b>
<b>Disagree</b>	2	4.76	2	4.76
<b>Neutral</b>	12	28.57	14	33.33
<b>Agree</b>	14	33.33	28	66.67
<b>Strongly Agree</b>	14	33.33	42	100.00

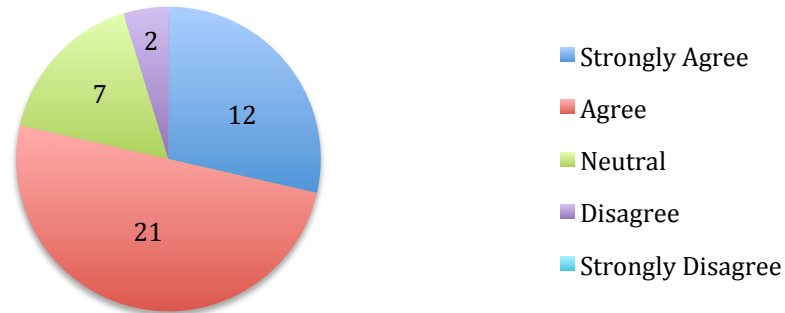
<b>Chi-Square</b>	9.4286
<b>DF</b>	3
<b>Pr &gt; ChiSq</b>	0.0241

Although this question had the largest p-value (0.0241), it is still statistically significant. This data is not as strong, but the online portal does motivate patients to talk with family and friends about the study they are enrolled in.

#### **Specific Aim IV**

The purpose of question 8 and specific aim IV was solely to determine if the research patients view the research portal as an accurate source of information. A majority of the patients considered the portal to be accurate with 79% responding favorably. Although some patients did not respond positively to the statement, “The research online portal is one of the best Internet sources for accurate medical information regarding my study,” there are many factors that could have influenced their decisions. For example, one patient stated during his office visit that he rated this question based on his confusion regarding the portal. This patient was perplexed about the terminology included in the website link at the bottom of his study’s informational page. The link took the patient to the official study website, which he did not like. The terminology and confusion caused by the website led him to negatively answer this question. Even though the information he accessed was not technically the Plaza’s research portal, it still caused him to view the portal negatively. This patient completed the survey at home, so it could not be explained to him that this question was only regarding the information provided by the Plaza Medical Center’s Research Department. Another patient said that she already received the information about the study when she enrolled, so she did not think the portal was useful. This patient had only been participating in her study for a few months, so the information given to her during enrollment was still fresh in her mind. It is also important to note that the portal can be accessed by anyone, so people who are not patients will be seeing the information provided for the first time.

**Figure 5.8: Q8 – The research online portal is one of the best Internet sources for accurate medical information regarding my study.**



**Table 5.10: Q8 – The research online portal is one of the best Internet sources for accurate medical information regarding my study.**

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Disagree	2	4.76	2	4.76
Neutral	7	16.67	9	21.43
Agree	21	50.00	30	71.43
Strongly Agree	12	28.57	42	100.00

**Chi-Square** 18.7619

**DF** 3

**Pr > ChiSq** 0.0003

Question 8 has strong statistical significance, as indicated by the p-value (0.0003).

Patients view the portal as a truthful and accurate website where they can find correct information about the study they are participating in.

## Study Related Questions Summary

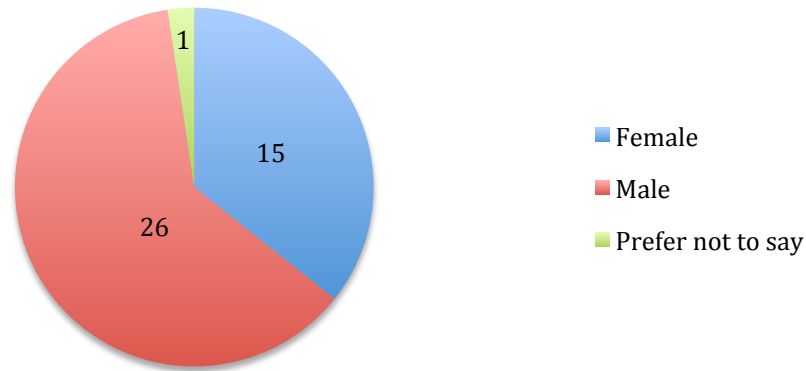
As seen in Tables 5.3 – 5.10, all of the responses for the study related questions portion of the survey resulted in statistically significant data, rejecting the null hypothesis that there is no association between the portal and patient knowledge. A majority of the subjects agreed with the statements in all eight questions, meaning the research portal is providing positive results. Table 5.11 displays the Chi-square values, as well as the p-values obtained. This was done to further simplify and combine the overall results. Again, the following parameters were used:  $\alpha=0.05$  and a degree of freedom of three.

Table 5.11: Chi-Square and P-Values for the Study Related Questions		
Question	Chi-Square	Pr > ChiSq
1	22.9524	< .0001
2	15.5238	0.0014
3	25.6190	< .0001
4	10.7619	0.0131
5	14.7619	0.0020
6	9.4286	0.0241
7	18.5714	0.0003
8	18.7619	0.0003

## Specific Aim V

This aim was directed towards defining demographical characteristics that affect the responses given in the survey. Figures 5.9 – 5.15 represent the answers given to the general information portion of the survey. Tables 5.13, 5.15, 5.17, 5.19, and 5.21 include the values obtained from the Mantel-Haenszel chi-square, which was used to analyze if there were demographical differences between responses for the study related questions.

**Figure 5.9: Q1 – Gender**



**Table 5.12: Q1 – Gender percentages**

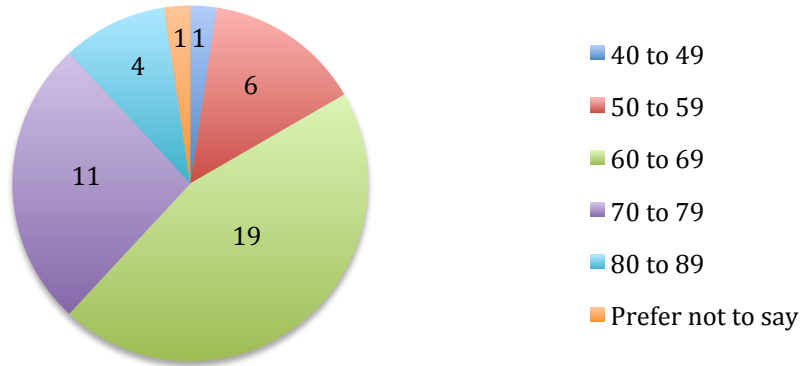
Gender	Number	Percentage
Male	26	61.90%
Female	15	35.71%
Prefer not to say	1	2.38%
Total	42	100%

**Table 5.13: Q1 – Gender**

Study Question	P-value
1	0.6422
2	0.7681
3	0.4979
4	0.8023
5	0.8565
6	0.6551
7	0.8341
8	0.5188

As seen in Figure 5.9 and Table 5.12, a majority of the subjects who completed the survey were men. There were no gender-related differences for any of the study related questions. None of the p-values were less than or equal to 0.05, which was determined using the Mantel-Haenszel chi-square method. This chi-square method may have slight errors in calculation because the data used was not evenly distributed. This is true for all of the following p-values as well.

