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Clinical research has an important role as the intermediate step before an investigational drug or procedure is approved for distribution to the public. Before an investigational drug is approved, researchers must prove there is a benefit to the public by conducting an ethical clinical research trial. This process relies on recruiting the study population that is representative of the general population. If too few individuals participate, this could skew the data and prevent the eventual approval of an investigational drug or procedure. Recruiting study participants for certain populations has become increasingly difficult, which is why this practicum report explores the communication habits of the population around Baylor All Saints Medical Center via survey. The results of this survey will help Baylor Research Institute in Fort Worth, Texas better address clinical trial recruitment by possibly implementing social media into their current recruitment practices.

ANALYSIS OF CURRENT RECRUITMENT METHODS:

MEASURING THE POTENTIAL

OF SOCIAL MEDIA

IN CLINICAL RESEARCH TRIALS

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CHAPTER ONE

INTRODUCTION

In partial fulfillment of requirements to receive a Master of Science in Clinical Research Management, students must complete a 26-week (40hr/week) internship. This project involves the internship site located at Baylor All Saints Medical Center in Fort Worth, Texas. Most of the activities performed at this site occurred under the Clinical Trials Office (CTO), which is a division of the Baylor Research Institute (BRI) housed at Baylor All Saints Medical Center. Baylor Research Institute has several locations located throughout the Baylor Scott & White Healthcare System that manage the clinical trials involving many different categories of research. Currently, there are ongoing studies involving women's studies, cardiovascular health, diabetes, transplants, and oncology at the Fort Worth location.

Recruiting patients for the variety of clinical research trials offered at BRI has been difficult for some of the more complicated studies, especially those that require travel time, long-term involvement, many screening procedures, and difficult assignments. This site has implemented recruitment methods other than the traditional poster, brochure, or physician referrals by trying to create radio ads; however, the results vary in degree of success. The topic of recruitment arose when talking about a relatively new uterine fibroid study in June of 2015. "The SONATA study" is a shortened name for "Sonography-Guided Transcervical Ablation of Uterine Fibroids." On June 15, 2015, there was a site initiation visit for the SONATA study

where the sponsor representatives reviewed information, such as regulatory binders, patient binders, staged a device demonstration, discussed Good Clinical Practice (GCP), and trained the CTO staff involved in the study about their specific electronic data capture (EDC). Because the sponsors emphasized that the SONATA study would have a high screen-fail rate, discussions on the best ways to recruit eight patients at Baylor All Saints became important.

The research staff of CTO was interested in determining if the trends in communication could elucidate the best way to create interest and reach appropriate target populations. BRI in Fort Worth conducts research on-site, but it also has partnered with clinics for specific studies. BRI continues to recruit physicians willing to work with them on new upcoming studies, but the main clinics the Fort Worth branch of BRI works with are the Diabetes Thyroid Center, Fort Worth Heart Clinic, and Texas Health Care, PLLC. In clinical research, the sponsor usually assigns a recruitment goal for each study site. It is imperative that this goal is reached because of the possibility of spending more money and time than what is originally budgeted. There is also an implication for statistically unsound data if the study, as a whole, is unable to procure the number of subjects they need from their multiple study sites. Therefore, this project involved a survey created to tabulate trends in communication for the community that directly or indirectly receive health care services from Baylor All Saints Medical Center and its affiliated clinics. The information included on the survey was the subject's gender, age, education level, and other questions concerning their use of social media. A conclusion is made on whether BRI should invest more of their effort with social media recruitment or continue using their old methods of recruitment.

BACKGROUND AND LITERATURE REVIEW

Clinical research is "the bridge" between laboratory science and clinical practice, which refers to its important intermediary role in the process of approving an investigational drug or device for public use (Rettig 2000). The allure of implementing new strategies into current recruitment practices for clinical research trials is due to the potential for direct communication with prospective research subjects (King et al. 2014). This potential is especially important when considering that approximately 86% of the trials conducted in the United States do not meet their enrollment goals within their recruitment window (Andrews 2012; Getz 2001). Tufts Center for the Study of Drug Development estimated that in 2013 as many as 37% of all sites in a given trial failed to meet their enrollment targets overall and more than 10% never enrolled a single patient (Griesel 2015; inVentiv Health Clinical 2013). Without sufficient recruitment of trial subjects, the study loses its "statistical power of predictive conclusion, as well as prolonging the time and increasing the costs associated with the study" (Shere et al. 2014; Maloff 1999; Anderson 2001; Khatri et al. 2015). In other words, without the necessary number of enrolled study subjects, the trial cannot succeed (Marks and Power 2002). This can be devastating for the success of a clinical research trial when time is an extremely important factor.

Time is Money

The incentive for companies to look for new strategies of recruitment involve the amount of time and resources invested in each trial drug or treatment. It takes nearly 10 years for a drug

to progress through the discovery and development phases into the market phase, and most of this time is spent in the clinical phase (Maloff 1999; PhRMA 2015). A typical drug spends over 6 years going through clinical trials and regulatory processes, and at least 3 years of that time is spent recruiting patients (Maloff 1999; PhRMA 2015). About 1 in 1000 compounds will advance from discovery to preclinical screening, where one-half of those will be unsuccessful in continuing to clinical trial portion. Of that amount, four-fifths of those remaining will be unsuccessful during the clinical trial phase and be unable to continue on to gain FDA approval (Maloff 1999).

Clinical trials are categorized into four different phases. Following the discovery and pre-clinical phases where a company has successfully found a viable compound and turned it into a drug that needs to be tested, Phase I will take place. This phase is where the initial safety testing for a drug is done with a small group of 100 or less healthy volunteers to test the safety of the drug when used in humans. The goal of Phase II is to measure the drug's effectiveness. Phase II clinical research trials will attempt to measure the safety and efficacy in a small group of about 100 to 500 volunteers. Afterwards, researchers will attempt to demonstrate the safety and efficacy of a new drug on a large group of about 1,000 to 5,000 patients in multiple locations around the world during Phase III. Lastly, the purpose of Phase IV is to gather additional information, such as additional safety information, post-marketing researching, and additional risk-benefit analysis (*Battelle Technology Partnership Practice, PhRMA* 2015; PhRMA 2015; "Clinical Trial Phases" 2008; Getz 2001).

Due to recruitment problems, the original timelines for Phase II through Phase IV studies usually end up doubling to meet desired enrollment levels, which means drugs or devices take more time to get to market (Griesel 2015). An inability to meet enrollment goals and deadlines

can contribute to significant costs for the study sponsor, such as a suggested cumulative loss of $1.3 million in sales per day for a new drug candidate (Getz 2001). Another reference pinpoints prospective losses as being as high as $37,000 in operational costs and between $600,000 and $8,000,000 in lost opportunity costs for each day of delay (Griesel 2015), and yet another reference estimates the average cost of researching and developing a successful drug to be about $2.6 billion (PhRMA 2015).

Clinical trials are long extensive processes that account for a large portion of a patented drug's life span, which means that for the 4,360 or so new drugs trying to gain regulatory approval, the potential to reduce related costs and time invested at this stage of the drug's or device's life is an important concern for sponsors. It follows that finding ways to maximize efficiency during this time has become a priority for many clinical research trials (Drennan 2002; Maloff 1999; Rettig 2000). The most common areas for delay during a clinical research trial involve patient recruitment and enrollment and study site initiation. In 1999, it was found that 45% of delays was due to patient enrollment and 25% to study site initiation, which contributed to 70% of study conduct delays (Maloff 1999). Pharmaceutical companies already have slim chances of success in terms of discovering viable compounds, which is pinpointed at 0.1% (Maloff 1999). These delays, combined with the costs associated with drug development, provides an even more important motivation to find a faster route to market for new drugs, especially when the money from successful drugs are used to sustain ongoing research and development expenditures (Maloff 1999). However, the overall probability of clinical success is estimated to be less than 12%, which includes the likelihood of a drug entering clinical testing and being eventually approved (PhRMA 2015).

Tapping into Contemporary Communication

The possibility of using social media in clinical research trial recruitment is an interesting option because today's population has become more reliant on social media to communicate with peers, family, and even strangers. It is reported that 88% of all U.S. adults own a cell phone, including seven in ten seniors (inVentiv Health Clinical 2013). It is a general misconception that social media would be an ineffective way to target individuals over the age of 50 years; however, besides the previous statistic for cell phone use, one in three online seniors will also use social networking sites such as Facebook. Individuals are not only using social media and new technologies to communicate with others, but they are also using it for greater access to information. There are a plethora of downloadable medical applications (apps) for cellular devices that are designed to make it convenient for individuals to access healthcare information. The fact that 33% of U.S. adults use social media to gather medical information, share symptoms and experiences, or rate drugs, providers and health plans illustrates how individuals are starting to rely on the Internet to retrieve healthcare information for themselves and others (inVentiv Health Clinical 2013). The Internet is also one of the first sources people will consult after receiving a cancer diagnosis, which indicates how individuals are becoming more proactive in learning about their health care options (Anderson 2001; Thompson 2014). The Pew Research Center reported that about 71% of U.S. adults between the ages of 50-64 years look online for health information. It also found that 58% of those over the age of 65 years also use online resources for the same reason (inVentiv Health Clinical 2013). These numbers show how social media has become a popular strategy for the dissemination of information across a wide range of

age groups. Because the Internet has afforded individuals the ability to take greater ownership of their health by opening more opportunities for communication and greater access to information, it would seem that social media may be the most logical focus to address the issue of poor recruitment (Shere et al. 2014). The importance of time was emphasized by a study of a Clinical Trials Group performed between 1986 and 1996. This study found that trials were more likely to succeed when they were able to achieve high rates of enrollment within the first two months of recruitment (Maloff 1999). This finding further emphasizes the importance of recruiting efficiently, and social media may aid in this endeavor because of its ability to spread information quickly.

Current Recruitment Strategies

Before the popularity of using social media to communicate within one's own communities, recruitment efforts have been predominantly completed via conventional methods or "traditional media," such as print media, mass media, or grassroots efforts (Griesel 2015; Andrews 2012). The pharmaceutical industry is rarely directly involved in the recruitment process and relies on investigational sites in a variety of different geographic areas to recruit the required study patients (Drennan 2002), which means investigational sites are responsible for finding and consenting the number of patients they were contracted to find by the Sponsor. Common consequences of inefficient recruitment efforts include delay in trial start time due to lack of test subjects, increases in budgets to address the lack of subjects, and analyses that are weak because there was not enough data collected for a proper evaluation (Andrews 2012; Shere

et al. 2014; Maloff 1999). Social media may be able to help address these problems, but it is not without its own weaknesses.

Classification of Print Media

Print media refers to items such as brochures, newsletters, posters, and newspaper ads. This has been a popular method of recruitment for quite some time; however, print media is also limited by geographic reach because its success in garnering attention depends on who happens to see the material (Andrews 2012). For example, to be successfully recruited via a clinical trial poster would mean the potential subject would have to stumble upon the exact poster's location, read its contents, contact the appropriate parties for more information, and then consider participating (Getz 2001). This would make it difficult to reach large numbers of subjects in a short amount of time. The study would also have to consider the costs associated with designing, printing, and distributing these items. If too much of the material is printed, the consequence would be a waste of funds, and if too little of the material is printed, the consequence would be the potential to fail to advertise adequately (Andrews 2012).

Classification of Mass Media

Drennan reports that in the year 2000 print advertising was still used with relative success, but radio and television advertising became more common because of their ability to

reach a wider audience (Drennan 2002). Mass media refers to television or radio, which are able to reach a wider geographical audience compared to print media (Anderson 2001; "Mass--Media" 2015). Unfortunately, this form of advertisement can be expensive because of the costs associated with production and reserving optimal time slots. Sponsors must also consider who their target population is and what radio stations or TV channels they would be more likely to tune into.

Another problem is that it is a common occurrence today for people to have bought or recorded programs that allow them to circumvent recorded advertisements, such as a digital video recorder to avoid TV commercials or iTunes to avoid radio ads by directly purchase music to play on their own devices. Grassroots efforts involve physician referrals or family and friend referrals and may be the most intimate method of connecting with potential subjects (Andrews 2012). However, there is evidence that suggests that approximately two-thirds of enrolling patients are self-referred due to external recruitment efforts, as opposed to being referred by physicians (Anderson 2001). Physician referrals are the method used most often at Baylor All Saints in Fort Worth. In situations where recruitment has been especially difficult, this internship site has created radio ad scripts to attempt to reach a wider audience. Both print and mass media can be classified as passive recruitment strategies that do not necessarily guarantee high returns, even though it may incur high costs (Shere et al. 2014).

Classification of Social Media

With social media or social networking sites (SNS), there is a greater potential to reach the appropriate audience and recruit in a timely manner because these web-based sites allow mass communication to occur, thus, creating instances where new information and ideas can be disseminated and discussed (Shere et al. 2014; Andrews 2012).

Social media is defined as "websites, technologies, and software applications used to interactively communicate and share information" for social or professional contacts, and most companies report that the use of social media for clinical research purposes started in 2010 or later (Lamberti et al. 2014; "Social-Media" 2015). Some popular methods of communication via social media are Twitter and Facebook. Twitter users have the ability to immediately share the events that have happened in their life via "tweets" limited to 140 characters (Andrews 2012; Khatri et al. 2015). In terms of being able to communicate quickly and succinctly, Twitter is the best example. Users have the ability to post short messages that may contain links to images, videos, blogs, news articles, etc. Other users or followers can then "retweet" these original tweets and share the content with their own followers. This means that one tweet has the potential to be seen by an enormous number of individuals (O'Connor et al. 2014). Twitter could also help foster interactive communication because "hashtags," which are short phrases, words, or acronyms, help users search for similar tweets. According to Farris Timimi, MD, the Medical Director for the Mayo Clinic Center for Social Media, physicians should get into the habit of interacting with patients through these means. He cites new hashtags that may be specific for certain diseases such as "#CardioOnc" as helping them "recognize and potentially track cross disciplinary topics including potential collaborators for clinical trials" (Thompson

2014). Large organizations like the U.S. Food and Drug Administration (FDA) and National Cancer Institute (NCI) have also resorted to communicating with various populations with the possibility of educating them about clinical trials (Thompson 2014); however, drug sponsors primarily use social media for commercial purposes only, such as distributing information and getting consumer feedback about their products (Lamberti et al. 2014).

Facebook is another popular method that many people use to communicate with friends, family, and even strangers all over the world. Since its launch in 2004, it has grown exponentially and reached 400 million users worldwide by March 2010 (Andrews 2012). By 2013, Facebook boasted 1.11 billion members from all over the world (inVentiv Health Clinical 2013). Facebook involves adding or rejecting friends. Accepting a friend request allows both people to appear on each other's "newsfeed", which is a constantly updated list of one's friends' activity on Facebook. Facebook users have the option of posting comments, pictures, and links on each other's "timeline", which is a web page specific to that individual. They also have the freedom to decide who is able to see the content on their timeline. A common occurrence is for companies to create Facebook pages, which allows them to advertise their products to interested groups of people and listen to the feedback that the users on Facebook give them. It is an interactive process that reflects the modern concept of communication (Andrews 2012).

Comparison of Current Recruitment Methods

Advantages of social media are many and include that it is cost effective, efficient, fast, convenient, and interactive (Anderson 2001). Social media is "largely a free-to-use medium,"

which can be used to target individuals who may not be "engaged within standard professional or institutional contact networks" (Khatri et al. 2015). Using the example of a Facebook page, a company could provide information about their product. If another Facebook user becomes interested, they have the option of asking questions or giving feedback immediately on that company's Facebook page. This opens up opportunities for direct communication and would allow potential buyers to become more informed about the product before initiating a purchase. With social media, clinical studies would be able to reach a wide audience in a short amount of time, in which case forms of communication like Facebook and Twitter are perfect candidates because of their current popularity. There is a potential to meet recruitment goals on time or ahead of schedule due to the time saved with this recruitment method (Andrews 2012; Anderson 2001; Griesel 2015).

Many individuals have handheld devices that allow them to continue using social media everywhere they go. The conveniences of having access to many outlets of communication have influenced the way people use their portable electronic devices. As mentioned previously, people now, more than ever, consult the Internet for health information (Anderson 2001; Andrews 2012). Although there are concerns with confidentiality, social media opens the doors to increased recruitment potential. Social media also makes it a reality to more accurately target a specific patient population, and, therefore, concentrate recruitment efforts on the appropriate group of people. There is also a degree of interactivity because interested potential subjects that have questions could ask for more information than what is provided on a poster or brochure. They could have a variety of questions such as those involving the possibility of traveling, what medications they would need to stop taking, or if there are additional expenses involved in their part. Because of the ease of communication, it has enabled individuals to receive information

faster than ever, which people have come to expect. If a person has questions, they want answers to those questions as soon as possible (Andrews 2012).

In contrast to print and mass media, which are classified as passive recruitment strategies, social media is more of an active recruitment strategy because personal research is usually what leads them to a particular ad about an upcoming clinical research opportunity. Print and mass media, on the other hand, involve chance occurrences of people hearing or reading about upcoming research via posters, brochures, radio ads, etc. Once they happen upon these forms of recruitment, they must decide if they are interested. For social media, these individuals have decided that the subject already interests them (Shere et al. 2014; Anderson 2001).

A recent study found that social media acted as an "adjunct" to traditional recruitment methods, accounting for 18.2% of collaborator registration in a short period of time with no associated financial costs (Khatri et al. 2015).