**Figure 5.10: Q2 – Age**



**Table 5.14: Q2 – Age percentages**

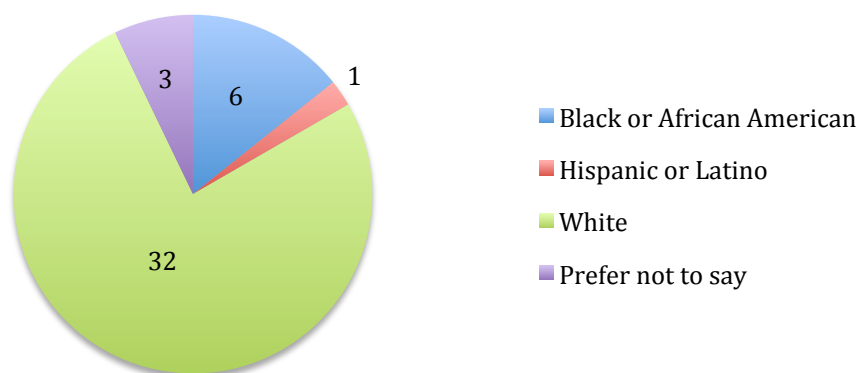
Age	Number	Percentage
40 – 49	1	2.38%
50 – 59	6	14.29%
60 – 69	19	45.24%
70 – 79	11	26.19%
80 – 89	4	9.52%
Prefer not to say	1	2.38%
Total	42	100%

**Table 5.15: Q2 – Age**

Study Question	P-value
1	0.5138
2	0.0715
3	0.6288
4	0.7912
5	0.5261
6	0.9313
7	0.1446
8	0.3731

The chart and table for question 2 represent the age for the subjects who turned in the survey. Most of the patients were in the 60 to 79 age range. Additionally, there were no statistical significance differences for any of the study related questions. Study related question 2 did have a smaller p-value of 0.0715, which was close to 0.05. However, this is still not statistically significant because it is greater than 0.05.

**Figure 5.11: Q3 – Race**



**Table 5.16: Q3 – Race percentages**

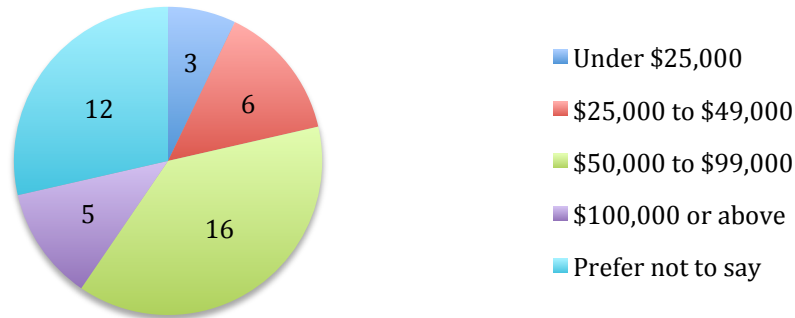
Race	Number	Percentage
White	32	76.19%
Black or African American	6	14.29%
Hispanic	1	2.38%
Prefer not to say	3	7.14%
Total	42	100%

**Table 5.17: Q3 – Race**

Study Question	P-value
1	0.3154
2	0.0817
3	0.3508
4	0.1241
5	0.0988
6	0.2683
7	0.4123
8	0.2779

Most subjects answered white for question 3 (76.19%), reflecting the typical patient demographics of Plaza. There were no significant differences in any of the study related questions based on race and ethnicity. Study related question 2 and 5 did have relatively small p-values, but again they were greater than 0.05 and therefore not statistically significant. As with all of the demographic questions, there was not an even distribution of the responses because of the small sample size and the results in the Mantel-Haenszel chi-square test could be inaccurate.

**Figure 5.12: Q4 – Estimated annual household income**



**Table 5.18: Q4 – Estimated annual household income percentages**

Income	Number	Percentage
< \$25,000	3	7.14%
\$25,000 - \$49,000	6	14.29%
\$50,000 - \$99,000	16	38.10%
≥ \$100,000	5	11.90%
Prefer not to say	12	28.57%
Total	42	100%

**Table 5.19: Q4 – Estimated annual household income**

Study Question	P-value
1	0.0902
2	0.1914
3	<b>0.0233</b>
4	0.0671
5	0.3032
6	0.4966
7	<b>0.0354</b>
8	0.0586

A majority of the patients who answered the survey were in the \$50,000 - \$99,000 annual income range. The responses to this question were more evenly distributed, but the sample size was still small, especially with over 25% of the subjects answering, “Prefer not to say.” Two study related questions, 3 and 7, were statistical significant in the Mantel-Haenszel chi-square test. The p-values were 0.0233 and 0.0354, respectively. This means that there was a difference in how the distinctive income groups answered these questions.



Subjects with higher income tended to answer these questions more favorably. It is notable that the p-values for most of the study related questions in this category were generally smaller than in any of the other demographical categories.

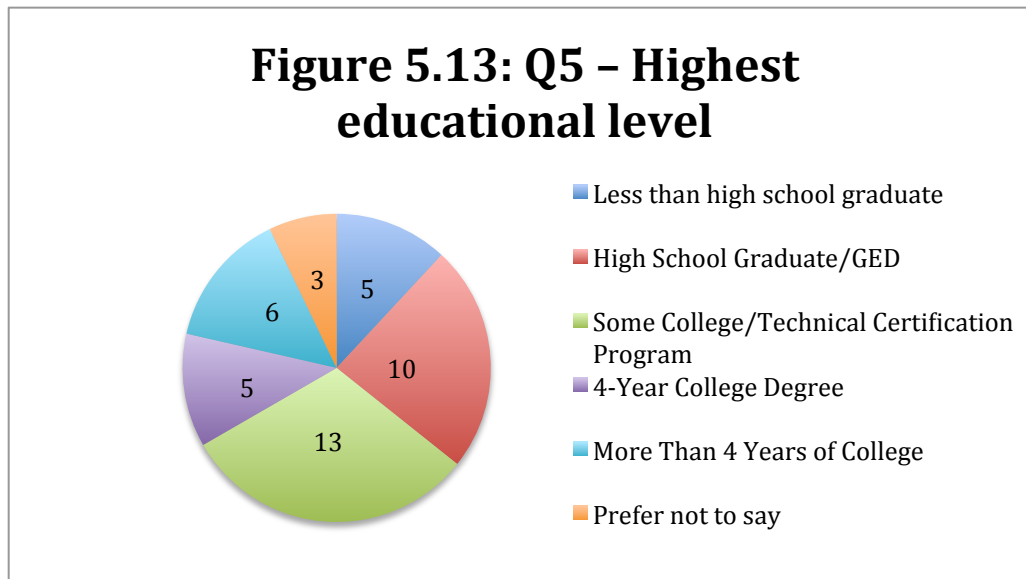


Table 5.20: Q5 – Highest educational level percentages		
Income	Number	Percentage
< High school	5	11.90%
High school graduate/GED	10	23.81%
Some college/Technical certification program	13	30.95%
4-year college degree	5	11.90%
> College degree	6	14.29%
Prefer not to say	3	7.14%
Total	42	100%

Table 5.21: Q4 – Highest educational level	
Study Question	P-value
1	0.8224
2	0.5115
3	0.6545
4	0.7330
5	0.6700
6	0.7612
7	0.6926
8	0.7231

Most subjects had completed some college or a technical certification program.

There were no demographic differences for the study related questions.

**Figure 5.14: Q6 – Do you have access to the Internet at home?**



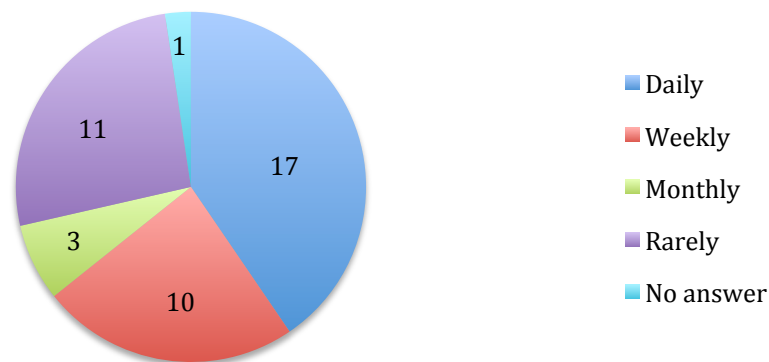
**Table 5.22: Q6 – Do you have access to the Internet at home?**

Gender	Number	Percentage
Yes	37	88.10%
No	4	9.52%
No answer	1	2.38%
Total	42	100%

**Table 5.23: Q7 – How often do you use the Internet?**

Income	Number	Percentage
Daily	17	40.48%
Weekly	10	23.81%
Monthly	3	7.14%
Rarely	11	26.19%
No answer	1	2.38%
Total	42	100%

**Figure 5.15: Q7 – How often do you use the Internet?**



A vast majority (88.10%) of the patients who answered the survey had access to the Internet at home. Moreover, most subjects (40.48%) also access the Internet on a daily basis. The Mantel-Haenszel chi-square method was not used to address either of these questions.

### General Information Summary

It was determined that the only demographical category that affected the patient answers towards the study related questions was estimated annual household income. This was the sole category that resulted in statistically significant results. Income affected both questions 3 and 7, which can be seen in the following table, Table 5.24. The small sample size, as well as the uneven distribution of answers, made this analysis less exact than the other four aims.

Table 5.24: Study Related Questions That Have Demographical Differences Based on Estimated Annual Household Income	
Question Number	Statement
3	The research online portal made me feel more invested in my study.
7	The research online portal helped me feel more knowledgeable about my important role in the study.

## CHAPTER VI

### *Significance of Practicum*

Clinical trials are vital in healthcare today because they assist in advancing medical knowledge, as well as patient care<sup>26</sup>. Those who are not familiar with the medical field often overlook this importance. In fact, some people think that clinical trials are unnecessary and driven by profit-hungry researchers. These patients want their physicians to choose the therapy that will benefit them the most. A key point to note is that sometimes physicians do not know which treatment is the best for their patients. This is one example where clinical research can step in<sup>13</sup>. Other instances involve determining the safety of a new approach or determining if a different strategy works well for a certain group of people<sup>26</sup>.

Heart disease, being the number one cause of death in the United States, has become a high priority in clinical trials<sup>16</sup>. In fact, ten percent of clinical trial participants are involved in a cardiovascular study<sup>5</sup>. Because of the prevalence of heart disease, the Plaza Medical Center of Fort Worth needs to spread the word about the value of participating in their ongoing trials. In most trials, there are personal benefits when participating. This includes more detailed medical attention and even better disease outcomes in some cases<sup>6</sup>. Certain trials also pay their participants for completing follow-up visits in order to offset travel costs or to compensate the patients for invasive procedures or protocols.

Whether the trial is directed towards cardiovascular disease or another disorder, accurate results can only be obtained with a large number of volunteers. Medicine will improve for everyone when patients are encouraged to participate<sup>13</sup>. Once patients have committed, it is also imperative to promote their continued contribution. Research staff should be easy to work with and adjust to patient needs. Additionally, keeping the patients well informed will lead to higher retention rates and therefore sample size.

The Internet online portal will not only reach out to the public, but it will also serve as an educational source for the current patients. Although the patients were informed about the details of their study when consenting, the information on the portal is a nice refresher for them. It can also serve as an easily accessible source for patients to share with their friends and family, which helps spread the word about clinical trials and their importance.

With the growing importance of cardiovascular clinical trials, it is important for researchers to obtain large sample sizes and to reach out to the general public. This project not only assisted this need by creating an online portal for the research department, but it also determined the efficiency of this newly created resource for the research staff, the current patients, and the general population.

## CHAPTER VII

### *Limitations of the Study*

#### **Limitation Due to Accessibility**

The project required each patient to review the new online research portal. When the patient did not have access to the Internet, they either could not complete the survey or were asked to complete the survey at a future appointment. Some patients in this category did not have a future appointment during the survey period, so they were not able to complete the requirements of the project. Two of the patients who were contacted did not return the survey because of this issue. Four patients who did not have access to the Internet at home completed the survey in the office after using the research department's laptop to review the online portal. However, one patient who did not have access to the Internet at home declined to complete the survey even though they were in the office for their appointment.

#### **Limitation Due to Design**

For this project, only one survey was administered to the patients of the Plaza Medical Center of Fort Worth's Research Department. The original intent of the project was to create two surveys, one for before the patient accessed the created portal and one for afterwards. The use of two surveys would have had higher statistical power, but this was

not done because of practicability. The short time frame of the internship was a limitation in this sense. With more time, two surveys could have been feasible. Unfortunately, it would have been difficult to reach an appropriate sample size if two surveys were used.

### **Limitation Due to Methodology**

For the patients who had follow-up visits during the time surveys were being collected, the methodology was simple. However, most patients did not have follow-up visits during the time frame of the internship. These patients were mailed surveys, which took time and did not guarantee delivery or return. The shortest amount of time between sending the project envelope, including cover letter, ICF, survey, directions, and prepaid mailing envelope, and return of the ICF and survey was six days. Although this is not too terribly long, the research office received only four envelopes within a week. The average time it took to receive the envelopes was 21 days. The postal service was not 100 percent reliable, causing other difficulties. For example, one patient mailed her envelope back, but the research department did not receive it. This patient thankfully filled out the paperwork again and personally returned the envelope herself. The time period could have been shortened and reliability obtained by using an Internet survey. This method requires additional precautions in order to not violate the Health Information Portability and Accessibility Act (HIPPA). This was a barrier that could not be overcome during the internship process, so a paper survey was used to retain privacy.

### **Limitation Due to Sample Demographic**

Since the average age of the research patients is 70 years old, it was difficult to obtain a high survey completion rate. Many of the older patients did not have access to Internet at home or an upcoming visit during the survey period. In addition, it was more complicated to contact these patients. Some patients could not be contacted during the entire survey period, while others said they were willing to complete the survey and never did. During additional attempts through phone calls, these patients could not be reached. Because of their advanced age, some patients who did have access to the Internet did not feel comfortable accessing the webpage or thought it was too time consuming. The study with the highest average age had the lowest survey completion rate.

### **Limitation Due to Sample Size**

The sample size for this project was limited by the number of patients the research department currently has. During my internship, there were six open studies that had patients who could be contacted. For one of the studies, not every patient was contacted because they did not have follow-up visits during the survey collection period. Additionally, this study is nearing closure, so some of the patients had finished their contribution to the study when the surveys were being distributed. For other patients who were not contacted, the likelihood of them being able to perform the tasks necessary for the project was extremely low because of factors such as age or medical condition. The patients who were approached about the project either had office follow-up visits or were contacted for phone follow-ups per the study protocol. Although the online portal is available to the general public, it was decided to only allow the surveys to be completed by current patients. This



was a good starting point for the portal, and changes to the information provided online will be made based on the current patients' responses. Another reason the sample was only taken from current patients is due to the nature of the project. Unlike most surveys, there was an extra step of accessing the online portal required from each participant. It was decided that asking the patients who have communicated with the research department before would be best and produce a higher yield than those who are not familiar with the department.

## CHAPTER VIII

### *Future Directions*

The patient survey results were important for identifying the areas of the research portal that need improvement. The Plaza Medical Center of Fort Worth's Research Department had set goals when creating the webpage. Regarding the current patients, the portal was designed to fulfill the following ambitions.

1. Enhance patient knowledge about their study
2. Educate the patients about their important role in their study
3. Increase patient involvement in their medical care
4. Increase patient investment in their study
5. Heighten patient communication with the research staff
6. Spread information about the research studies taking place with others
7. Create an accurate resource for the research patients to access

Most importantly, the portal was powerful in increasing patient knowledge about their studies. A few areas that need improvement are related to questions 4, 5, and 6. These questions can be seen in Table 8.1 shown below.

Table 8.1: Questions that Represent Weak Areas of the Portal	
Question Number	Statement
4	The research online portal increased my motivation to continue participating in my study.
5	The research online portal increased my willingness to communicate with the research doctors and staff.
6	The research online portal encouraged me to talk more about the study with friends and family.