Current Concerns with Social Media

Although the use of social media shows promise, it is not without some challenges. Because social media affords individuals easier communication electronically, there is the implication that personal data could be at risk for hacking and confidentiality breaches. The purpose of the Health Insurance Portability and Accountability Act of 1996 was to protect patient health information, but this would be put at risk if somehow someone were able to gain access into certain databases. The simplest solution would be stronger electronic security methods; however, the specifics of that are unclear. There is still the possibility that social media

recruitment efforts could be misleading to subjects. It is important for studies to be transparent with potential subjects or risk promising cures or benefits to subjects that could sway their participation. These recruitment methods would also be prohibited from promising monetary gain for participating because it could be seen as coercive (Andrews 2012). The gray areas surrounding the use of social media is precisely the reason why biotech and pharmaceutical companies have been slow to engage others on social media because they fear there would be regulatory violations, bad public relations, or other consequences due to the relative unexplored nature of social media in clinical trials (Thompson 2014).

Currently, there is no clear FDA guidance regarding the use of social media as a means of recruiting subjects for clinical trials. Social media and forms of communication have quickly evolved in a short period of time, yet the government has been slow to respond to this huge growth. Having the government generate some form of regulation would be the best way to assure patient safety, especially due to the fact that there is little regulation for the use of social media in clinical trials. Although social media would allow easier communication with potential subjects, there lies the risk of giving too much information and overwhelming these subjects as well. Companies will have to decide how to effectively relay information to subjects over the Internet in an efficient manner (Thompson 2014; inVentiv Health Clinical 2013; Andrews 2012).

It is also important to note that although social media can reach a wide range of individuals, it cannot reach everyone. For example, some individuals do not have access to computers or cellular devices, and even though the older generation of people are finding themselves becoming more assimilated into the technology era, there would be certain people within these groups where it would be inefficient to recruit them via social media (Andrews 2012; Khatri et al. 2015). Social media users may also differ from the general population, which

could introduce selection bias by possibly over-representing the individuals who happen to spend more time on social media (Khatri et al. 2015). An interesting trend is how 86% of internet users between the ages of 18-29 years use social media compared to the 34% who are aged 65 years and older that also use social media (inVentiv Health Clinical 2013). There are other trends worth noting as well. For example, social media users tend to be typically more educated and better off socioeconomically (Getz 2001; Frandsen et al. 2014), which makes the implication that certain demographics may be left out. However, because social media use is "becoming more mainstream" and the age of the average Facebook user has continually increased (Frandsen et al. 2014), the potential to reach a wider audience via social media makes it an interesting endeavor for clinical trials to use as a recruitment method.

Another concern that should be noted is that just because an organization is better at recruiting and attracting attention does not mean that they will be successful in retaining those patients. Only one out of every twenty patients who respond to a recruitment strategy will actually complete a trial. Also, only one of five patients who respond to a recruitment promotion will actually show up for an initial screening appointment (Getz 2001). However, it is important to educate as many people about a clinical trial as efficiently as possible to compensate for an inability to retain all study subjects.

CHAPTER TWO

SPECIFIC AIMS

This practicum tests the hypothesis that alternative recruitment strategies, specifically implemented use of social media, will have a positive impact on the amount of patients successfully recruited for clinical trials in the population served by Baylor All Saints Medical Center. Many individuals of different demographic backgrounds use social media. Communication trends will be examined and used to determine if demographic differences will determine how an individual chooses to communicate. This practicum will suggest future recruitment strategies based on the information tabulated from the community on their preferred method of communication. Different clinical studies have varying requirements and populations they are trying to target for their trials. Depending on each study, different demographics may be needed to test a novel drug or treatment, which also means different recruitment strategies may be needed to attract the appropriate number of subjects. These special populations will be addressed and specific recruitment strategies suggested by the end of this practicum.

Aim 1: To study the general trends in communication for the community that the Clinical Trials Office (CTO) at Baylor All Saints Medical Center serves.

Aim 2: To determine if demographic differences will determine how one chooses to communicate.

Aim 3: To suggest implementation of specific recruitment methods that takes into account the way the community communicates and the different demographics a future study may be targeting.

SIGNIFICANCE

Clinical research has a storied history that spans the first recorded trial studying legumes in biblical times to the modern day clinical trials testing novel drugs and therapies. Throughout this time clinical trials have undergone an evolution because of changes concerning its scientific, ethical, and legal regulation (Bhatt 2010). During its evolution, the ethical implications of clinical trials came to the forefront and brought about several efforts to protect the rights of humans, including the Nuremberg Code, Declaration of Helsinki, Belmont Report, and the 1996 International Conference of Harmonization Good Clinical Practice guidance (Bhatt 2010; Getz 2001). These momentous changes helped define what constituted appropriate conduct in scientific trials performed on human beings because they came about as a response to previous missteps due to the inhuman treatment of individuals during World War II. The Belmont Report specifically discusses upholding three basic ethical principles: respect for persons, beneficence, and justice (ASH 2015). The protection guaranteed to human subjects also encompasses indirect means of their involvement, including guidelines enforced on advertisements and recruitment strategies. Now, it is important to meet IRB and FDA requirements for ethical treatment of human subjects and further guidance on what constitutes as appropriate methods to recruit patients relying on their anonymity in deciding to participate.

Subjects have always been important for the successful completion and validity of clinical trials; however recruitment has traditionally been given lower priority. This is due to clinical trials being largely conducted by academic medical centers in the past where there were

large numbers of willing participants available. Recruitment is considered to be the responsibility of the individual study sites conducting the studies (Anderson 2001). Much of a drug's life time is spent in the clinical research phase where slow progress in recruitment can lead to a delay in study completion and increases in costs (inVentiv Health Clinical 2013; "Clinical Trial Phases" 2008; *Battelle Technology Partnership Practice, PhRMA* 2015; PhRMA 2015).

In order to test the effectiveness and efficacy of drugs throughout these phases, a testing population that fits specific characteristics is needed; however, it is incredibly difficult to recruit the number of patients required for each study site (inVentiv Health Clinical 2013). Recruitment is important in this aspect because the effectiveness and efficacy of a procedure or product cannot be statically proven without an appropriately sized test population. In summary, having a large pool of subjects to test a product helps a research trial obtain reliable data in a timely manner without raising the costs allocated from the budget to recruitment efforts (Shere et al. 2014), and addressing the inefficiencies of current recruitment methods may elucidate better strategies to shorten the timeline afforded to recruiting patients and save the sponsors time and money (Andrews 2012). While recognizing there are ethical considerations when recruiting, social media offers an interesting option for clinical research trials to recruit interested subjects.

CHAPTER THREE

MATERIAL AND METHODS

In this practicum, the trends in communication by the CTO at Baylor All Saints Medical Center are addressed. The aims of the practicum are accomplished by distributing an anonymous questionnaire to the study population (see Appendix B). The first section of the questionnaire collected data regarding the age, gender, education level, race, and insurance status of the study subjects. The next section of the questionnaire asked specifically, in multiple-choice form, if they have participated in research trials, how they would like to receive information about clinical research trials, and how they communicate on a daily basis. The population sampled was individuals that came into the hospital or select medical clinics associated with the Baylor Research Institute during the time period of August 24th until October 9th. An amendment was made at the suggestion of the major professor to extend the survey to the University of North Texas Health Science Center (UNTHSC), and these surveys were collected from October 27th until October 28th. The total number of surveys collected after the amendment was 265. There were 215 surveys on October 9th and 50 more surveys were collected from UNTHSC. The study excluded individuals who were younger than 18 years of age and those that could not read English. Because the survey was anonymous, there was minimal risk involved for the subject. There were no plans to contact subjects for any reason after the completion of the survey, and their contact information or any other identifying information was not required to complete the survey. There were no expected benefits for the subjects participating in this study. Their input

was used as a means to study the best forms of reaching out to interested individuals for studies and will help the Baylor Research Institute with their future recruitment efforts.

The survey was distributed to Baylor All Saints Medical Center common areas, including waiting rooms and the cafeterias. It was also distributed at clinics affiliated with Baylor Research Institute, such as the Diabetes and Thyroid Center (DTC) in south Fort Worth and the Texas Health Care facility located in the Professional Pavilion Building adjacent to Baylor All Saints Medical Center. Both of these locations were chosen because they are sites that the CTO staff are contracted to collaborate with on clinical research trials. As CTO relies on physician referrals for the majority of their recruitment efforts, it was important to include these individuals in the survey because they are the population that CTO would want to target in the future. These individuals were allowed about ten minutes to look over the study cover letter, decide it they would like to participate, and complete the short questionnaire. The survey was also distributed on the UNTHSC campus, specifically at Gibson D. Lewis Library.

The Baylor Institutional Review Board (IRB) approved this study and all related material on August 4th, 2015. After the Baylor IRB approved the study, the eight-question survey and all other material (see Appendix C) were submitted to the UNTSHC IRB, which approved all material on August 19th, 2015. On October 14th, 2015, the Baylor IRB approved an amendment to the study. An additional survey site was added. After Baylor IRB approval, the UNTHSC IRB also approved the new changes on October 16th, 2015. The reason for this change was to compare the two populations and allow for a statistical analysis via the two-way ANOVA test.

Statistical Analysis

Once the surveys were collected, the results were entered into Microsoft Excel and separated by demographic information. Afterwards, the data was tabulated and analysis conducted using the statistical program software, "GraphPad Prism." This program was also used to create the graphs and tables. A chi-square test was performed on data first because the data is categorical in nature. There are at least two nominal variables and they have one or more possible values. The goal is discover if the proportions for one variable are different among values of the other variable. The chi-square tests the hypothesis of independence and will show if there is an existence of nonexistence of the relationships between the variable that are investigated (McDonald 2014). A two-way ANOVA statistical analysis was also performed. This test requires one measurement variable and two nominal variables. It tests three null hypotheses: that the means of the measurement variable are equal for different values of the first nominal variable, the means of the measurement variable are equal for different values of the second nominal variable, and there is no interaction (McDonald 2014). Both tests were performed with an alpha of 0.05.

CHAPTER FOUR

RESULTS AND DISCUSSION

The first group of surveys was collected from August 24th until October 5th. The total number of surveys originally collected was 215, but with the new IRB amendment this number grew to 265 with the last surveys being collected on October 28th. Figure 1.1 shows the overall demographic data of survey subjects for the 265 survey participants. The age makeup of the 215 survey participants at Baylor All Saints was relatively equal in distribution with 20% within the age range of 18 and 29 years, 32% were between 30 and 49 years, 27% were between the ages of 50 and 64 years, and 21% were 65 years and older. The study population at UNTHSC consisted of 98% of study participants that were between the ages of 18-29 years (Figure 10.1, see Appendix D). With the additional surveys taken at UNTHSC, the total percentage of subjects between 18-29 years of age increased from 20% to 34% overall. The total percentage of those between the ages of 30-49 years decreased from 32% to 26%. The age groups for those 50-64 years and those 65 years and older also experienced a slight percentage decrease due to the increase in individuals at UNTHSC who were mostly were been the ages of 18-29 years.

The gender comparison of the survey participants was 72% female and 28% male at the Baylor Research Institute sites, while the participants from the UNTHSC campus consisted of 32% females and 68% males (Figure 10.2, see Appendix D). This is not surprising considering Baylor All Saints was voted the "Best Workplace for Women" in 2013 by the Fort Worth Chamber of Commerce and proudly display these banners throughout the hospital. It is also important to consider that women are traditionally the caregivers in a relationship, so it was not

odd to see more women in the waiting areas of the hospital (*Family Caregiver Alliance: National Center on Caregiving* 2013).

The race makeup of the first 215 surveys distributed at Baylor was 20% African American, 7% Asian, 61% Caucasian, 11% Hispanic, and 1% as other. The study population at UNTHSC differed in that the distribution of race is as follows: 4% African American, 60% Asian, 26% Caucasian, 6% Hispanic, and 4% other (Figure 10.3, see Appendix D). The percentage of Asians increased from 7% to 17% overall and all other races experienced an overall decrease because of the additional individuals who identified as Asian (see Figure 1.1).

The highest level of education for those surveyed also varied. About 20% from the Baylor sites had obtained a high school degree or less. There were 32% that had some college and 45% that had a college degree or more. About 3% or seven study participants who did not indicate their highest education level obtained. At the UNTHSC site, 96% of the participants from that study population had a college degree or more and 4% had only completed some college. No participants indicated that they had obtained a high school degree or less (Figure 10.4, see Appendix D). This is not surprising, considering UNTHSC is a higher-education academic institution.

The last demographic question asked was if the surveyed individuals had insurance. Approximately 82% of survey participants at the Baylor sites indicated they were insured. 7% of study participants were uninsured, 4% had Medicaid, 1% said they did not know, and 6% of the surveyed subjects did not indicate their insurance level. The reason for a subject not responding to any of these questions could be because the subject absentmindedly forgot to fill out all questions or it was information they did not want to share with study staff. The study

participants from the UNTHSC site consisted of 94% insured, 4% uninsured, and 2% had Medicaid (Figure 10.5, see Appendix D).

The rationale for requesting this data from the subjects participating in this study is because there are several stereotypes associated with a person's likely participation in clinical trials. According to (Getz 2001), the median age of the U.S. population is thirty-six years, while the average clinical trial subject is forty-three years. The median household income of the overall U.S. population is about $40,000 per year. In contrast the median income for the average clinical trial participation is about $33,000 per year (Getz 2001). The education level of the average clinical trial participant also differs from that of the general population. Only 72% of clinical trial subjects have a high school education or higher, and 38% of subjects will have taken some college classes or will have completed college. In contrast, there are 82% in the general population that have at least a high school diploma, 49% will have some college education, and 29% of the overall population has a bachelor's degree or higher. The U.S. Census reports that 71% of the general U.S. population is Caucasian, 12% are African American, 12% are Hispanic, and 4% are Asian (Getz 2001). For clinical research trials, it has been postulated that minorities are underrepresented in these studies (Getz 2001). There are also stereotypes associated with Internet users. In 2001, Internet users were better educated, had higher household incomes, and may have had a higher likelihood of completing a study (Getz 2001).

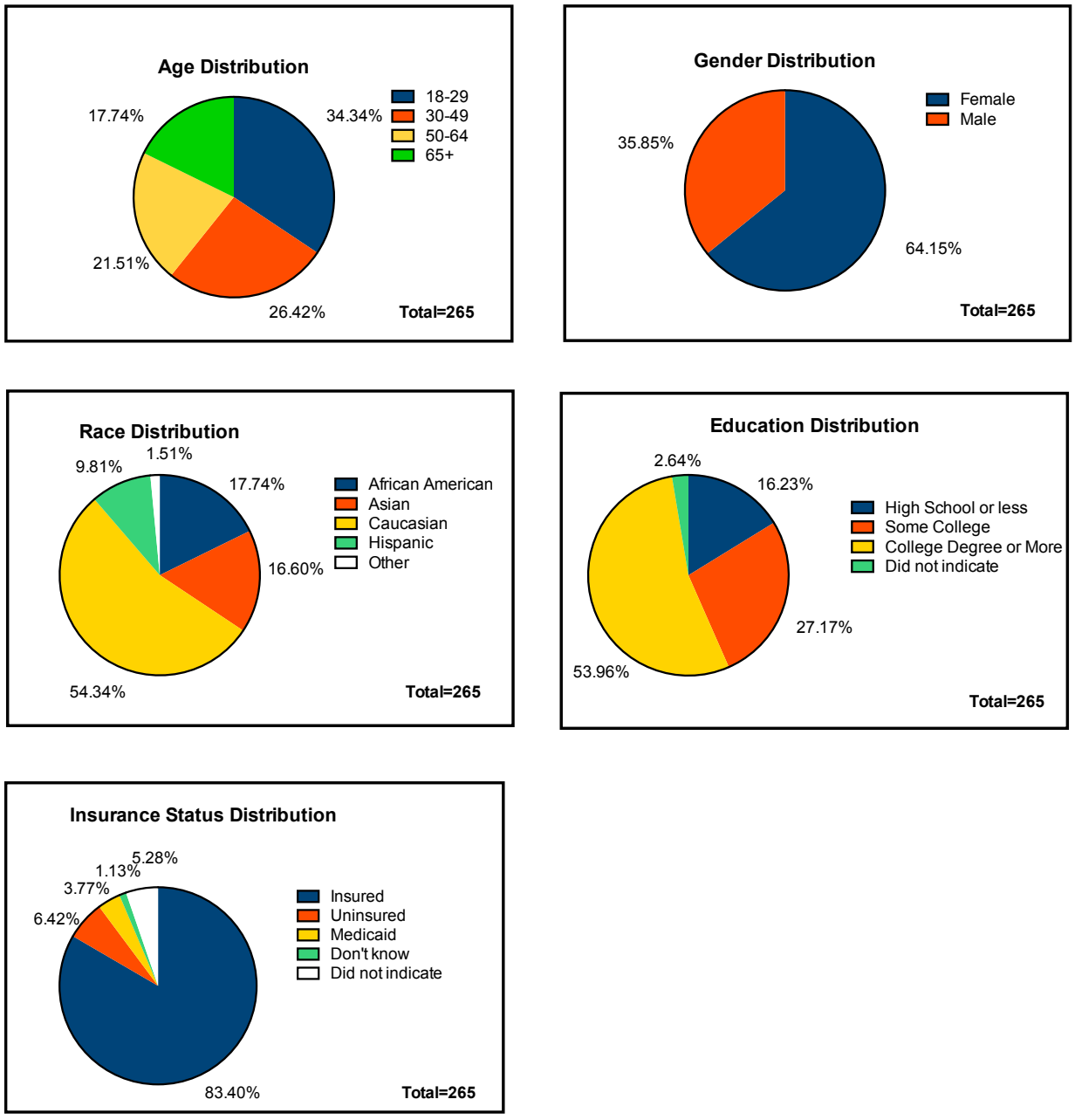


Figure 1.1: Overall Demographic Information from Surveys

Question 1

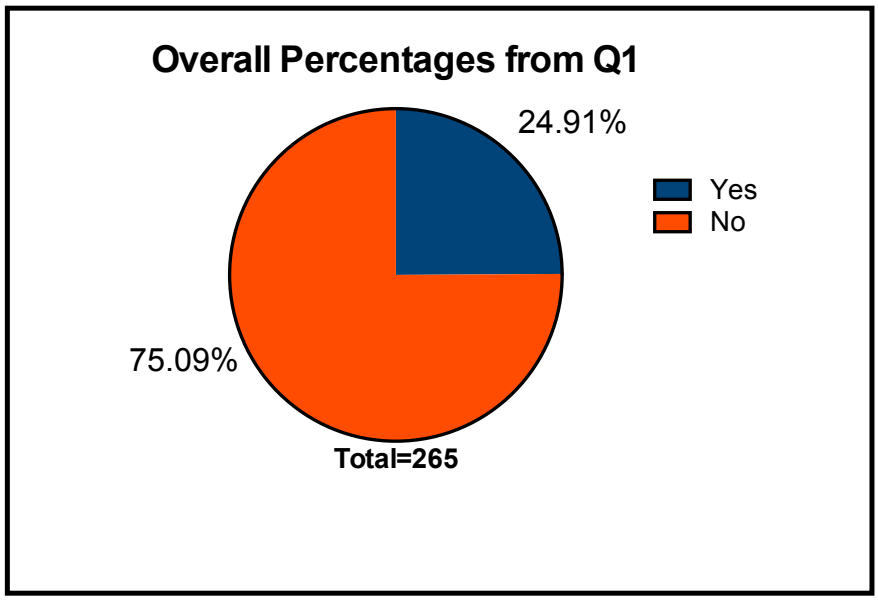


Figure 2.1: Overall Percentages of Total Responses for Question 1: "Have you taken part/been asked to take part in clinical trials before?"

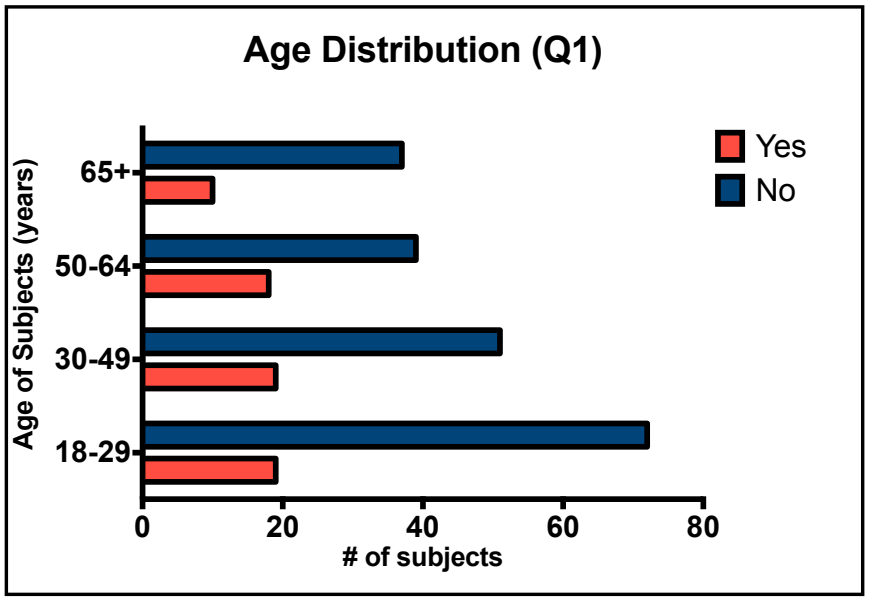


Figure 2.2: Distribution of Age for Question 1

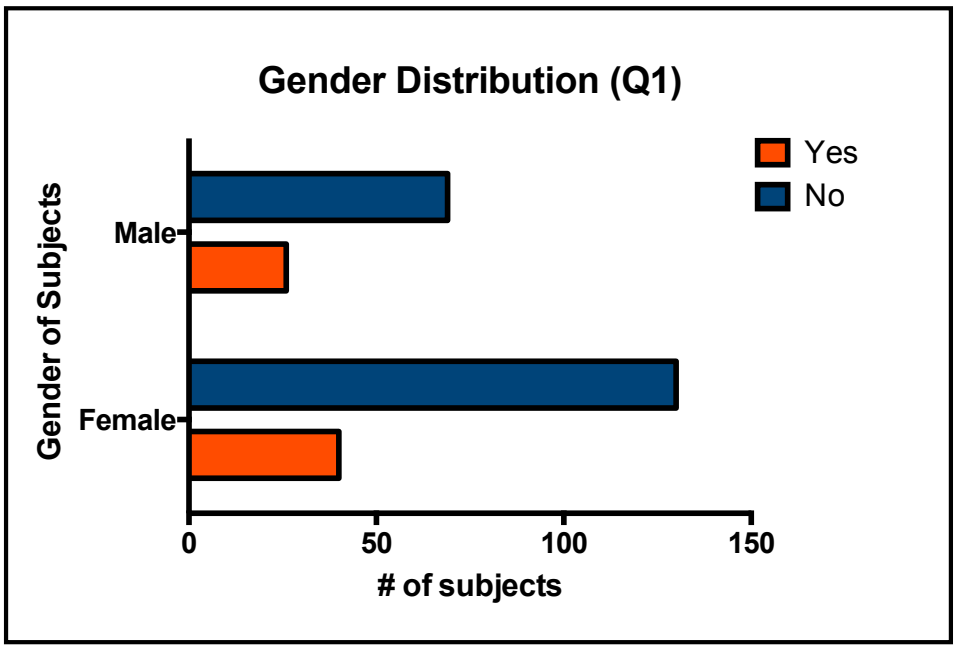


Figure 2.3: Distribution of Gender for Question 1

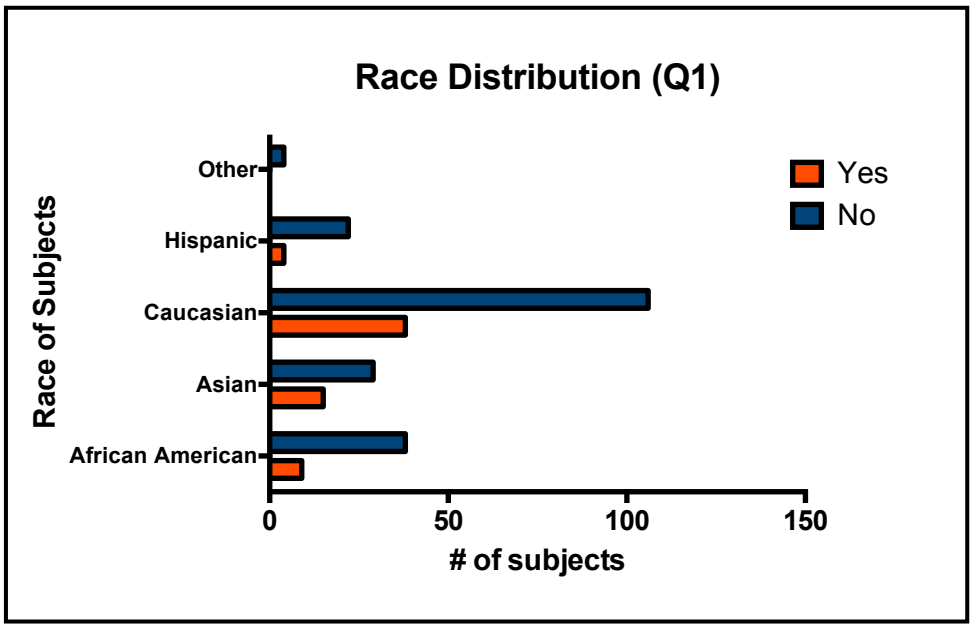


Figure 2.4: Distribution of Race for Question 1

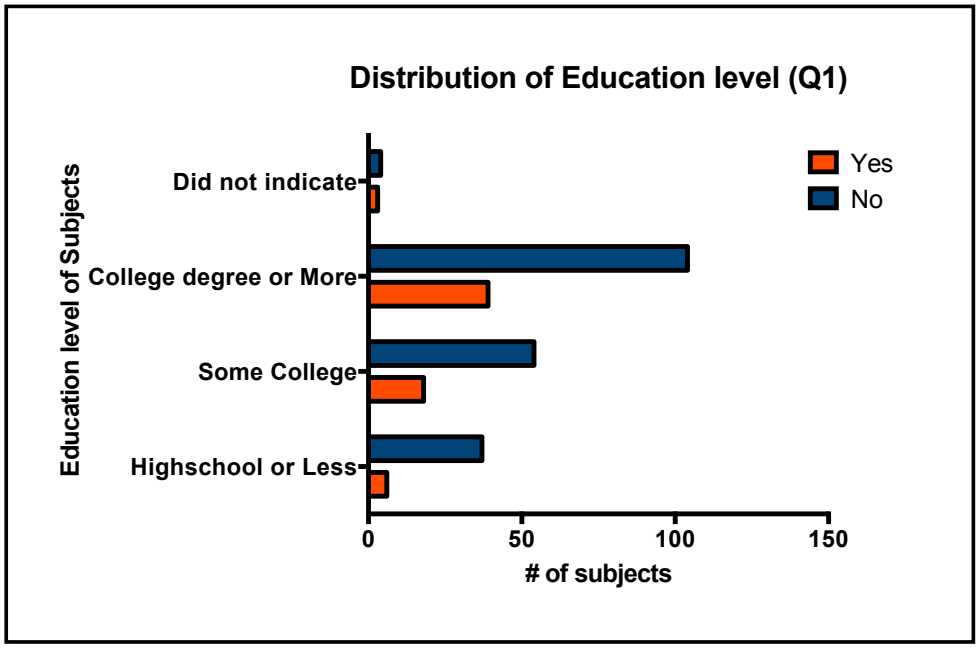


Figure 2.5: Distribution of Education Level for Question 1

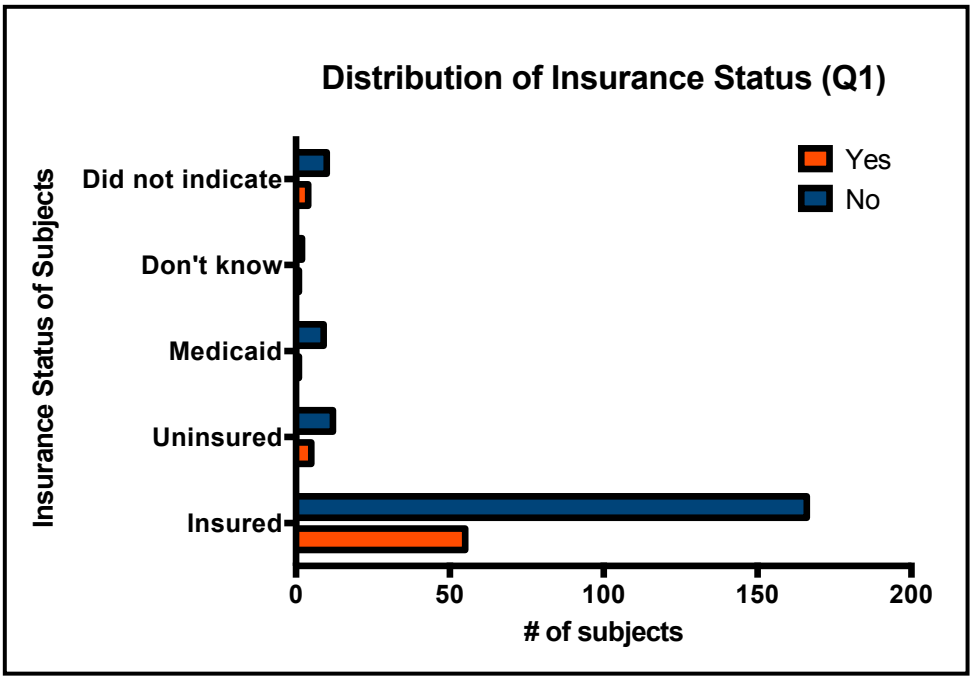


Figure 2.6: Distribution of Insurance Status for Question 1

Figures 2.1 – 2.6, illustrate the responses to question 1 of the survey. This question asked "Have you taken part/been asked to take part in clinical trials before?" The original purpose of this question was to gain insight into how many people within the hospital setting at Baylor All Saints Medical Center have participated in research. This question was extended to see what the individuals at UNTHSC, an educational facility, felt about the same question. Table 1 (see Appendix D) illustrates the frequencies of answer choices for the first question in terms of the demographic information of the survey participants. Of the 265 participants that took the survey, 52 individuals or 25% said that they had been asked to take part or had taken part in a clinical research trial before as illustrated above in Figure 2.1. The frequencies for both the Baylor and UNTHSC sites are found in Table 17.1 (see Appendix D).

Of the participants who completed this question approximately 75% answered "No." One of the biggest barriers to participation in clinical trials is a lack of information about clinical trials that are open for recruitment. This includes an inability to understand what clinical trials entail and a lack of awareness for current ongoing clinical trials (Khatri et al. 2015; Williams 2004). Baylor Research Institute is housed inside Baylor All Saints on the 7th floor of Building C, but many individuals stated verbally that they did now know what a clinical trial was. In order to notify potential subjects about upcoming clinical trials, it may be important for Baylor Research Institute to focus on making their presence known in the hospital setting. Baylor Research Institute is currently working on an application for cellular devices that will notify individuals about all of the available clinical trials available, which could help in addressing this problem. Baylor Research Institute is not necessarily interested in the study population at UNTHSC because many of ongoing studies involve sick individuals who are older, but it offers an interesting comparison between two different study populations. For trials conducted at

UNTHSC and that recruit from within the school, it will be necessary to consider these differences.

In terms of age, most individuals, regardless of age, had not been approached to participate in a clinical trial or have participated in clinical trials. More participants who fell in-between the ages groups of 30 - 49 years and 50 - 64 years had been approached to participate or have participated in a clinical trial (see Figure 2.2). It was previously stated that the average clinical trial participant is about 43 years of age (Getz 2001), which is similar to what was found in the current survey. Of the survey participants between the ages 50 – 64 years who answered this question, 38% answered, "Yes" compared to 26% for those between 18-29 years, 27% for those between 30-49 years, and 21% for those 65 years and above. More individuals between the ages 18 – 29 years at UNTHSC had participated in clinical research than at the Baylor sites. This could be due to the fact that young people are not getting sick and not needing to visit hospitals as often as older people, which would also explain the small sample size of survey participants between the ages 18 – 29 years.

At the Baylor site, more Caucasians claimed to have been recruited for a clinical trial. More of the men had also been approached to participate in a clinical trial overall. About 27%, or 26 men out of 95 surveyed, said they had been approached about a clinical research trial, while 24% of the women, or 40 of the total 170, answered that they had also been approached to participate in a clinical trial. Similarly, many men at UNTHSC had also claimed to be recruited for clinical trials more than the female participants. Approximately 38% of participants at the Baylor sites that answered "Yes" to question 1 also had a college degree or more. It was also more common for these clinical trial participants to have insurance. The individuals surveyed at the Baylor sites were found throughout the hospital because they were waiting for family

members or personally receiving healthcare services at the hospital; therefore, it is not surprising that the majority of those surveyed happened to be insured. The majority of survey subjects at UNTHSC were also insured. Considering that students at UNTHSC are required to have proof of insurance, it is not surprising that the study population at UNTHSC had many young insured participants.

As previously stated, the average clinical research trial subject has at least a high school diploma (Getz 2001). There were more individuals surveyed at Baylor All Saints and UNTSHC that were highly educated; however, according to Getz, Internet users were also generalized as being educated and having higher incomes. Therefore, it makes sense that the majority of individuals had not participated in clinical research, but that the community surveyed has a potential to be successfully recruited with social media.

Table 1.2: Chi-square Results for Question 1

	Age	Gender	Race	Highest Education	Health Insurance
Chi-square	2.664	0.3293	5.574	4.393	1.587
Degrees of freedom	3	1	4	3	4
p-value	0.4463	0.566	0.2333	0.2221	0.8111

Table 2 above shows the results of the chi-square test for question 1. All p-values are above 0.05, which means the null hypothesis is accepted because the result of this chi-square test indicates the independence of these categories from each other. Because the chi-square statistic for race is the highest, which means there is a stronger relationship between whether an individual answers "Yes" or "No" to question 1 and their race compared to any of the other demographic categories. Because all p-values are above 0.05, it is not necessarily feasible to generalize from the sample population in the survey to the general population.

Question 2

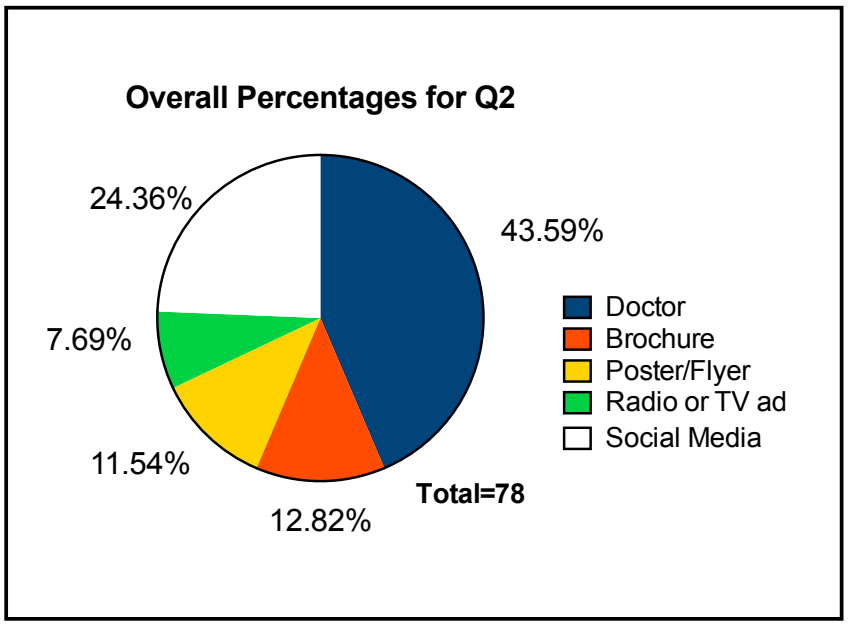


Figure 3.1: Overall percentages for Question 2: "If you answered YES to the previous question, how were you approached to take part?"