The research staff can address the above weaknesses and edit the portal to further accomplish their set goals. Specific aim II in particular needs to be focused on. Although most patients responded favorable to questions 5 and 6, some improvements can be made to increase the statistical significance of these questions.

## CHAPTER IX

### *Conclusion*

The research portal was effective in increasing patient knowledge about their respective study according to the chi-square analysis. The portal was also beneficial for other aspects as well, such as increasing patient involvement and motivation. The null hypothesis, that there was no association between the portal and patient knowledge, was denied based on the results from the chi-square tests. Demographic factors, except for estimated annual household income, were not very influential to patient answers. The research portal is an asset to the research department, and further improvements will assist the research staff even more. With the increasing importance of research and the Internet, it is essential for research departments to take advantage of any resources available. The information provided online will inform the general public about the cutting-edge clinical research taking place at this research site.

## CHAPTER X

### *Internship Experience*

This internship was completed with the Plaza Medical Center of Fort Worth's Research Department during a six-month period. Before beginning my internship, I fulfilled the requirements put forth by the Plaza's IRB and HR department. This included National Institutes of Health (NIH) training titled Protecting Human Research Participants and routine TB testing. The research department is under the direction of Dr. Rubina Muzina, MD, MPH, CCRC. Dr. Muzina's background was beneficial throughout the internship and research project process. During the first two months of my internship, there were three research coordinators, Brenda, Bhagawathy, and Laura. However, the bulk of my internship was under the supervision of two of these coordinators. The research department was busy during my six months because they had six different research studies throughout my internship, and they added four more studies while I was there. Because of this, I was able to assist with a variety of tasks.

My internship site was a valuable resource for me to learn about working in the clinical research field. Not only did I gain patient contact experience, but I also learned the regulatory steps that are in place for clinical research. For example, I aided the research department by completing appendix documents, cover letters, and obtaining physician signatures for IRB submissions. Additionally, I attended a Plaza IRB meeting at the

beginning of my internship. This allowed me to observe the process and understand what happened to the many documents I assisted with. I gained patient contact through patient follow-up and consenting visits. Since the research department now has an array of studies, follow-up visits varied. All visits incorporated collecting information about patient adverse events or medication changes. Most visits also included a stroke scale and neurological examination, which the research coordinators would complete. Other study follow-ups included ultrasounds, dopplers, or EKGs, which required escorting the patients to the hospital. Some protocols required physicals to be preformed, and a cardiovascular fellow would come to the research office to complete them. Sometimes it was necessary to view cath lab procedures in order to determine if a patient could be included in a study. This was done after consenting the patient for the study. No matter the visit, I noticed that all of the research patients were satisfied with their care. The research staff members have created a welcoming and nourishing environment for their patients.

The research department at the Plaza Medical Center of Fort Worth is an outstanding environment for clinical research to be conducted properly. I learned an invaluable amount of information and added hands-on experience, as well as gained great mentors.

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## APPENDIX A

### Week 1

June 1-3 2015

- a) Clinical research orientation
- b) Reviewed past student projects
- c) Brainstormed thesis topic
- d) Finalized a thesis topic
- e) Completed NIH training for IRB

June 4, 2015

- a) First committee meeting
- b) Approval of thesis topic
- c) Researched background for thesis topic

June 5, 2015

- a) Met with HR about vaccination records
- b) Completed paperwork from first committee meeting

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

### Week 2

June 8-12, 2015

- a) Researched background for thesis topic
- b) Met with HR to finalize records
- c) Completed TB skin test for HR
- d) Familiarized myself with the ODYSSEY clinical trial for the research site by reviewing the complete study protocol
- e) Familiarized myself with the COBRA clinical trial for the research site by reviewing the complete study protocol

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

### **Week 3**

June 15, 2015

- a) Began research proposal draft to be sent to the UNTHSC committee for review
- b) Completed the summary, significance, research design and methodology, limitations, and chapter sections of proposal
- c) Discussed survey questions and process of survey

June 16, 2015

- a) Continued working on research proposal
- b) Modified research design and methodology section of proposal to include more details on informed consent
- c) Completed IRB Submissions Training with the IRB Coordinator at Plaza 11am – 12pm
- d) Discussed changing the survey methods and the pros and cons of only having the patients fill out one survey each

June 17, 2015

- a) Decided to change the survey methods to only include one survey
- b) Modified the research design and methodology section of proposal to include only one survey instead of two surveys
- c) Re-wrote the significance section of research proposal
- d) Started the background section of the research proposal
- e) Designed the survey, including possible questions to be included in the survey
- f) Created a rough draft of the informed consent document
- g) Research meeting

June 18, 2015

- a) Completed hypothesis and background sections of research proposal
- b) Secured a title for the practicum
- c) Completed the research proposal draft to send to committee
- d) Completed the survey questions to send to committee
- e) Completed the informed consent document

June 19, 2015

- a) Created a bibliography to include in the research proposal
- b) Adjusted survey questions to include Dr. Shi's suggestions
- c) Created the official survey on survey monkey website
- d) Filled out appendix documents for IRB
- e) Discussed information for research online portal
- f) Completed paperwork needed for IRB and turned it in – informed consent form, research proposal, final survey, CV, NIH training certificate, and appendix 1, 2, 3, 10

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

#### **Week 4**

June 22, 2015

- a) Created research binders for upcoming patients for the PLATINUM study; binders included: informed consent form, protocol, physician summary page, baseline section, index procedure section, discharge section, follow-up sections, and an antiplatelet medication section.
- b) Researched background for thesis

June 23, 2015

- a) Went through patient database for heart center to flag patients that are not labeled as research patients and need to be labeled as such
- b) Researched background for thesis
- c) Added notes to each yearly visit for the 5-year ODYSSEY study on the shared calendar
- d) Added missed appointment dates for ODYSSEY study on the shared calendar
- e) Added notes to 9 month visits for each COBRA patient on the shared calendar

June 24, 2015

- a) Finished completing research binders for the PLATINUM study
- b) Added appointment dates for each DANCE patient on the shared calendar
- c) Added notes to the appointment dates for each DANCE patient on the shared calendar
- d) Assisted in filing necessary paperwork for the PLATINUM study that was just approved
- e) Notified that my research study was approved by the Plaza IRB on 6/23/15

June 25, 2015

- a) Screened patients scheduled for Cath Lab procedures next week (6/29/15 – 7/3/15) based on their medical records for inclusion in PLATINUM study; these patients will be contacted about possible participation in the study
- b) Took better printed and colored copies of surveys and obtained IRB stamps on the new copies
- c) Put together packet for UNTHSC IRB approval
- d) Visited the Cath Lab to watch a procedure on a PLATINUM study patient in order to ask Dr. Malik questions required for the PLATINUM study

June 26, 2015

- a) Filed new paperwork in the correct locations in various patient binders for the ongoing studies at the Plaza Medical Center
- b) Created a new IRB binder for the COBRA study
- c) Created a new physician and employee directory for those involved with the research studies at the Plaza Medical Center
- d) Visited the hematology laboratory to centrifuge a patient sample and perform the correct procedures for a patient's adverse event; set up the package to ship via UPS

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 5**

June 29, 2015

- a) Filed paperwork in their appropriate patient binders (adverse events, patient visit logs)
- b) Filed paperwork in their appropriate study binders (delegation of authority logs, training logs)
- c) Screened hospital patient records for potential inclusion in research studies
- d) Added new contacts to Heart Center of North Texas Directory
- e) Began a patient list for the PLATINUM study including their scheduled window dates for their follow up visits

June 30, 2015

- a) Began writing thesis (set up format, cover page, table of contents, etc)
- b) Added patient visit window dates to the shared research calendar for the PLATINUM study
- c) Added stickers to each patient binder for the ODYSSEY study stating which arm the patient needs their BP taken at each patient visit (depending on which was higher on their first visit)
- d) Added Adverse Event Forms to every future visit section (about 25 visits per patient) in each patient binder in the ODYSSEY study