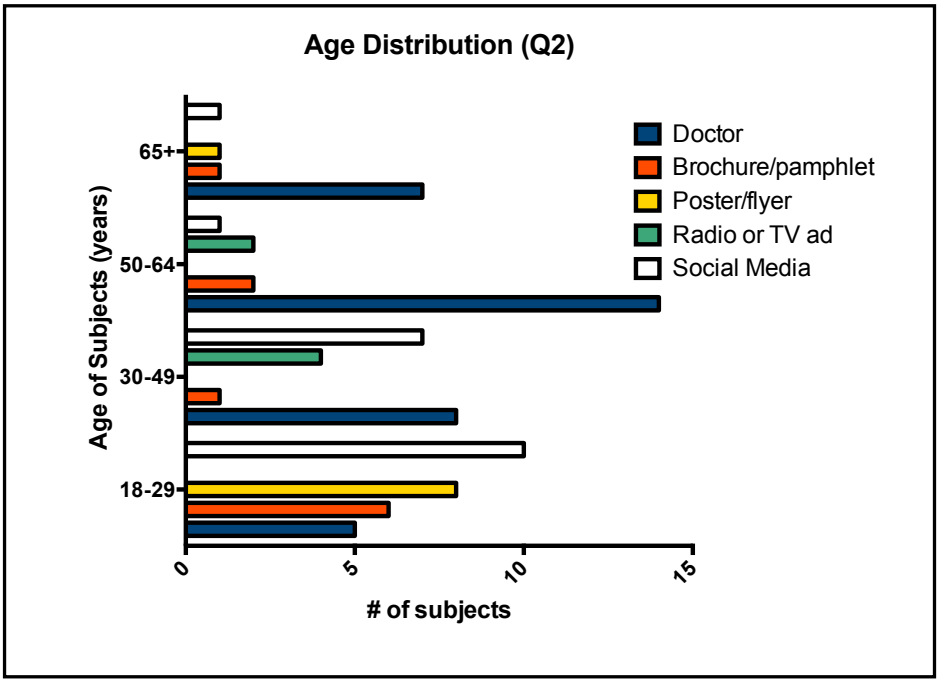


Figure 3.2: Distribution of Age for Question 2

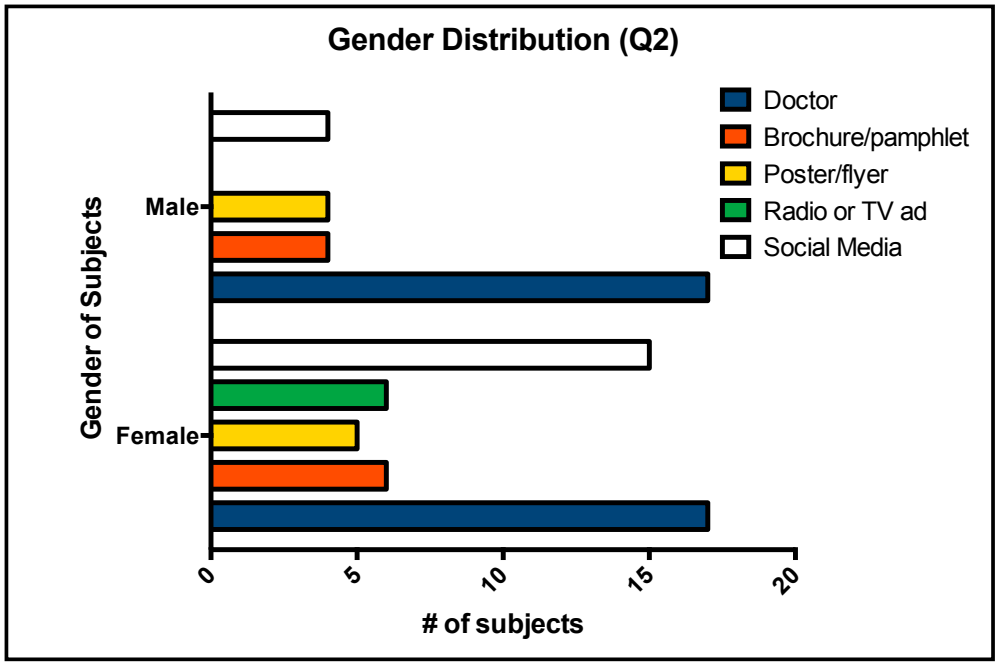


Figure 3.3: Distribution of Gender for Question 2

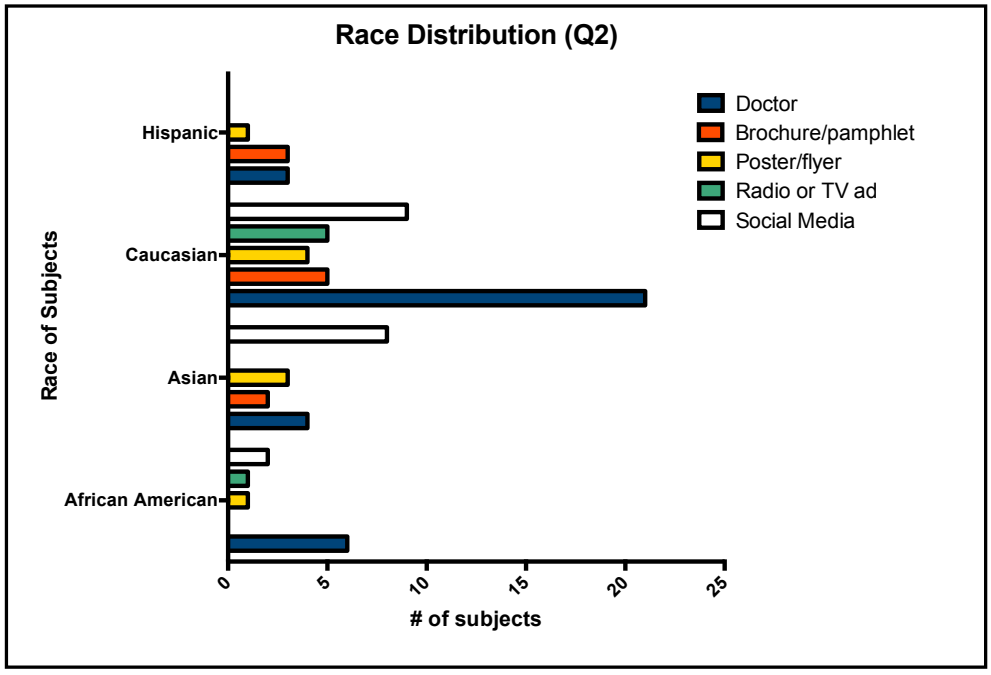


Figure 3.4: Distribution of Race for Question 2

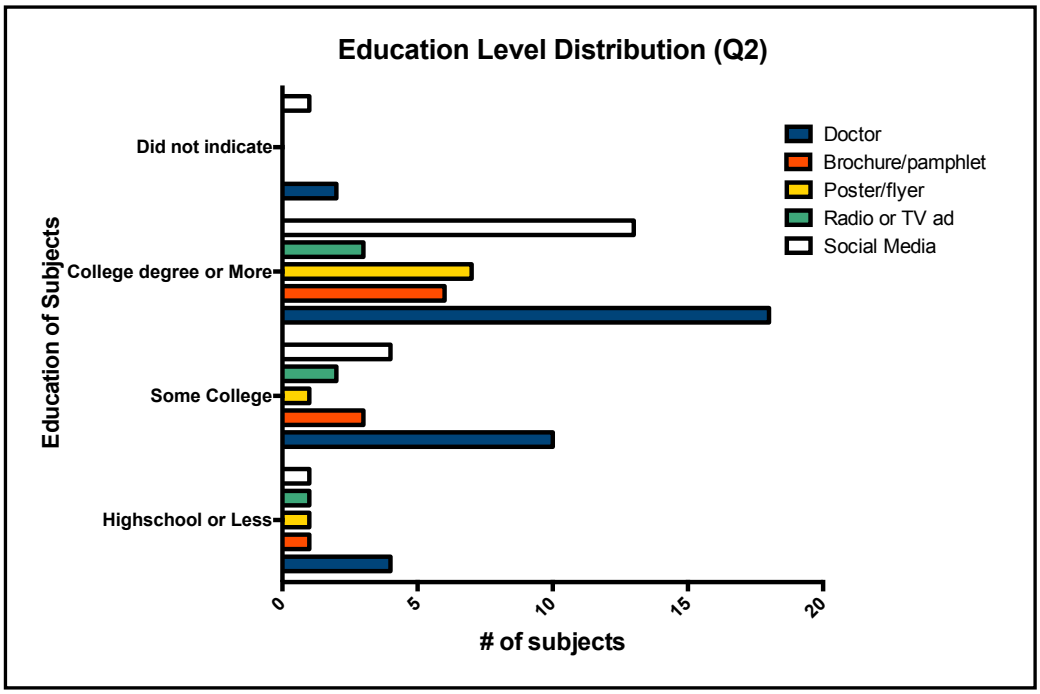


Figure 3.5: Distribution of Education Level for Question 2

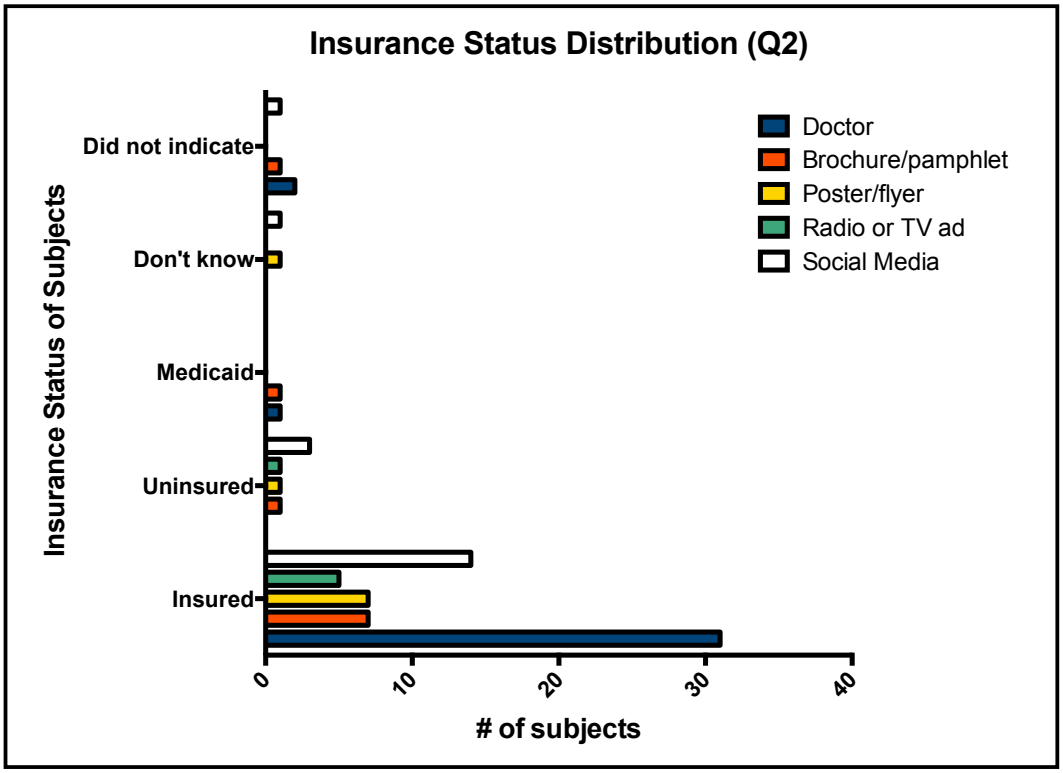


Figure 3.6: Distribution of Insurance Status for Question 2

Question 2 in the survey asked participants how they were recruited to participate in clinical trials. Only those who had answered, "Yes" to question 1 were required to answer question 2. The survey response frequencies are shown in Table 2 (see Appendix D). A comparison of the relative frequencies between the two sites is located in Table 18.1 (see Appendix D). The reason the answer choices "Doctor, brochure/pamphlet, poster/flyer, radio/TV ad, and social media" were selected in the current survey was due to their history in the past as methods that the Clinical Trials Office (CTO) have implemented in the past. If the subject had answered "Yes" to question 1, it was important to determine how they received that information to see if it was comparable to the methods that CTO already uses (physician referrals, radio ads, social media, and print media).

The majority or 44% of participants said their physicians had referred them. Approximately 50% of those surveyed at the Baylor site responded that physicians had referred them and 20% at UNTHSC responded similarly. Because inclusion of data from UNTHSC decreased the total percentage of subjects choosing the answer choice involving doctor referrals, all other answer choices increased. As previously mentioned, those within the age group 18 – 29 years may not need to see their physician as often as their older counterparts, which would make it difficult to recruit a younger population in this manner. For this younger age group, social media was the most often chosen answer, followed by posters and flyers. Considering how dependent the younger generation is with social media, this is not surprising. More participants between the ages of 18-29 years at the Baylor sites had been recruited via posters or flyers than any of the other age groups. Radio or TV advertisements were an answer choice chosen by participants between 30 – 49 years and 50 – 64 years, but they were not the most popular choice

among these groups, as illustrated in Figure 3.2. The two most popular choices for the UNTHSC study participants were social media and posters or flyers (Figure 18.1, see Appendix D).

More females than males at the Baylor sites had been recruited via social media and there were no males that had been recruited via radio or TV advertisement (see Figure 3.3). More males were recruited in all methods at UNTHSC, except for radio or TV ads because no males or females chose this answer. No Hispanic subjects from the Baylor sites chose social media or radio or TV ads as ways in which they were recruited for clinical trials. No African American subjects reported being recruited via brochures or pamphlets. Most Caucasian, Asian, and African American subjects who participated in clinical trials in the past had been recruited via doctor referral. The second most popular answer choice among these three groups was social media (See Figure 3.4). For the UNTHSC site, only Asians indicated they had been recruited via social media, and no participants chose radio or TV ads as an answer either (Figure 18.1, see Appendix D).

Of these recruitment methods, physician referrals are the most intimate method, as it involves speaking with one's physician with whom a potential subject may be more trusting of than the other methods (Andrews 2012). As of late, however, about two-thirds of enrolling patients were self-referred due to external recruitment efforts, instead of being referred by physicians (Anderson 2001). Perhaps due to the expenses involved with seeking health care needs addressed, individuals are more likely to research their options independently before seeking a professional opinion, which means they may hear about a clinical trial somewhere else before a physician refers them. The results obtained from this question shows how dependent clinical trials are on their physicians to refer patients, but also illustrates how social media is an up and coming recruitment strategy that may not have been utilized to its full potential.

Overall, most of the individuals surveyed had a college degree or more. Of the individuals that had participated in a clinical trial, physicians had recruited the majority of them (see Figure 3.5). Social media was also another way that individuals had been recruited, but this was not a common answer choice for those who had only obtained a high school degree or less. This may have to do with the generalization about Internet users being more educated than the average person (Getz 2001). Most of the individuals that were surveyed were insured and they were more likely to have been approached about a clinical trial from their physician at the Baylor sites or social media at UNTHSC.

Table 2.2: Chi-square Results for Question 2

	Age	Gender	Race	Highest Education	Health Insurance
Chi-square	29.19	6.066	14.32	3.624	8.939
Degrees of freedom	12	4	12	12	16
p-value	0.0037	0.1943	0.281	0.9893	0.9159

Table 4 above displays the chi-square analysis of data for question 2. It is important to note that the chi-square statistic for age is higher than the other categories, which means the relationship between the independent and dependent variable are stronger. Also, because the p-value is less than 0.05, it is possible to generalize from the random sample surveyed to the general population and claim that the two variables are associated.

Question 3

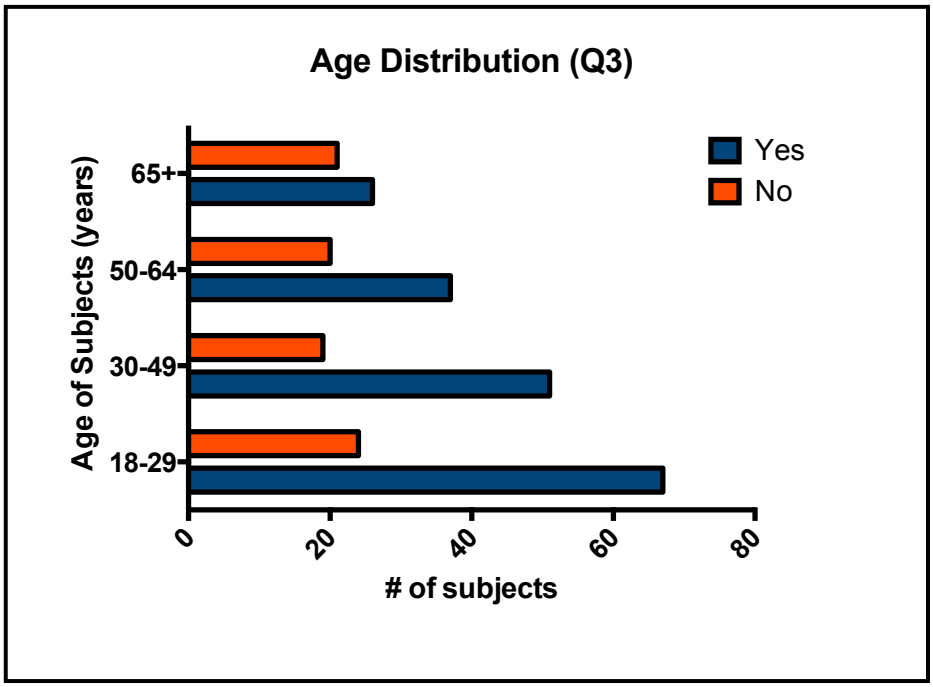


Figure 4.2: Distribution of Age for Question 3

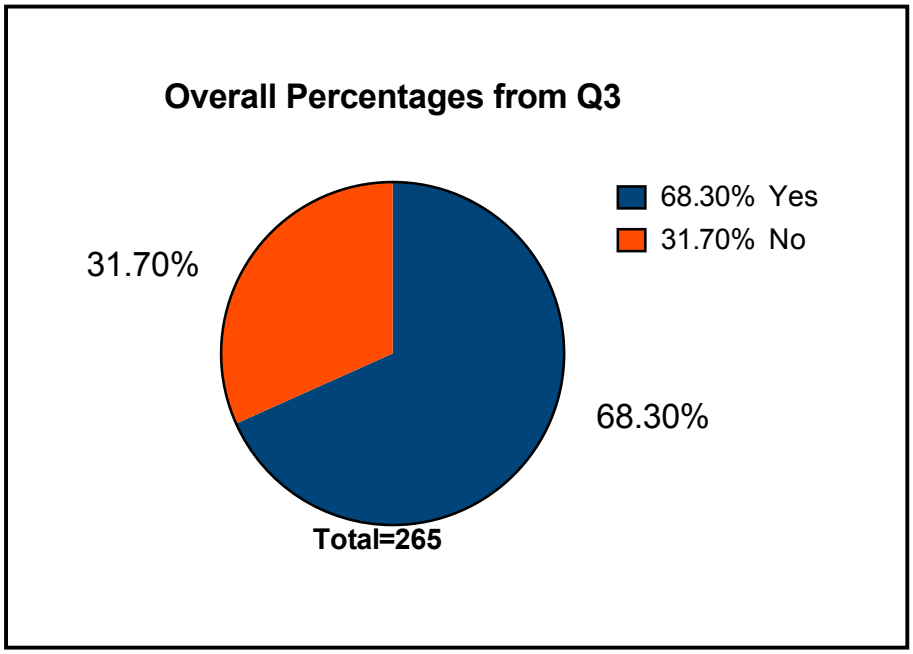


Figure 4.1: Overall Percentages for Question 3: "Would you be interested in taking part in clinical trials if more information was available to you/easier to access?"

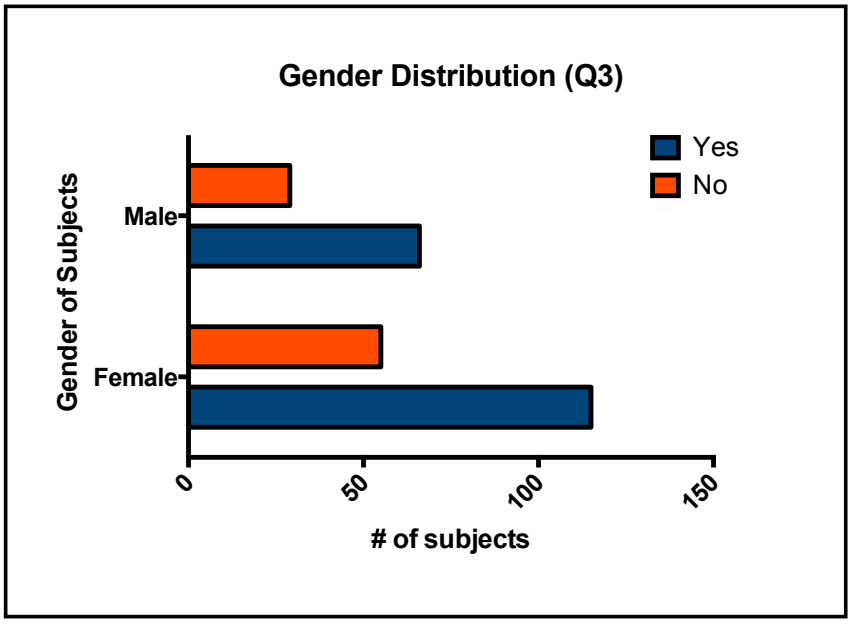


Figure 4.3: Distribution of Gender for Question 3

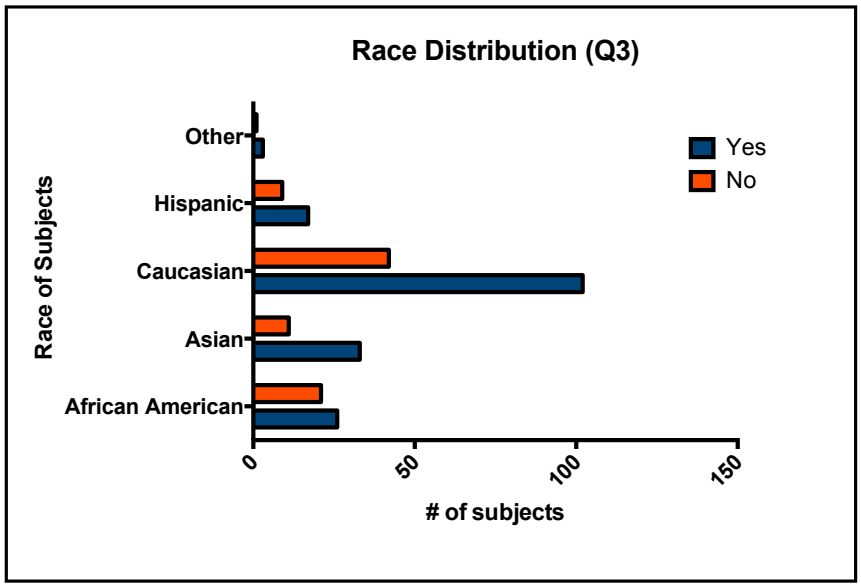


Figure 4.4: Distribution of Race for Question 3

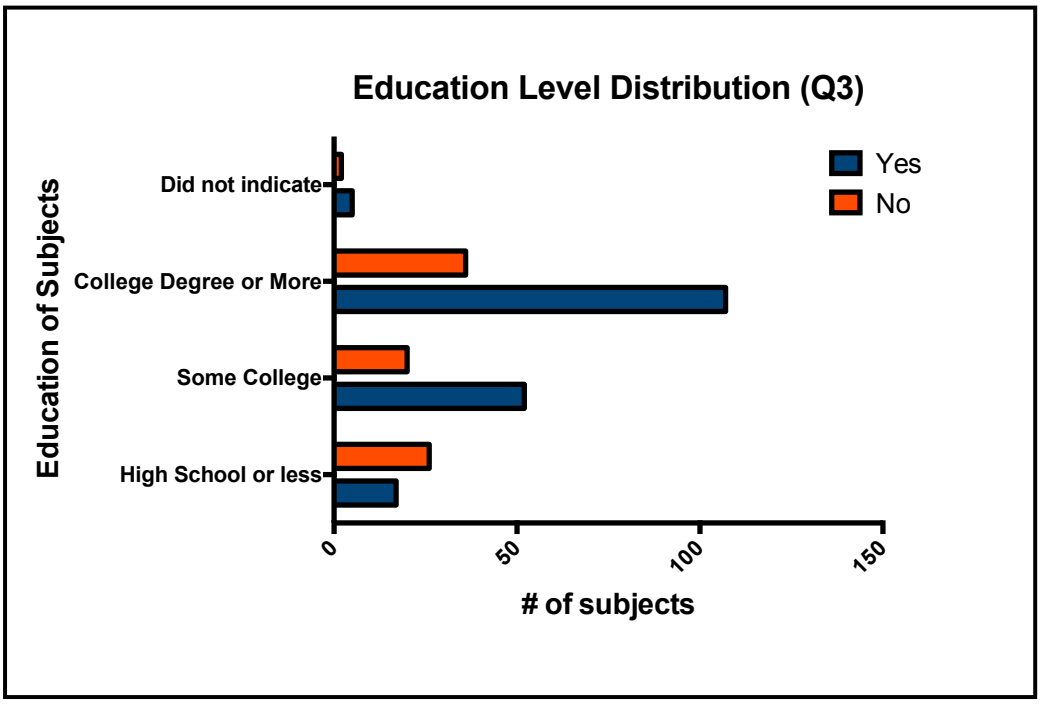


Figure 4.5: Distribution of Education Level for Question 3

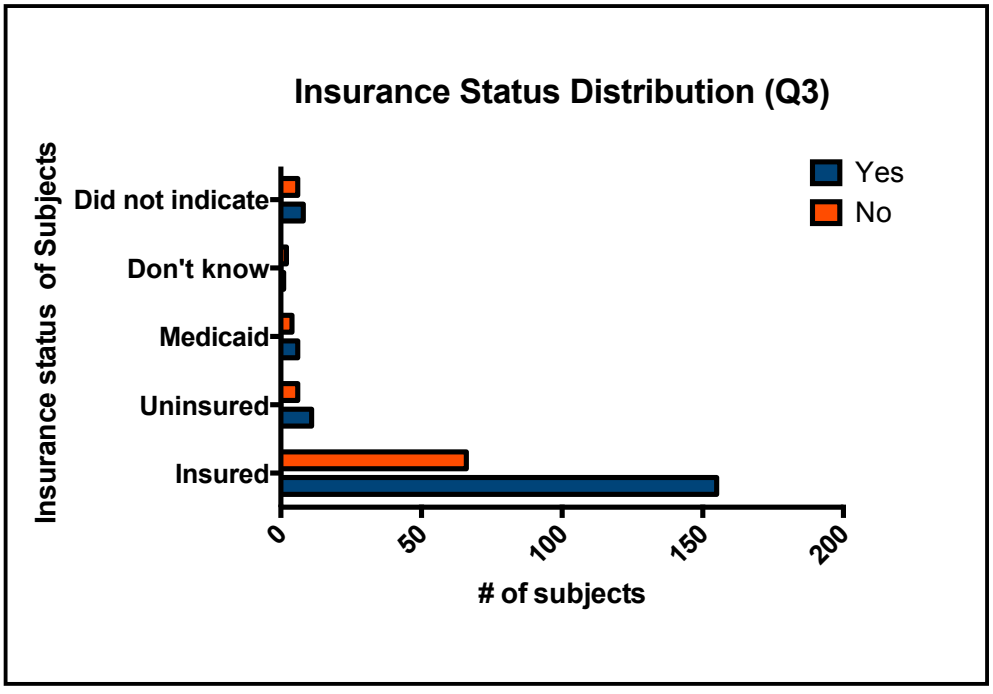


Figure 4.6: Distribution of Insurance Status for Question 3

The third question in the survey asked if the subject would be willing to participate in clinical trials if more information was available or easier to access. This question was designed to gain insight and address the issue of whether "lack of information," in regards to clinical trials as a whole, may be a barrier to their participation in a clinical trial (Khatri et al. 2015; Williams 2004). Reportedly, 40% of adults do not understand what is involved during clinical trials. In another study of 1,013 U.S. adults, only 34% had heard of clinical trials (Williams 2004). Approximately 68% of the individuals who took the survey at one of the Baylor sites answered, "Yes," which is a promising result because that means if more information was available for them, they would consider participating in a clinical research trial (see Figure 4.1). More survey participants between the ages of 30-49 years answered, "Yes". It is understandable that those aged 18-29 years would answer, "Yes" less frequently than other age groups because they are less likely to get sick. Individuals aged 65 years and older answered the question where it was more evenly split. Those individuals are more likely to get sick, but because they are approaching the senior years of their lives they may not be willing to undergo undue risk to their health.

Individuals, regardless of gender, answered, "Yes" more often than "No," as illustrated in Figure 4.3. In Figure 4.4, there was a higher frequency of Caucasians that also answered, "Yes" to question 3. African Americans were more evenly split, but this might have to do with the bad reputation clinical research trials have had in the past, especially with the Tuskegee syphilis experiment that was performed specifically on African American men (Getz 2001; Williams 2004).

Subjects with some college or college degree or more answered, "Yes" more often than individuals who had only completed high school or less (Figure 4.5). This may have to do with

the general lack of information about clinical trials and what they entail. The majority of those that were insured answered that they would be interested in participating in a clinical trial if more information was available to them (Figure 4.6). The majority of survey subjects at UNTHSC also answered, "Yes" to this question (Figure 19.1, see Appendix D).

Table 3.2: Chi-square Results for Question 3

	Age	Gender	Race	Highest Education	Health Insurance
Chi-square	5.824	0.09392	5.182	19.79	3.263
Degrees of freedom	4	1	4	3	4
p-value	0.2127	0.7593	0.2691	0.0005	0.5149

Table 5 above illustrates the chi-square results for question 3. The chi-square statistic for the highest education obtained is greater than any of the other chi-square statistics values. It also has the lowest p-value, which means that the relationship between the independent and dependent variable is a stronger relationship and that a generalization can be made based on the study population to the general population based on these variables.

Question 4

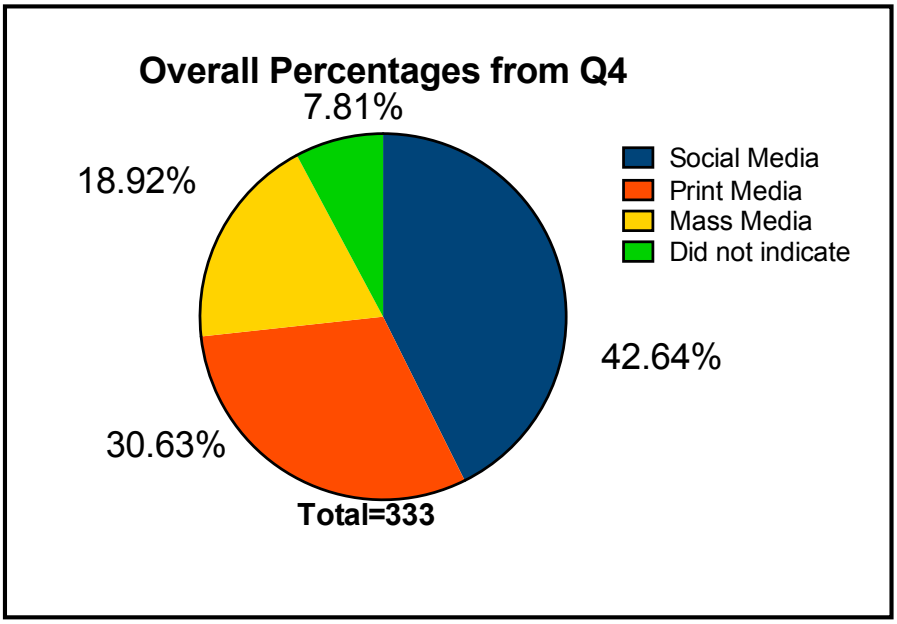


Figure 5.1: Overall Percentages for Question 4: "How would you prefer to receive such information?"