July 1, 2015

- a) Added Adverse Event Forms to every future visit section in each patient binder in the SUPERNOVA study
- b) Screened next weeks patients in the Cath Lab for possible inclusion in the PLATINUM and DANCE studies
- c) Screened Cath Lab patients for future carotid stent procedures and filled out the Medicare coverage forms for the patients
- d) July 4<sup>th</sup> office party/lunch

July 2 – 3, 2015

- a) Holiday for July 4th

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 6**

July 6, 2015

- a) Added Adverse Event Forms to every future visit section in each patient binder in the COBRA study
- b) Added a patient to the patient list document for the PLATINUM study including their scheduled window dates for their follow up visits
- c) Added the new PLATINUM patient's upcoming visits to the research shared calendar
- d) Converted research physician CVs from PDF to word documents for sponsors

July 7, 2015

- a) Sick day – stayed at home
- b) Researched background information for thesis

July 8, 2015

- a) Sick day – came to work, left at 11am
- b) Converted more research physician CVs from PDF to word documents for sponsors

July 9, 2015

- a) Sick day – stayed at home
- b) Researched background information for thesis

July 10, 2015

- a) Sick day – came to work, left at 11am to go to doctor
- b) Looked up patient vial numbers for the DANCE study and recorded them on a log
- c) Converted more research physician CVs from PDF to word documents for sponsors



Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 7**

July 13, 2015

- a) Volunteered for a TABS event at UNTHSC

July 14, 2015

- a) Scheduled a UPS pick-up to be returned to central lab, Covance
- b) Added new PLATINUM patients to patient list
- c) Added the new PLATINUM patients' upcoming visits to the shared calendar
- d) Began the CANOPY annual review IRB submission documents and cover letter
- e) Organized the study binders in order to make room for the upcoming studies
- f) Removed study binders that are unnecessary now due to closed enrollment of some of the studies
- g) Archived binders that do not need to be on site anymore
- h) Organized the shared Cath Lab research folder

July 15, 2015

- a) Wrote 3-year follow up letters for a few CANOPY patients
- b) Mailed the follow up letters for the CANOPY patients
- c) Made labels for the ODYSSEY study and placed them in patient binders
- d) Assisted in screening next week's Cath Lab patients for possible inclusion in studies
- e) Reviewed study protocols
- f) Retrieved patient snacks from the hospital

July 16, 2015

- a) Visited the mailroom to mail letters and check inbox
- b) Created labels for new studies (PROTEGO and CREST-2)
- c) Completed a cover letter and appendix 7 document for the CANOPY 48 month study status report and took the documents to the IRB coordinator
- d) Read Phong's (previous intern's) thesis to get ideas for introduction of thesis
- e) Assisted with retrieving Principal Investigator signatures at the Cath Lab
- f) Assisted with a CANOPY patient's 3-year follow up and completion visit
- g) Inputted information from the 3-year follow up into the online system

July 17, 2015

- a) Turned in research proposal and intent to graduate forms at UNTHSC
- b) Scheduled a UPS pick-up to be returned to central lab, Covance
- c) Reported COBRA patient visits that have been completed in the patient visit calculator documents
- d) Participated in the monthly Plaza IRB meeting
- e) Reviewed USPELLA IRB documents

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 8**

July 20, 2015

- a) Dropped off archive forms in the hospital office for the boxes that were archived
- b) Checked research refrigerator temperature in the hospital
- c) Picked up butterfly needles from hospital lab
- d) Wrote 3-year follow up letter for CANOPY patient and took it to mailroom
- e) Read Covance documents for ODYSSEY and filed them in the appropriate binder
- f) Wrote acknowledgement section of thesis
- g) Wrote a rough draft of the introduction section of thesis
- h) Oversaw the informed consent process with a potential patient

July 21, 2015

- a) Assisted in a CANOPY patient's 3-year follow up and completion of study visit
- b) Inputted information from the 3-year follow up into the online system
- c) Inputted information about the patient's changed medications into the online system
- d) Inputted information about the patient's completion of study into the online system
- e) Added PLATINUM patients to the complete patient list in the shared Cath lab folder
- f) Screened next week's Cath lab patients for possible inclusion in studies

July 22, 2015

- a) Printed appropriate paperwork for the new study USPELLA to be submitted to the Plaza IRB
- b) Filed appropriate paperwork
- c) Checked the hospital's research refrigerator and recorded it on the log
- d) Reviewed collected articles from previous background research
- e) Began rough draft of background section of thesis

July 23, 2015

- a) Assisted in putting together the PROTEGO study regulatory binder
- b) Edited introduction for thesis
- c) Continued/expanded rough draft of background for thesis
- d) Went to Heart Center of North Texas to achieve signatures for study
- e) Filed paperwork in appropriate binders
- f) Copied physician CV and placed it in all study regulatory binders

July 24, 2015

- a) Filed paperwork in appropriate binders
- b) Added new tabs (AE/SAE, Device Deficiency, Protocol Deviations) and related documents to all PLATINUM binders
- c) Continued writing rough draft of background for thesis
- d) Researched new background sources
- e) Made a works cited page

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 9**

July 27, 2015

- a) Filed paperwork in appropriate binders
- b) Created instruction pages for nurses involved with care for DANCE patients
- c) Updated heart center directory
- d) Wrote and mailed appointment confirmation for scheduled appointment for a CANOPY patient
- e) Wrote follow up visit reminders for a few CANOPY patients
- f) Changed works cited format and updated it with new sources

July 28, 2015

- a) Assisted with consenting a new patient for the PLATINUM study
- b) Assisted with the necessary preparations since the patient consented
- c) Assisted with spinning blood with centrifuges in the laboratory for appropriate blood tests from a patient's yearly follow up
- d) Dropped off follow up visit reminder in the hospital's mailroom
- e) Dropped off a patient's physician note log in the medical records office
- f) Filed paperwork in appropriate binders
- g) Continued rough draft of background section
- h) Edited instruction pages for nurses involved with care for DANCE patients

July 29, 2015

- a) Filed paperwork in appropriate binders
- b) Set up new cubicle space
- c) Wrote and mailed appointment confirmation for scheduled appointment for a COBRA patient
- d) Continued rough draft of background section
- e) Researched more sources for background section
- f) Assisted in consenting a patient for the PLATINUM study

July 30, 2015

- a) Filed paperwork in appropriate binders
- b) Took a physician note to medical records in the hospital
- c) Created new ODYSSEY binders with appropriate paperwork
- d) Assisted in consenting a patient for the DANCE study
- e) Edited thesis

July 31, 2015

- a) Created new PLATINUM binders with appropriate paperwork
- b) Assisted with PROTEGO new study IRB submission
- c) Created new PLATINUM binders with appropriate paperwork
- d) Faxed all study informed consent forms and protocols to colleague to upload onto server
- e) Assisted with necessary documents for the online portal
- f) Assisted with DANCE ICF revision IRB submission including cover letter and appendix 10
- g) Edited thesis

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 10**

August 3, 2015

- a) Recorded medications given to a patient and received from the same patient in the ODYSSEY medication log binder
- b) Recorded a new shipment in the ODYSSEY medication log binder
- c) Assisted with a patient follow up visit for CANOPY
- d) Made a cover letter and faxed a request for medical records from a CANOPY patient's recent ER visit
- e) Inputted CANOPY patient visit information into online database for sponsor
- f) Assisted with packaging blood work to be sent to Covance lab
- g) Scheduled a UPS pick-up to be returned to central lab, Covance
- h) Edited thesis
- i) Researched background sources for thesis
- j) Added new source information into background section of thesis
- k) Called Harris Methodist to confirm patient record request

August 4, 2015

- a) Dropped off patient record in medical records office in the hospital
- b) Checked the mail in mailroom
- c) Assisted with patient visit involving giving COBRA patient an industrial strength cooler for his medications in a study
- d) Assisted with getting physician signatures for study paperwork
- e) Blacked out patient information from recent ER visits and copied them
- f) Assisted with collecting all paperwork for new study, CREST-2, submission
- g) Edited thesis