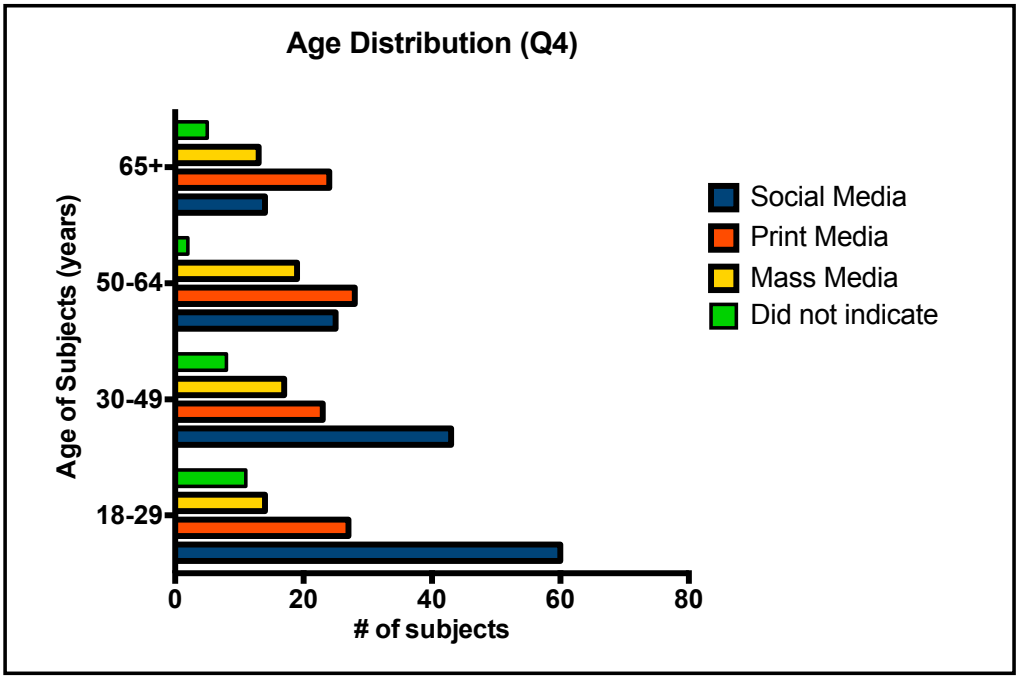


Figure 5.2: Distribution of Age for Question 3

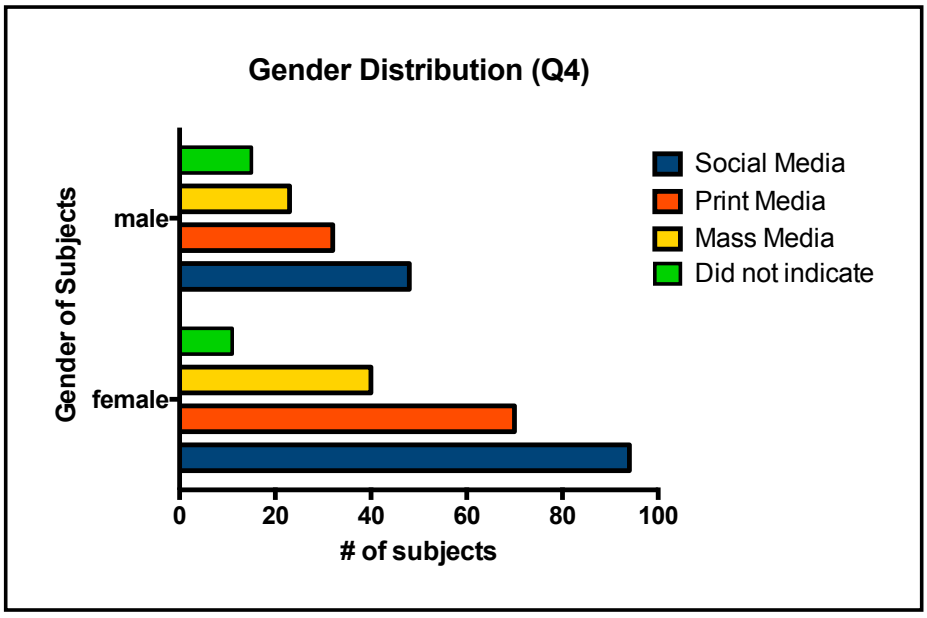


Figure 5.3: Distribution of Gender for Question 4

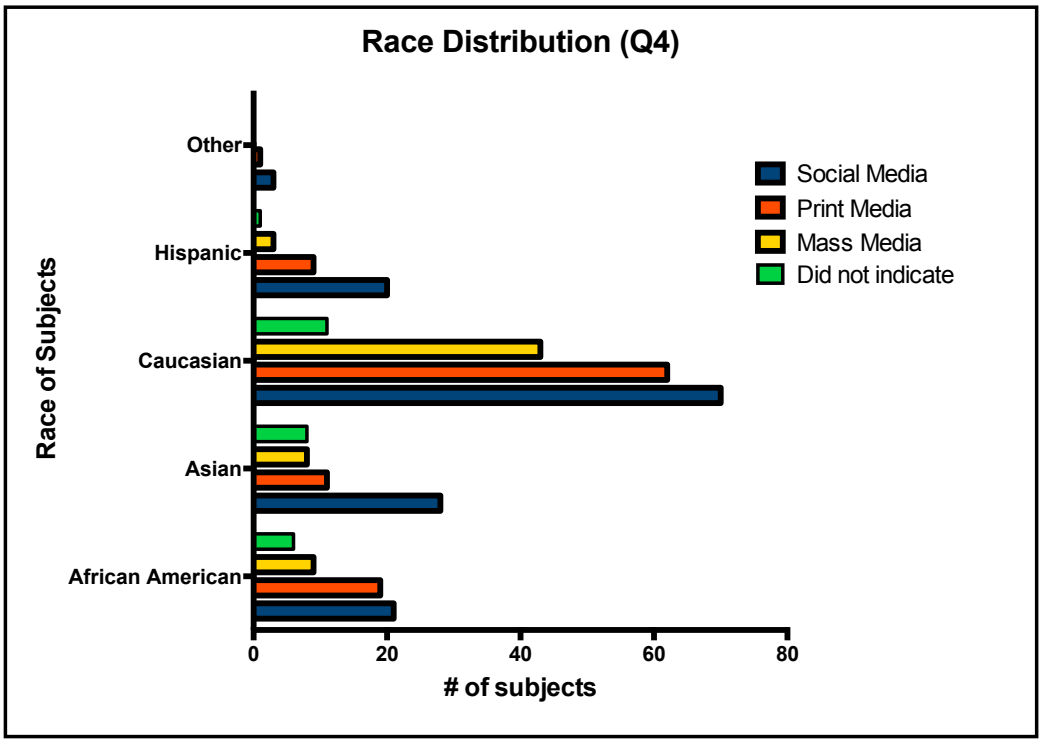


Figure 5.4: Distribution of Race Question 4

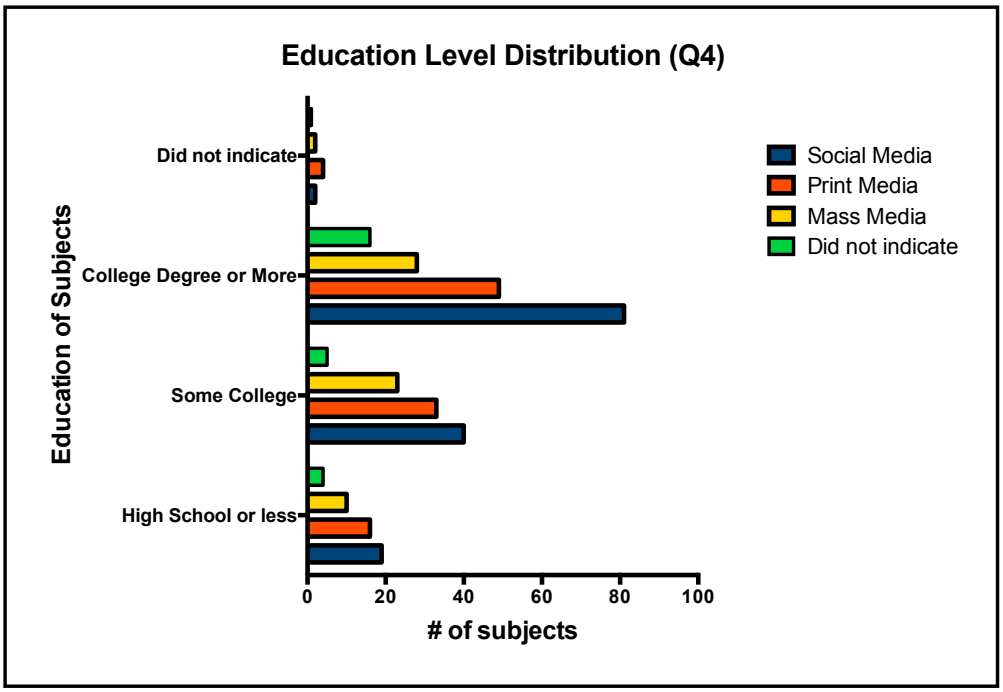


Figure 5.5: Distribution of Education Level for Question 4

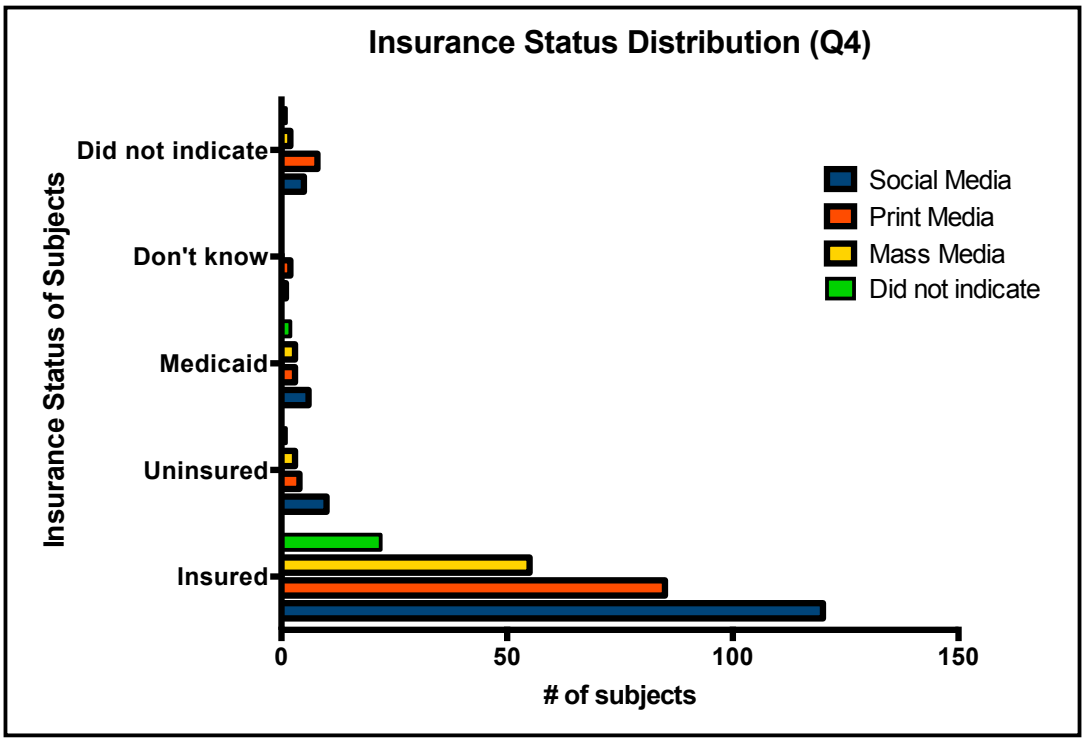


Figure 5.6: Distribution of Insurance Status for Question 4

The fourth question asked participants for clarification on if they were to receive information about clinical trials, what method would they prefer to learn about upcoming clinical research trials. The three options and examples reflect the three modes of communication that are implemented in recruitment efforts today. As illustrated in Figure 5.1, the majority of individuals chose social media, which correlates with people being more reliant on social media to communicate with others. Mass media was the least chosen option. There were some individuals who chose not to answer this question; this could be due to a misunderstanding of the question. Some individuals may have assumed that if they answered "No" to the previous question, they did not have to answer this question. With regards to age, for individuals between the ages of 18 – 29 and 30 – 49 years social media was a popular answer choice. In those between the ages of 50 – 64 years and 65 years and older, print media was the most commonly chosen answer. With all ages, mass media was the least chosen response (Figure 5.2).

For both males and females, receiving information about clinical trials via social media was the overall popular choice, followed by print media and then mass media (Figure 5.3). All races had a similar ranking of choices (Figure 5.4). Social media was the most popular, followed by print media, and then mass media. This data illustrates how common social media use is today, and how many people are relying on social media for multiple forms of communication. All individuals, regardless of highest education level obtained, chose social media (Figure 5.5). The same trend continued for those that were insured, uninsured, and with Medicaid, but the sample population for those individuals was smaller (Figure 5.6). The same trends extended to the survey participants at UNTHSC for all demographic categories.

Table 4.2: Chi-square Results for Question 4

	Age	Gender	Race	Highest Education	Health Insurance
Chi-square	23.46	6.563	19.55	6.26	7.524
Degrees of freedom	9	3	12	9	12
p-value	0.0052	0.0872	0.0761	0.7136	0.8212

Table 8 above illustrates the chi-square analysis results for Question 4. Of these values, age is the highest value for the chi-square statistic and race is the second highest. The p-value for age is also the lowest. This means that the results for age from this specific question can be generalized to the population and that the relationship between the variables is stronger than it is for the other demographic categories. The relationship between independent and dependent variables for age and race are both stronger than they are for gender, education, and insurance, but only age can be applied to the general population.

Question 5

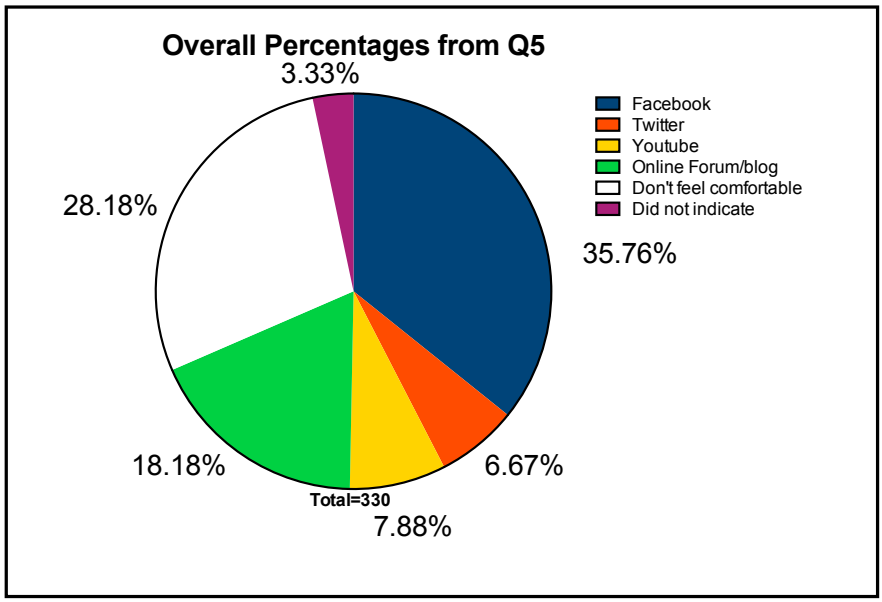


Figure 6.1: Overall Percentages for Question 5: "What form of social media would you like or would prefer to receive information about clinical trials from?"