August 5, 2015

- a) Dropped off patient record in medical records office in the hospital
- b) Checked the mail in mailroom
- c) Edited thesis
- d) Added tables to thesis background section
- e) Filed paperwork in appropriate binders
- f) Assisted with ODYSSEY patient 1 month visit
- g) Consented first patient for my thesis project and gave her a copy of the ICF form and the survey to mail back to the research office
- h) Wrote "One time use ONLY, Discard after use" on all ODYSSEY prescription cards to be given to patients for free medication needed for the study
- i) Added a conclusion paragraph to background section of thesis
- j) Added a folder with documents that include portal information on the research laptop for my project

August 6, 2015

- a) Added my study information to everybody's login desktop and favorited the website that the patients will need to look at for my study
- b) Retrieved orange juice and apple juice from hospital's kitchen
- c) Placed dividers in new ODYSSEY binders
- d) Wrote a cover letter and filled out Appendix 10 for an IRB submission to inform referring physicians that our study drug was FDA approved
- e) Printed out patient letter information about the cooler for ODYSSEY medication and took it to the mailroom
- f) Worked on thesis

August 7, 2015

- a) Worked on thesis
- b) Added new sources to thesis
- c) Website on Plaza's website went live for project
- d) Wrote a patient follow up reminder letter for DANCE and took it to mailroom
- e) Pizza lunch party
- f) Wrote cover letter to patients informing them of my project and encouraging them to fill out the informed consent and survey
- g) Printed materials needed to mail to the patients (cover letter, survey, ICF, and screenshots for directions)
- h) Put together letters to mail for project

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 11**

August 10, 2015

- a) Consented patient for my project
- b) Gave the patient survey, directions for accessing website, copy of ICF, and a prepaid mailing envelope
- c) Mailed a survey to a patient for return
- d) Changed the cover letter to send to patients asking them to complete my survey
- e) Set up directions including pictures on how to access the website and the different studies the patients are in
- f) Put together ICF forms with "sign here" and "print here" stickers
- g) Put together envelopes for DANCE patients (cover letter, ICF, survey, directions for survey, prepaid mailing envelope) and mailed them
- h) Filed paperwork in appropriate binders
- i) Went to IRB coordinator and helped her IRB stamp my colored surveys to send out in envelopes this week
- j) Picked up colored copies of directions for patients to access the website

August 11, 2015

- a) Assisted with ODYSSEY patient visit at 7:30 am
- b) Consented ODYSSEY patient for my study
- c) ODYSSEY patient looked at website at the research office
- d) ODYSSEY patient completed the survey and dropped it in the survey drop box; this was the first survey turned in
- e) Filed paperwork in appropriate study binders
- f) Made cover letter about my project to send to COBRA patients
- g) Put "sign here" and "print here" stickers on new set of ICFs
- h) Made "please mail survey & permission form back in this" sticky notes to place on all pre-paid envelopes to go into patient mailed envelope for project
- i) Put together COBRA patient directions on how to access the website
- j) Put together envelopes for COBRA patients (cover letter, ICF, survey, directions for survey, prepaid mailing envelope) and mailed them
- k) Checked refrigerator temperature for study medications
- l) Filed CMS form in patient binder in hospital and copied it for records

August 12, 2015

- a) Wrote a follow-up visit scheduled for next week reminder and mailed it to patient
- b) Dropped a patient CSA document in medical records
- c) Checked refrigerator temperature in hospital for study medications (s degrees – 6 degrees)
- d) Filed paperwork in appropriate study binders
- e) Assisted with DANCE patient 6 month visit
- f) Went with research staff to have a Doppler ultrasound done in the hospital on the DANCE patient
- g) Assisted with vital signs for DANCE patient
- h) Entered DANCE patient visit information in sponsor database
- i) Made an excel document for the DANCE study stating how many vials of Dexamethasone each patient was given during their initial procedure
- j) Put together direction packets for PLATINUM and SuperNova studies for the website
- k) Made cover letters to send to PLATINUM and SuperNova patients

August 13, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- b) Filed paperwork in appropriate study binders
- c) Added visit completion checklists and medication lists to upcoming visits of ODYSSEY patient binders
- d) Blacked out patient information on hospitalization record for an ODYSSEY patient
- e) Put together more ICF documents
- f) Put together directions for CANOPY patients to access the website
- g) Put together SuperNova and PLATINUM patient envelopes for my study (cover letter, survey, ICF, directions, prepaid envelope)
- h) Started an excel file with patient contact information

August 14, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Blacked out patient information on hospitalization records for a patient
- c) Assisted with DANCE patient visit
- d) Consented COBRA patient for my project and went over the website with him
- e) Patient completed survey and returned it via the drop box
- f) Assisted with CANOPY 3-year follow up visit
- g) Assisted in calling ODYSSEY patients about receiving the envelopes about my study
- h) Added other studies to my Excel document including patient contact information

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 12**

August 17, 2015

- a) Wrote follow-up reminders for CANOPY patients 3 year visits
- b) Mailed CANOPY follow-up reminder patient letters
- c) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- d) Approached COBRA patient during their visit at the Heart Center about my project and patient agreed
- e) Took down PLATINUM unused binder because the study is closed to enrollment now
- f) Placed paperwork in ODYSSEY binders for each upcoming visit
- g) Made an Excel document with how many ICFs and surveys have been received via mail and how many have been finished in the office
- h) Added patient phone numbers into Excel document

August 18, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- a) Printed out study information pages to give to patients
- b) Assisted with a CANOPY patient 3-year visit
- c) Consented CANOPY patient for my project and went over the website with him; patient took home survey and will mail it back
- d) Logged CANOPY patient visit information in online database for sponsor and filled out completion of study page and medication change page
- e) Assisted with COBRA patient 9-month visit
- f) Consented COBRA patient for my project and went over the website with him; patient took home survey and will mail it back
- g) Received patient surveys in mail and documented them in Excel document



August 19, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- a) Assisted with writing letter to ODYSSEY patient primary care physicians and cardiologists to remind them of the study and not to take the patients off certain medications or run certain tests
- b) Assisted with finding addresses and fax numbers for the physicians to mail and fax the letters
- c) Mailed letters to physicians
- d) Went to heart center to retrieve signatures from PI for ODYSSEY study
- e) Called ODYSSEY and DANCE patients to follow up about surveys being returned via mail
- f) Filed paperwork in ODYSSEY patient binders (visit checklist and medication lists) for each future visit
- g) Received patient surveys in mail and documented them in Excel document
- h) Took IRB documents to IRB office to be stamped

August 20, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- b) Went to hospital for hazardous waste box, hazardous waste bag, and toner for copy machine
- c) Received two surveys and two ICFs in the mail
- d) Created a binder for ODYSSEY with physician communication documents
- e) Mailed ICF form copies for my project back to patients with all signatures
- f) Called ODYSSEY patients to follow up about surveys being returned via mail
- g) Called a DANCE patient who signed the ICF for my project in the office and took the survey home to mail back
- h) Assisted with calling COBRA patients about my project
- i) Mailed out new envelope to a COBRA patient who did not receive the letter in the mail
- j) Sent out SuperNova and Platinum envelopes with my survey and other documents
- k) Met PLATINUM patient in hospital to have him fill out my survey
- l) Mailed ICF form copies for my project back to patients with all signatures
- m) Mailed FedEx package
- n) Filed paperwork from patient visits and lab reports in appropriate binders

August 21, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- b) Added all COBRA patient information into Excel document
- c) Called DANCE patient and COBRA patient about returning the survey for my project
- d) Went to physician office to approach a research patient about my project
- e) Assisted with approaching a patient about the DANCE study in the hospital before his procedure
- f) Assisted in calling COBRA patients about my project
- g) Filed paperwork in appropriate binders
- h) Mailed PLATINUM patient his ICF with all signatures

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

### **Week 13**

August 24, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Received an ICF in the mail from an ODYSSEY patient
- c) Called an ODYSSEY patient regarding my study
- d) Consented COBRA patient for my project and went over the website with them
- e) Patient completed survey and returned it via the drop box
- f) Wrote patient follow-up and confirmation letters and mailed them
- g) Sent an ICF copy with all signatures back to patient
- h) Received 3 surveys and ICFs in the mail
- i) Blacked out patient identifying information for an expired patient hospital record and an ODYSSEY patient SAE record

August 25, 2015

- a) Assisted with ODYSSEY patient randomization visit
- b) Consented patient for my project and went over the website with them
- c) Patient completed survey and returned it via the drop box
- d) Blacked out patient identifying information on a hospitalization record
- e) Filed paperwork in appropriate binders
- f) Scheduled a UPS pickup for a package to Covance labs with blood tests
- g) Created an Excel file to document the number of patients of the research department
- h) Assisted with creating appendix documents to submit to the IRB regarding the SuperNova stent FDA approval
- i) Retrieved all delegation of authority logs from study regulatory binders for PI signature involving an end date for a research coordinator

August 26, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Filed IRB documents in study regulatory documents and created new IRB documents
- c) Blacked out patient identifying information on a hospitalization record for a recently expired patient
- d) Assisted with a CANOPY patient 3-year follow up visit
- e) Entered the follow up information in the online database for sponsor
- f) Consented patient for my project and went over the website with them
- g) Patient completed survey and returned it via the drop box
- h) Received an ICF and survey from a patient

August 27, 2015

- i) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- j) Mailed ICF form copies for my project back to patients with all signatures
- k) Sent an envelope regarding my project to a PLATINUM patient who we had the incorrect address for
- l) Filed paperwork in appropriate binders
- m) Copied ODYSSEY diary and placed copies in each ODYSSEY patient upcoming visit
- n) Called patients to follow up with them about my project
- o) Mailed project envelopes to a few CANOPY patients
- p) Added site number and patient number to the top of their hospitalization record for a recently expired patient

August 28, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Created an outline for significance section of thesis
- c) Began collecting data on the received surveys
- d) Created Excel documents reporting if patients finished survey in the office or in through the mail and all dates related
- e) Received 2 signed ICFs and surveys in the mail
- f) Updated Heart Center of North Texas Directory
- g) Created binders for SMART study with tabs, required documents, patient wristbands, and research stickers
- h) Blacked out patient identifying information on a hospice record for a recently expired patient

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## Week 14

August 31, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Set up a UPS pickup for a package to Covance labs with blood tests
- c) Collected data on the 25 received surveys
- d) Tallied how many answers for each answer choice on surveys
- e) Numbered surveys for data collection
- f) Assisted with a patient follow-up visit

September 1, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- b) Added study documents to SMART study binders
- c) Updated Heart Center of North Texas Directory to include a new medical assistant
- d) Edited collected data
- e) Filed paperwork in appropriate binders
- f) Meeting on campus in the afternoon

September 2, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 3 degrees)
- a) Had copies made of the new study, CREST-2, informed consent forms
- b) Placed “sign here” and “date & time” stickers on new study, PROTEGO, informed consent forms
- c) Created new documents to tally survey answers and transferred numbers already collected
- d) Picked up orange juice and granola bars from the hospital cafeteria for the research patients
- e) Assisted with a COBRA patient 9 month follow-up visit including EKG
- f) Consented COBRA patient for my study and received their survey via drop box
- g) Went to the Heart Center of North Texas to assist with a CANOPY patient 3 year follow up
- h) Consented the CANOPY patient for my project and received their survey

September 3, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- a) Wrote a COBRA patient her visit confirmation letter and mailed it out
- b) Assisted with an ODYSSEY patient follow-up visit
- c) Picked up correct ODYSSEY patient medications at the hospital pharmacy
- d) Consented ODYSSEY patient for my project and received their survey via drop box
- e) Scheduled a UPS pickup for a package to Covance labs with blood tests
- f) Copied multiple ICFs with all signature and mailed them to patients for my project
- g) Picked up water bottle from the hospital cafeteria for the research patients
- h) Filed paperwork in appropriate binders
- i) Recorded data from recent surveys received
- j) Assisted with a CANOPY patient follow-up visit
- k) Consented CANOPY patient for my project and received their survey via drop box

September 4, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- a) Attended meeting with the VP of Plaza
- b) Edited thesis
- c) Picked up copy of the ODYSSEY investigator's brochure from mailroom
- d) Created a new patient binder for an ODYSSEY transfer patient, including all materials from their old site
- e) Wrote the hypothesis & specific aims section of thesis
- f) Began research design & methodology section of thesis

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 15**

September 7, 2015

- a) Labor Day Holiday

September 8, 2015

- j) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- a) Adjusted thesis chapter titles
- b) Edited hypothesis & specific aims section of thesis
- c) Began sample demographic section in the results chapter of thesis
- d) Received surveys and ICFs in mail
- e) Filed paperwork in appropriate binders

September 9, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- a) Assisted with a SMART patient's 1 day follow-up
- b) Explained my project to the SMART patient, who agreed to complete the survey
- c) Copied ICFs with all signatures and mailed them to patients
- d) Assisted with another SMART patient's 1 day follow-up
- e) Explained my project to the patient, who also agreed to complete the survey
- f) Received a survey in the mail
- g) Filed new IRB documents in the correct regulatory binders

September 10, 2015

- a) Began researching for the significance of practicum section of thesis
- b) Assisted with a COBRA patient's 9 month follow-up visit in the hospital
- c) Approached patient about my project, and she said she may complete the survey at home
- d) Wrote the significance section of thesis
- e) Added new sources to bibliography of thesis

September 11, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- a) Assisted with an ODYSSEY patient's follow-up visit
- b) Retrieved ODYSSEY study medications for the patient to take home
- c) Filed paperwork in appropriate binders
- d) Mailed patient letters
- e) Changed format of citing sources within thesis
- f) Assisted with reminder phone calls to patients
- g) Scheduled a UPS pickup for a package to Covance labs with blood tests

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## Week 16

September 14, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- a) Mailed patient follow-up reminders
- b) Filed paperwork in appropriate binders
- c) Wrote limitations section of thesis
- d) Wrote general internship experience section of thesis
- e) Assisted with a DANCE patient follow-up visit
- f) Dropped off records at medical records office

September 15, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- a) Retrieved ODYSSEY patient medication kits from refrigerator in pharmacy
- b) Assisted with ODYSSEY patient follow-up visit
- c) Consented patient for my project and received their survey
- d) Assisted with DANCE patient post-procedure follow-up in the hospital
- e) Created injection calendars for ODYSSEY patients and placed them in the correct binders
- f) Filed paperwork in appropriate binders
- g) Scheduled a UPS pickup for a package to Covance labs with blood tests

September 16, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Created injection calendars for ODYSSEY patients and placed them in the correct binders
- c) Assisted with a CANOPY patient 3-year follow up
- d) Entered patient visit and study completion information into online database
- e) Received survey and ICF from the CANOPY patient
- f) Created pie charts for survey answers
- g) Received ICF and survey in mail
- h) Began collecting data on age of patients that were possible subjects for my project

September 17, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Wrote “One time use only, discard after use” on ODYSSEY patient medication vouchers
- c) Filed paperwork in appropriate binders
- d) Scheduled a UPS pickup for a package to Covance labs with blood tests
- e) Copied patient ICFs for my project and mailed them
- f) Finished collecting data on age of patients that were possible subjects for my project
- g) Began collecting statistics on the surveys based on demographics