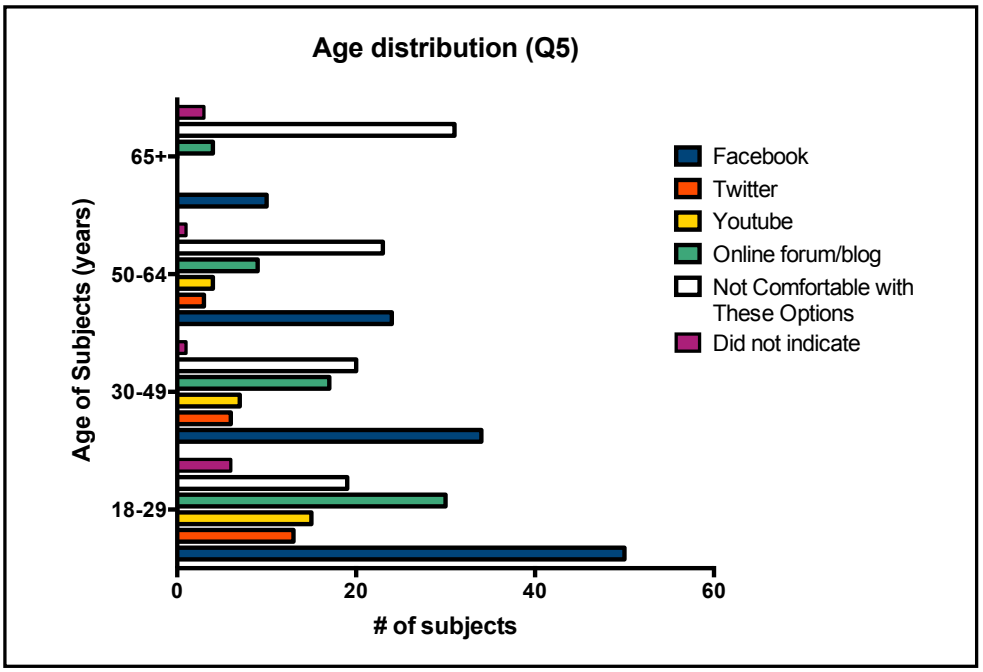


Figure 6.2: Distribution of Age from Question 5

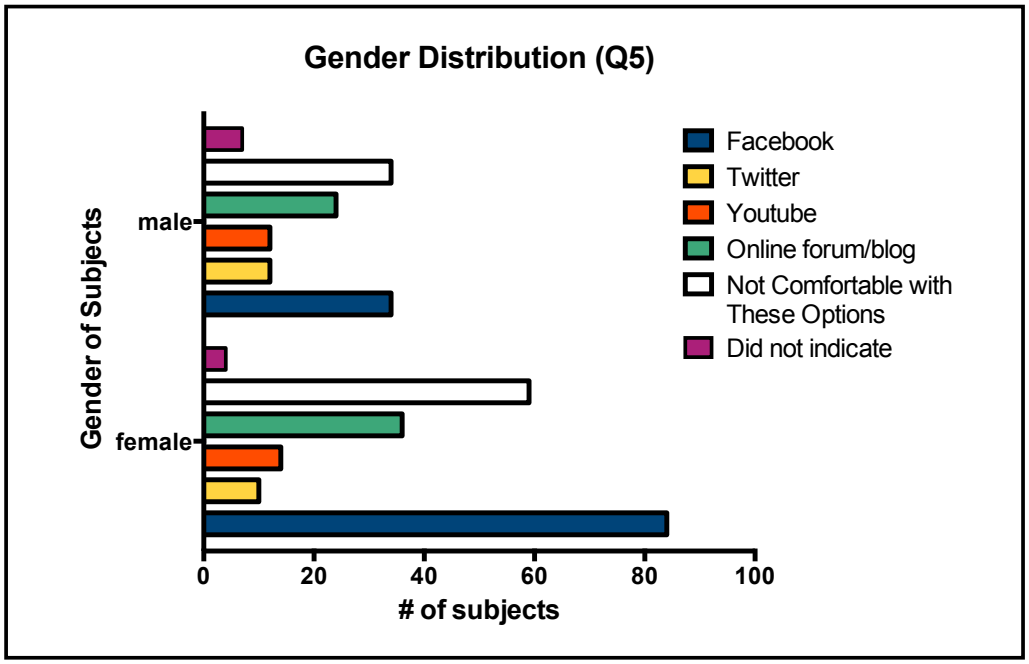


Figure 6.3: Distribution of Gender for Question 5

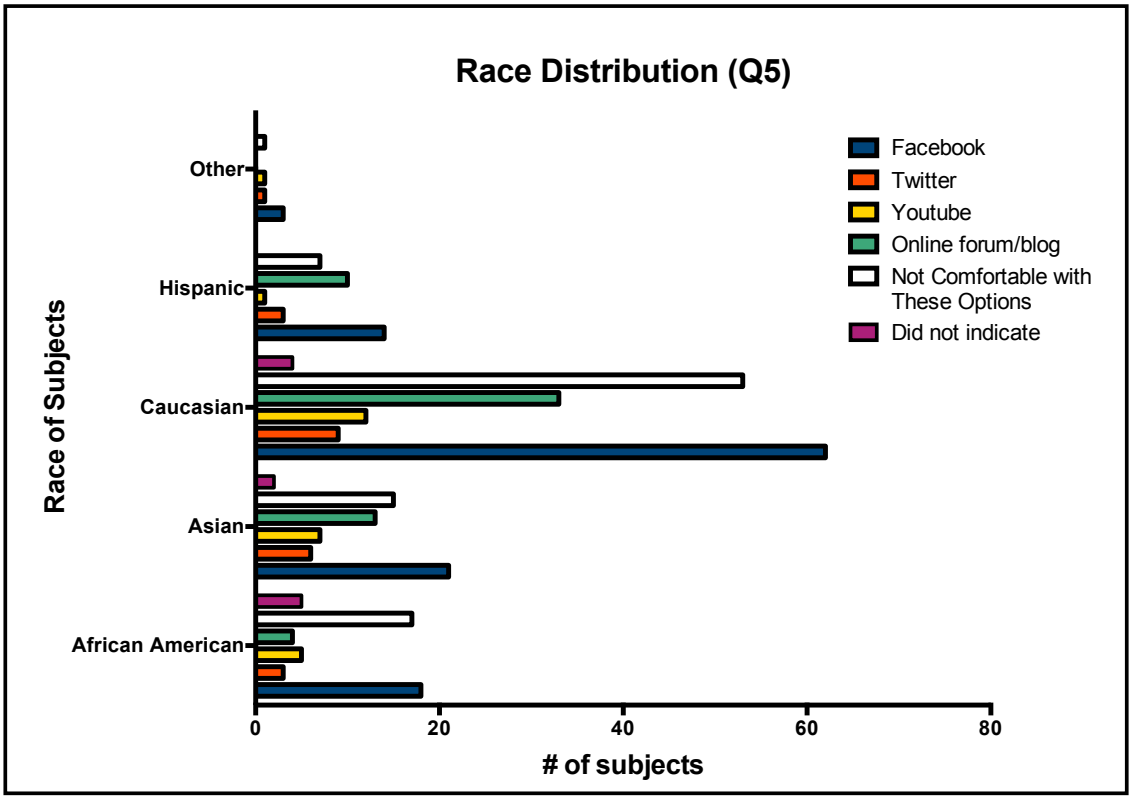


Figure 6.4: Distribution of Race for Question 5

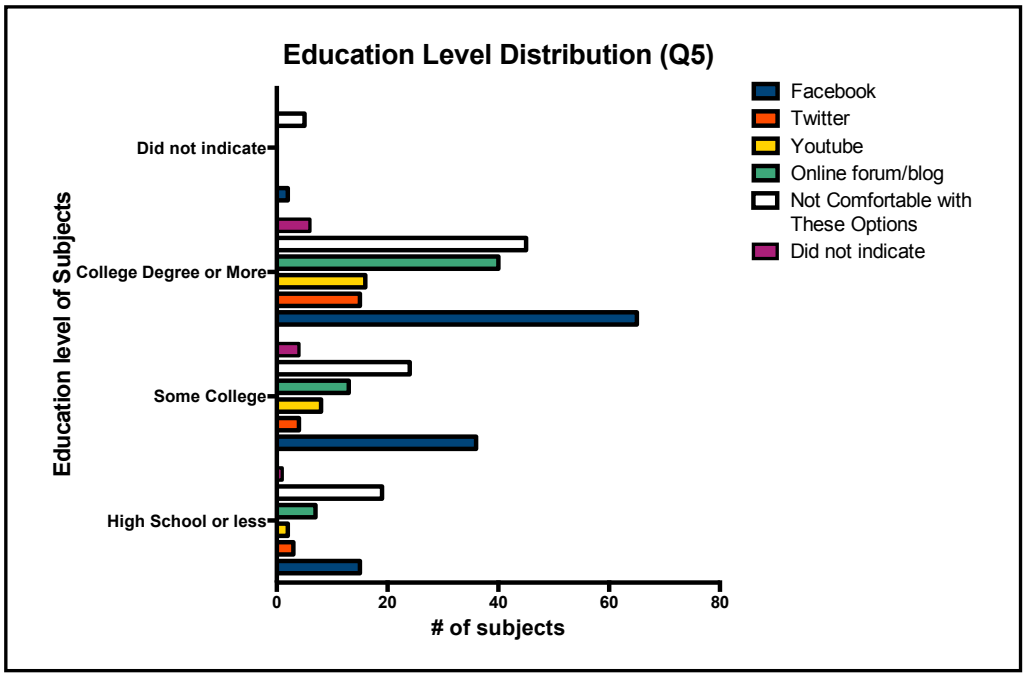


Figure 6.5: Distribution of Education Level for Question 5

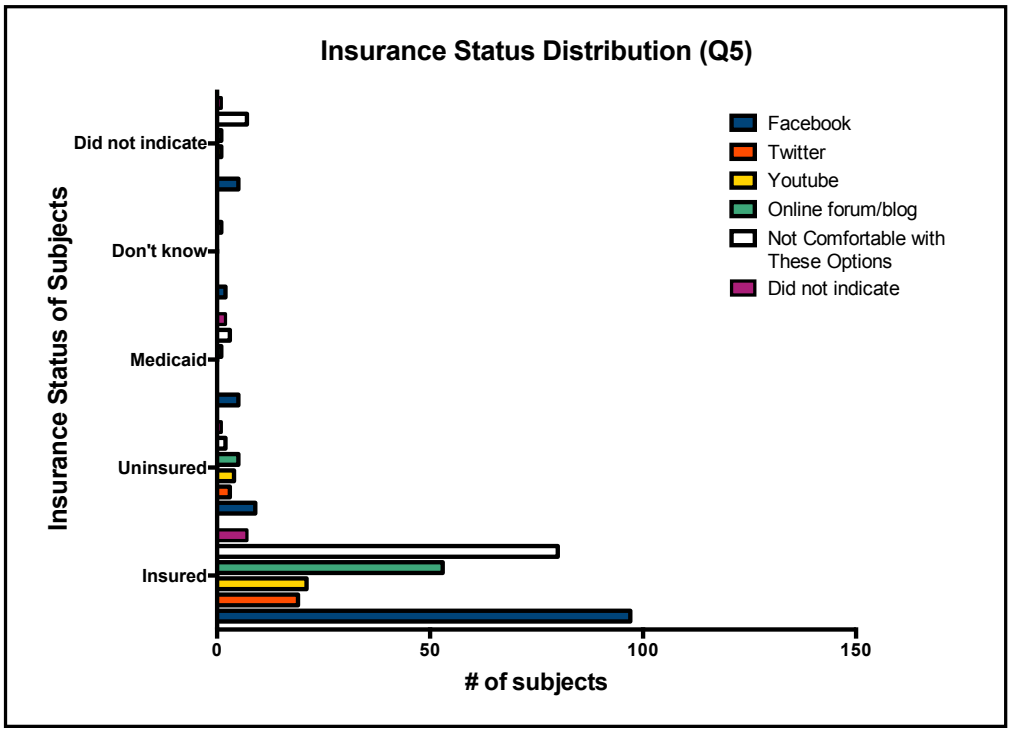


Figure 6.6: Distribution of Insurance Status for Question 5

Question 5 asked for the subject to specifically answer what form of social media they would prefer to receive information about clinical trials. The reason each option was chosen is because of their current popularity. In a study by Pew Research Center completed in late 2014, it found that eight-in-ten Latino, African American, and Caucasian adults who are online use at least one of five social media sites: Facebook, Instagram, Pinterest, LinkedIn, and Twitter (Krogstad 2015). Facebook's significance was discussed earlier, but it is also important to stress the prevalence of its use here. For example, it was announced by the company that on August 27th, 2015, Facebook had 1 billion users, or 1 in every 7 subscribers, on the site at one time ("Company Info | Facebook Newsroom" 2015). Facebook is the most widely used social media platform, irrespective of race or ethnicity, and it claims that 71% of adult internet users as using their website (Krogstad 2015; Duggan et al. 2015a). In 2014, 56% of all online adults aged 65 years or older used Facebook; this represents 31% of all seniors (Duggan et al. 2015c). This is quite surprising because Facebook's overall growth has actually slowed, but it has seen increased use by individuals 65 years and older (Duggan et al. 2015c). It is also reported that Facebook use among women is higher than men (Duggan et al. 2015a), which may mean that studies specific for women may need to implement recruitment methods involving Facebook.

Instagram has a large audience of users as well, and they recently boasted a clientele of 400 million, with more than 75% living outside of the United States ("Celebrating a Community of 400 Million" 2015). It claims about 26% of internet users as members of its community, which amounts to 21% of the entire adult population measured (Duggan et al. 2015a). Instagram is more popularly used among younger adults. Pew Research Center claims that 53% of online adults aged 18 to 29 years uses Instagram, but only 25% of those aged 30 to 49 years use the site. These numbers continue to decrease with each increasing age group. Only 11% of those aged 50

to 64 years and 6% of those aged 65 years and older use Instagram (Krogstad 2015; Duggan et al. 2015c; Duggan et al. 2015a). Other generalizations made about those who use Instagram are that they are more likely to be young women who are Hispanic or African American and live in urban or suburban environments (Duggan et al. 2015a).

Twitter use, however, was more evenly distributed with regards to race and gender compared to Instagram. About one-in-four Hispanics and African Americans use the site, as do 21% of Caucasians (Krogstad 2015). There are about 23% of adult internet users that use Twitter, which is 19% of the entire adult population measured (Duggan et al. 2015a). It is popular among those who are under the age of 50 years and are college-educated (Duggan et al. 2015a). YouTube also has over 645 million users, which means that a dedicated YouTube channel to a clinical research trial could be an excellent method to expose individuals to upcoming studies and recruit subjects (Khatri et al. 2015).

Snapchat is a newer platform that has seen growths in its use within the past few years after its 2011 launch. In 2013, Snapchat, now one of the top-ranked and downloaded apps, said more than 400 million messages were sent on its app every day, and there are reportedly at least 30 million monthly active users (Shontell 2013). Snapchat has made attempts to provide ways to educate their users on current events because of its collaboration with several different companies including Buzzfeed, Cosmopolitan, the Daily Mail, National Geographic, etc. The majority of Snapchat users are female and they most commonly fall within the ages of 13 and 25 years (Ballve 2014). The use of Snapchat then drops significantly with age (Ballve 2014).

There has also been an increase in multi-platform use where 52% of online adults will now use two or more social media sites, which was only at 42% in 2013 (Duggan et al. 2015c). Facebook acts as the "home base" and has overlap with other platforms. There have been more

Facebook users each year who also use other forms of social media, including Twitter, Instagram, and Pinterest. For those users that claim to use only one form of social media, 79% of those individuals report using Facebook (Duggan et al. 2015c). The same logic was used for question 7, which asks what forms of social media the subject specifically uses most often. For question 7, there have been several statistics that show that Latinos and African Americans are more likely than Caucasians to use Instagram (Krogstad 2015).

A large number of survey participants at the Baylor and UNTHSC sites chose Facebook as their preferred method of social media to receive information about clinical trials and the second most popular choice is that many individuals do not feel comfortable with receiving this information via social media (Figure 6.1). For example, many participants at the Baylor site who were 65 years and older chose the answer "I do not feel comfortable receiving information from social media." In the other age categories, that same answer choice was chosen, but social media was still the most popular choice in these as well (Figure 6.2). Online forums or blogs was the second choice chosen by survey participants at UNTHSC, and the third most chosen answer was "I do not feel comfortable receiving information from social media." This is interesting because, although it is the third popular answer choice, study participants at UNTHSC seem to be more comfortable receiving information about clinical trials from social media.

With regards to gender, many women surveyed at Baylor indicated that social media was their preferred method to receive information about clinical trials (Figure 6.3). Facebook was also the top chosen answer choice for males. The race distribution, highest education level, and insurance status all had similar results. Facebook was popular, especially among those who had attended some college or had a college degree or more. Those who had completed high school or less chose the answer "I don't feel comfortable receiving clinical trial information from any of

these options." Those who were insured had similar results as the previous demographic categories (Figure 6.6).

Facebook use is popular among a variety of demographic categories, which makes its use as a conduit for information about upcoming clinical trials more acceptable than receiving this information via Twitter, YouTube, and Online forums or blogs. The online forums or blogs, however, would be one of the first sources that individuals would look up if they were trying to independently search for information regarding health conditions. This may be why it is the third popular answer choice behind Facebook and those that did not feel comfortable receiving information from the choices available.

Table 5.2: Chi-square Results for Question 5

	Age	Gender	Race	Highest Education	Health Insurance
Chi-square	57.06	10.78	22.96	16.46	23.96
Degrees of freedom	15	5	20	15	20
p-value	<0.0001	0.056	0.2907	0.3524	0.2443

Table 10 illustrates the chi-square analysis of results for Question 5. The highest chi-square statistic value is for age and age also has the lowest p-value, which is less than 0.05. This means that the relationship between the independent and dependent variable are strong. It also means the results from this specific question for age can be generalized to the population.

Question 6

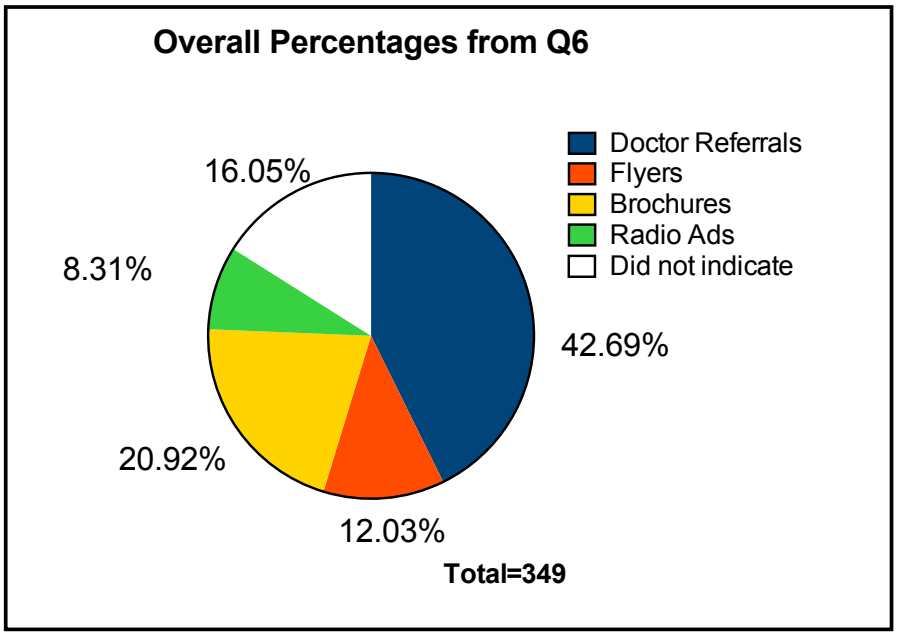


Figure 7.1: Overall Percentages from Question 6: "If you don't feel comfortable receiving clinical trial information from social media, where would you prefer to receive this information?"