September 18, 2015

- a) Assisted with an ODYSSEY patient's first visit at our research site (transfer patient)
- b) Scheduled a UPS pickup for a package to Covance labs with blood tests
- c) Collected statistics on the surveys based on demographics
- d) Filed paperwork in appropriate binders
- e) Listened into a phone call from a monitor for the SuperNova study
- f) Assisted with disposing of expired ODYSSEY visit kits (included all blood test tubes, slides, needles for visits)
- g) Assisted with organizing the new ODYSSEY visit kits
- h) Created a new tally sheet and recorded data to verify there were no errors in recordings

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 17**

September 21, 2015

- k) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- a) USPELLA (new study) training
- b) Created a patient list Excel document for the new study, USPELLA (all patients are already known since it is a retrospective study)
- c) Created a follow-up reminder letter for a CANOPY patient and mailed it
- d) Filed paperwork in appropriate binders
- e) Continued collecting statistics on the surveys based on demographics

September 22, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- b) Edited first half of thesis
- c) Assisted with a COBRA patient's 9 month follow-up, including EKG and escorting the patient to and from the hospital
- d) Consented patient for my study and received ICF and survey
- e) Created tabs and dividers for the new study, USPELLA, regulatory binder
- f) Filed paperwork in appropriate binders
- g) Wrote and mailed a patient letter



September 23, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Edited second half of thesis
- c) Assisted with a COBRA patient 9 month follow-up visit, including EKG and escorting the patient to and from the hospital
- d) Received a survey and ICF from a CANOPY patient
- e) Entered a CANOPY patient's 3 year follow-up/end of study visit information into the online data system (EDC-electronic data capture)

September 24, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- b) Blacked out patient identifying information on an IRB submission
- c) Began printing hospital documents for patients in a retrospective study, USPELLA

September 25, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- b) Filed paperwork in appropriate binders
- c) Took paperwork out of the unused CANOPY patient binders
- d) Continued printing hospital documents for patients in a retrospective study, USPELLA
- e) Received patient survey in the mail
- f) Picked up copies of USPELLA documents from the mailroom
- g) Screened next week Cath Lab patients for possible inclusion in DANCE study and for any carotid procedures
- h) Assembled patient binders for the USPELLA study, including source documents and patient hospital documents

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## Week 18

September 28, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- b) Continued printing hospital documents for patients in a retrospective study, USPELLA
- c) Met with an ODYSSEY patient in the hospital lobby to take her to a phlebotomist to draw her blood
- d) Filed paperwork in appropriate binders
- e) Printed and added note pages to all USPELLA binders
- f) Scheduled a UPS pickup for a package to Covance labs with blood tests

September 29, 2015

- a) Out of office

September 30, 2015

- a) Out of office

October 1, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Wrote and mailed patient reminder letters
- c) Scheduled a UPS pickup for a package to Covance labs with blood tests
- d) Printed lab documents for USPELLA patients
- e) Printed source documents for USPELLA patients
- f) Filed paperwork in appropriate binders
- g) Adjusted order of USPELLA binders
- h) Added new patients and their documents to USPELLA binder

October 2, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- b) Printed follow-up visits for USPELLA patients
- c) Blacked out patient information on USPELLA documents
- d) Scanned USPELLA documents
- e) Added pictures to thesis

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## Week 19

October 5, 2015

- f) Blacked out patient identifying information on USPELLA documents
- g) Scanned USPELLA documents
- h) Wrote "One time use only, discard after use" on ODYSSEY patient medication vouchers
- i) Flu shot
- j) Picked up water, orange juice, apple juice, and granola bars from hospital's cafeteria for patients
- k) Dropped off records at medical records office
- l) Filed paperwork in appropriate binders

October 6, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 7 degrees)
- b) Blacked out patient identifying information on USPELLA documents
- c) Scanned USPELLA documents
- d) Dropped off records at medical records office
- e) Filed paperwork in appropriate binders
- f) Received a patient survey and consent in the mail
- g) Consented CANOPY patient for project
- h) Received survey via dropbox

October 7, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Blacked out patient identifying information on USPELLA documents
- c) Scanned USPELLA documents
- d) Dropped off mail in mailroom
- e) Finished collected survey answers for data collection

October 8, 2015

- a) Out of office

October 9, 2015

- a) Out of office

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 20**

October 12, 2015

- a) Out of office

October 13, 2015

- a) Out of office

October 14, 2015

- a) Filed paperwork in appropriate binders
- b) Assisted with an ODYSSEY patient visit
- c) Edited thesis

October 15, 2015

- a) Met with major professor for statistical analysis
- b) Checked refrigerator temperature in hospital for study medications (3 degrees – 5 degrees)
- c) Began analysis and results section of thesis
- d) Dropped off records at medical records office

October 16, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- b) Continued analysis and results section of thesis
- c) Added tables and charts to analysis and results section of thesis
- d) Filed paperwork in appropriate binders

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 21**

October 19, 2015

- e) Checked refrigerator temperature in hospital for study medications (3 degrees – 5 degrees)
- f) Continued analysis and results section of thesis
- g) Added tables and charts to analysis and results section of thesis
- h) Met with major professor for statistical analysis

October 20, 2015

- a) Sick day

October 21, 2015

- a) Checked refrigerator temperature in hospital for study medications (3 degrees – 3 degrees)
- b) Retrieved patient medications from hospital pharmacy
- c) Began conclusion section of thesis
- d) Scheduled a UPS pickup for a package to Covance labs with blood tests
- e) Filed paperwork in appropriate binders
- f) Edited thesis to send to committee members

October 22, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- b) Blacked out patient identifying information on USPELLA documents
- c) Scanned USPELLA documents

October 23, 2015

- a) Checked refrigerator temperature in hospital for study medications (3 degrees – 5 degrees)
- b) Blacked out patient identifying information on USPELLA documents
- c) Scanned USPELLA documents
- d) Assisted with a patient follow-up visit

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 22**

October 26, 2015

- a) Edited thesis with committee member comments
- b) Checked refrigerator temperature in hospital for study medications (3 degrees – 5 degrees)
- c) Blacked out patient identifying information on USPELLA documents
- d) Scanned USPELLA documents

October 27, 2015

- a) Checked refrigerator temperature in hospital for study medications (3 degrees – 5 degrees)
- b) Edited thesis
- c) Blacked out patient identifying information on USPELLA documents
- d) Scanned USPELLA documents

October 28, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- b) Created abstract for thesis
- c) Last edits for thesis
- d) Blacked out patient identifying information on USPELLA documents
- e) Scanned USPELLA documents

October 29, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 5 degrees)
- b) Blacked out patient identifying information on USPELLA documents
- c) Scanned USPELLA documents
- d) Filed paperwork in appropriate binders

October 30, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 6 degrees)
- b) Blacked out patient identifying information on USPELLA documents
- c) Scanned USPELLA documents
- d) Filed paperwork in appropriate binders

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_

## **Week 23**

November 2, 2015

- e) Blacked out patient identifying information on USPELLA documents
- f) Scanned USPELLA documents
- g) Filed paperwork in appropriate binders

November 3, 2015

- a) Blacked out patient identifying information on USPELLA documents
- b) Scanned USPELLA documents
- c) Filed paperwork in appropriate binders
- d) Began printing more source documents for USPELLA patients

November 4, 2015

- e) Checked refrigerator temperature in hospital for study medications (2 degrees – 4 degrees)
- f) Blacked out patient identifying information on USPELLA documents
- g) Scanned USPELLA documents
- h) Filed paperwork in appropriate binders
- i) Wrote & mailed letters to DANCE patients

November 5, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 4 degrees)
- b) Began PowerPoint for defense
- c) Filed paperwork in appropriate binders

November 6, 2015

- a) Checked refrigerator temperature in hospital for study medications (2 degrees – 4 degrees)
- b) Continued PowerPoint for defense
- c) Blacked out patient identifying information on USPELLA documents
- d) Scanned USPELLA documents

Student \_\_\_\_\_ Date \_\_\_\_\_

Mentor \_\_\_\_\_ Date \_\_\_\_\_