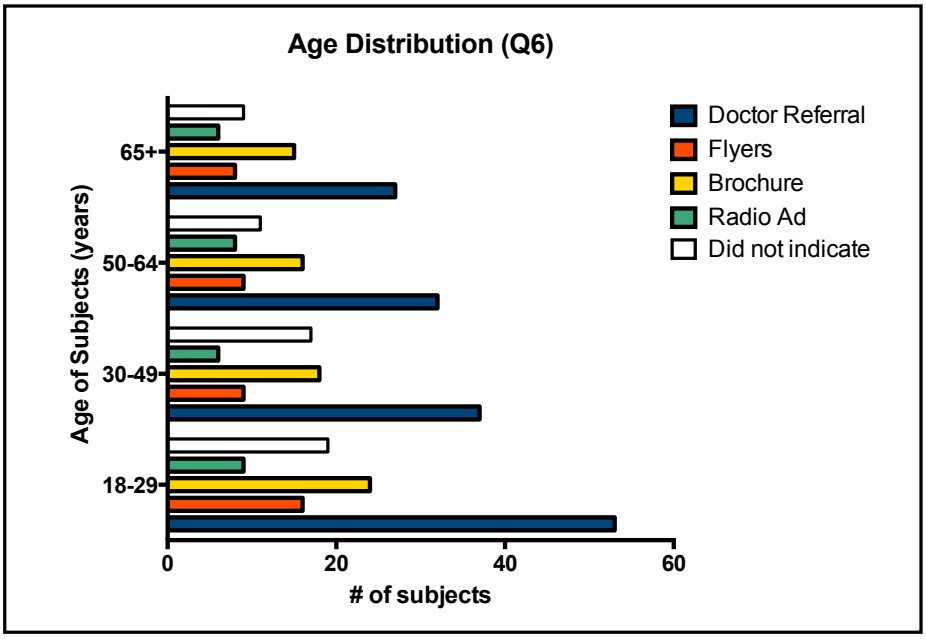


Figure 7.2: Distribution of Age for Question 6

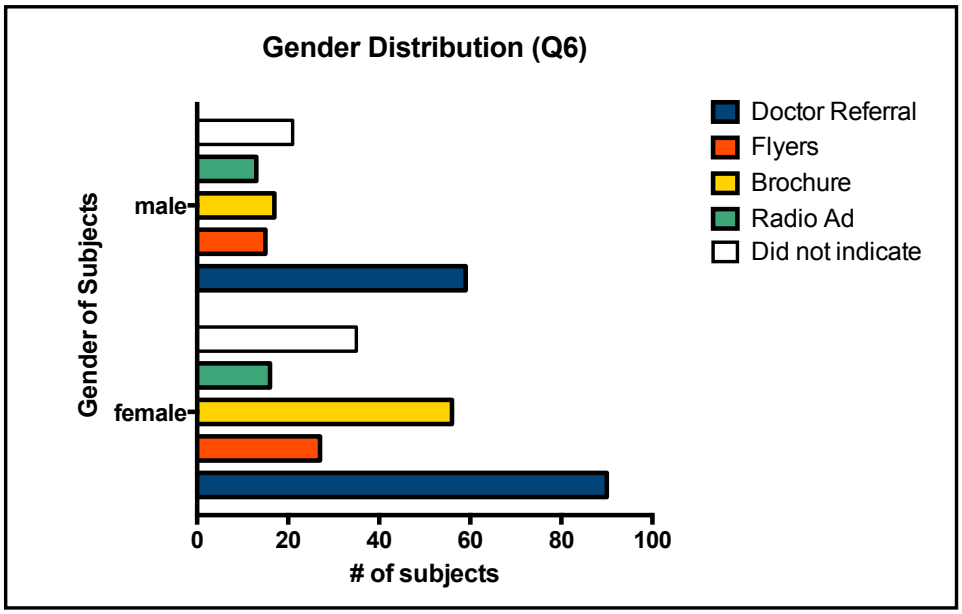


Figure 7.3: Distribution of Gender for Question 6

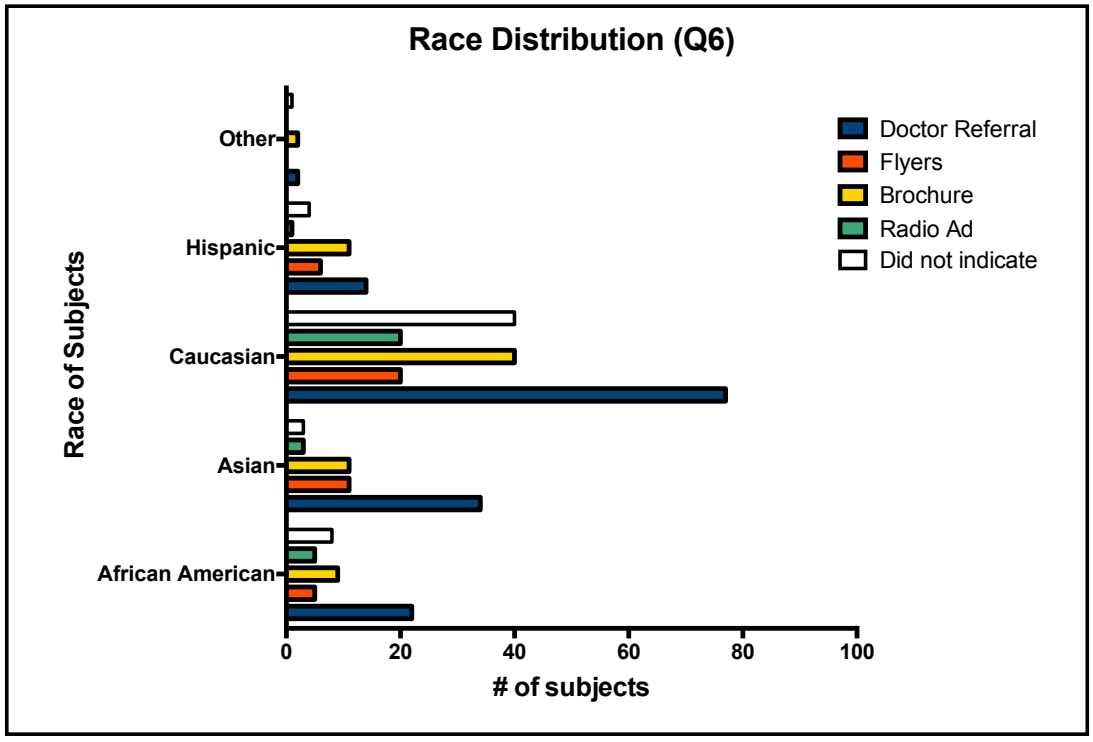


Figure 7.4: Distribution of Race for Question 6

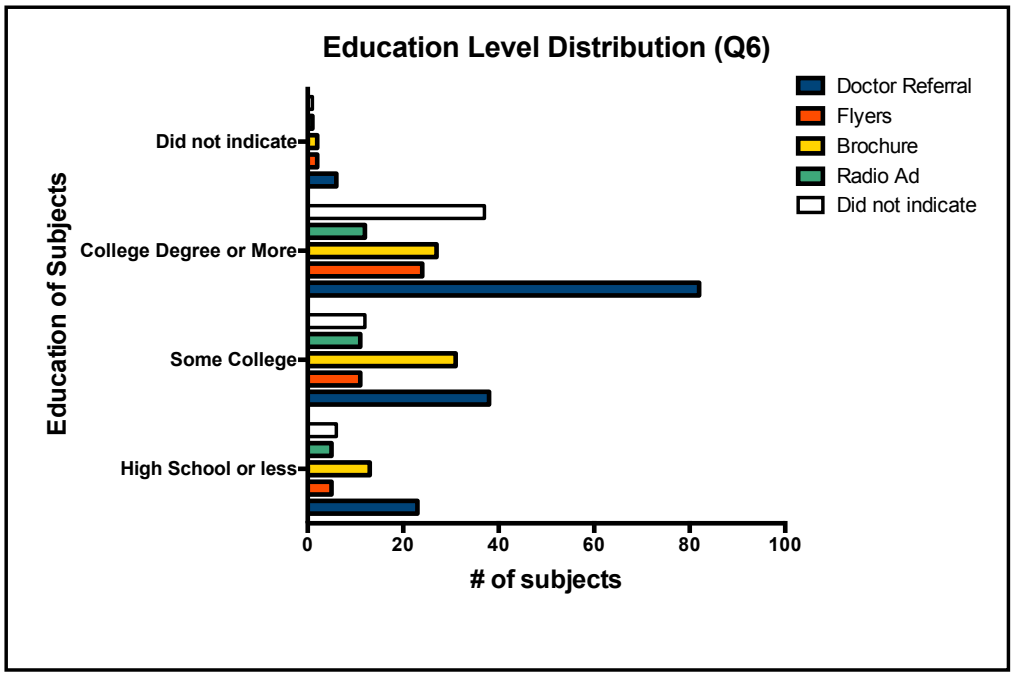


Figure 7.5: Distribution of Education Level for Question 6

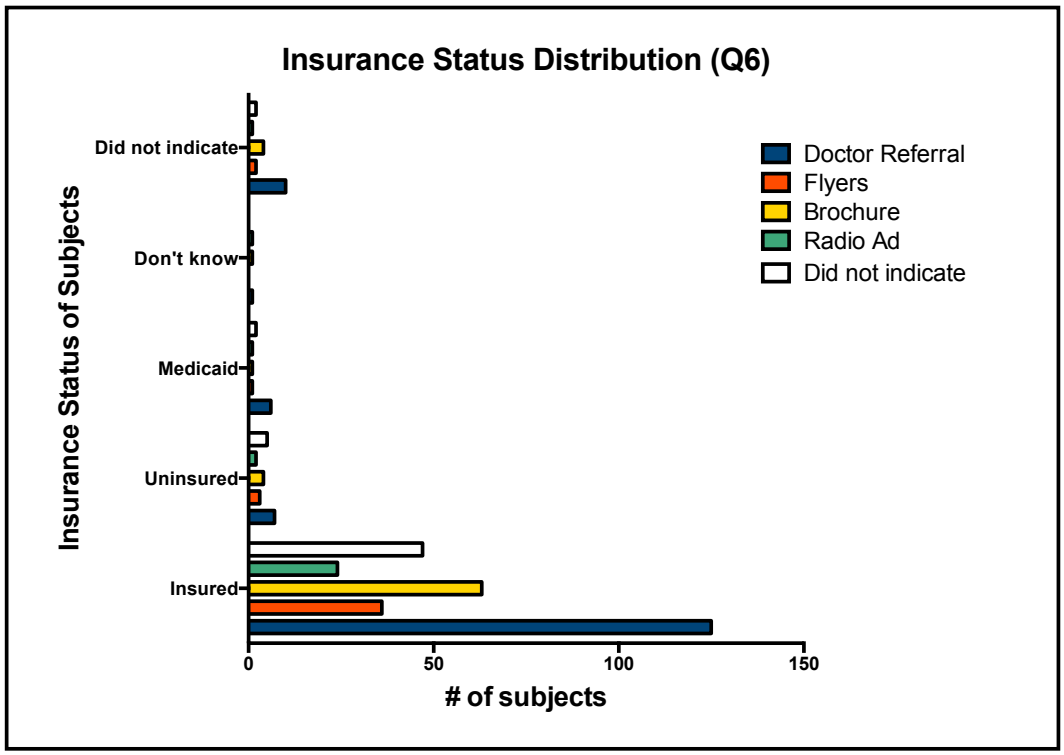


Figure 7.6: Distribution of Insurance Status for Question 6

The purpose of Question 6 was to ask about forms of communication other than social media that individuals would be willing to receiving information about clinical research trials. Not all individuals use social media to communicate and may want to be approached for participation in a clinical research trial a different way. The options listed included doctor referral, flyers, brochures, and radio ads. These refer to the methods that CTO has used to recruit subjects in the past. In 1995, a physician or nurse would refer patients only two-thirds of the time, while in 1999, 58% of patients said they self-referred into a clinical trial and less than 40% said that their physician or nurse had referred them (Getz 2001). A survey performed in the United States found that out of the 1,000 people interviewed, 85% felt it was important their doctors or nurses be responsible to refer them into a clinical research study (Getz 2001), but as the earlier numbers indicate, there are less instances where physicians or nurses are actually referring patients to studies.

If subjects were to choose other ways to receive information about clinical research besides social media, most indicated that they would prefer to be referred by their physicians (Figure 7.1). No matter the age, the response was relatively the same (Figure 7.2). Doctor referrals had higher frequencies in each age group. After doctor referrals, study participants chose brochures, flyers, and then radio ads in terms of its preference among all age groups and other demographic categories. Survey participants at UNTHSC also chose doctor referrals at a higher frequency than the other methods listed. This was true, regardless of demographic category. There were some individuals who did not indicate an answer choice. This may be due to the fact that the question is not clearly worded.

Table 6.2: Chi-square Results for Question 6

	Age	Gender	Race	Highest Education	Health Insurance
Chi-square	2.452	7.005	20.86	15.81	7.085
Degrees of freedom	12	4	16	12	16
p-value	0.9983	0.1356	0.1841	0.2	0.9716

Table 12 illustrates the chi-square analysis of results for question 6. Race has the highest chi-square statistic compared to the other demographic categories. It also has the lowest p-value. Both of these suggest a strong relationship between the independent and dependent variable; however, the p-values that resulted was not equal to 0.05 or less, so the results cannot be generalized from the study population to the general population.

Question 7

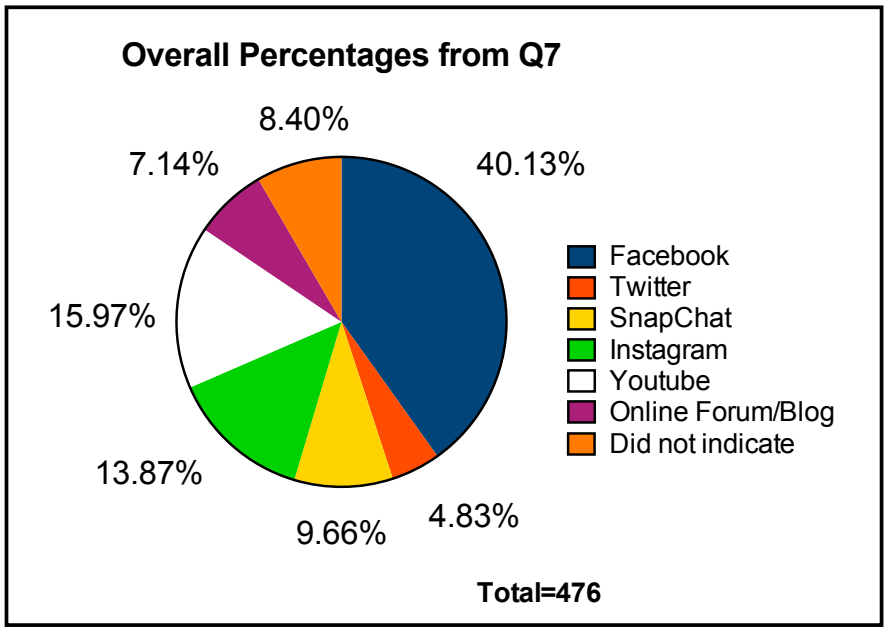


Figure 8.1: Overall Percentages from Question 7: "What forms of social media do you use most often?"

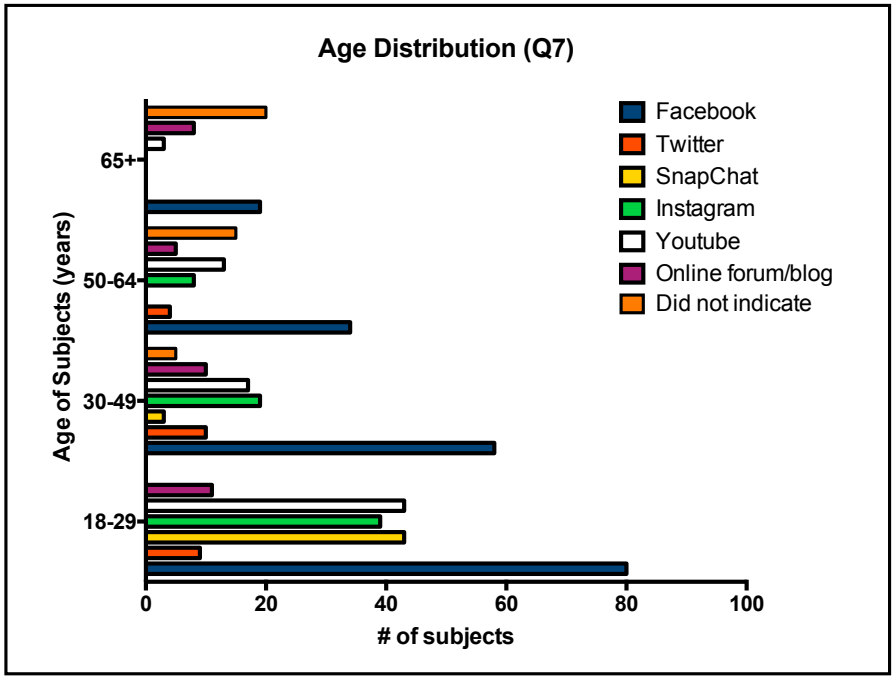


Figure 8.2: Distribution of Age from Question 7

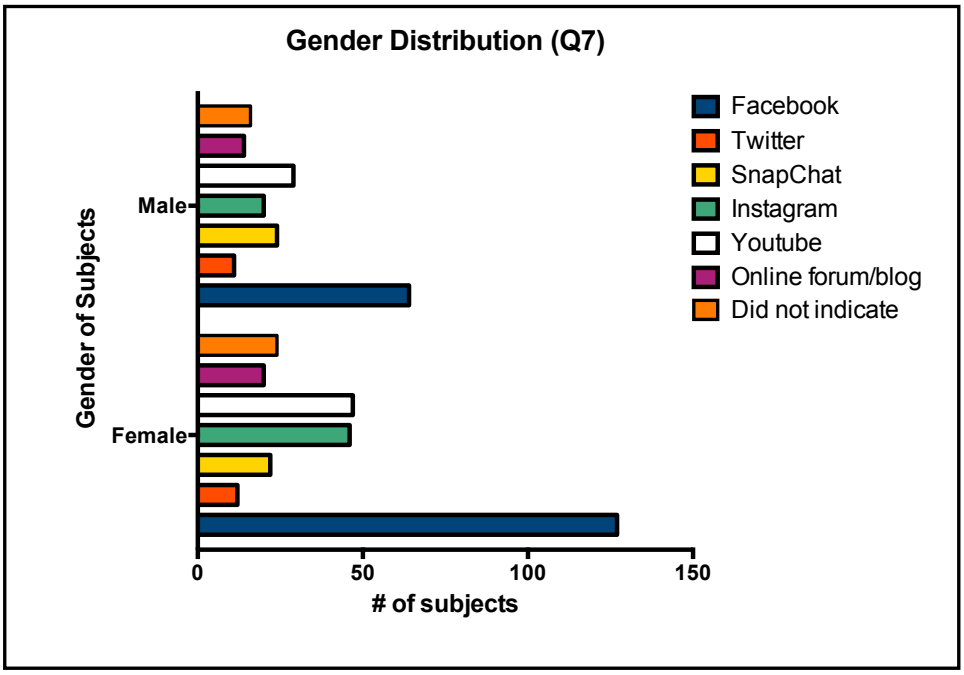


Figure 8.3: Distribution of Gender for Question 7

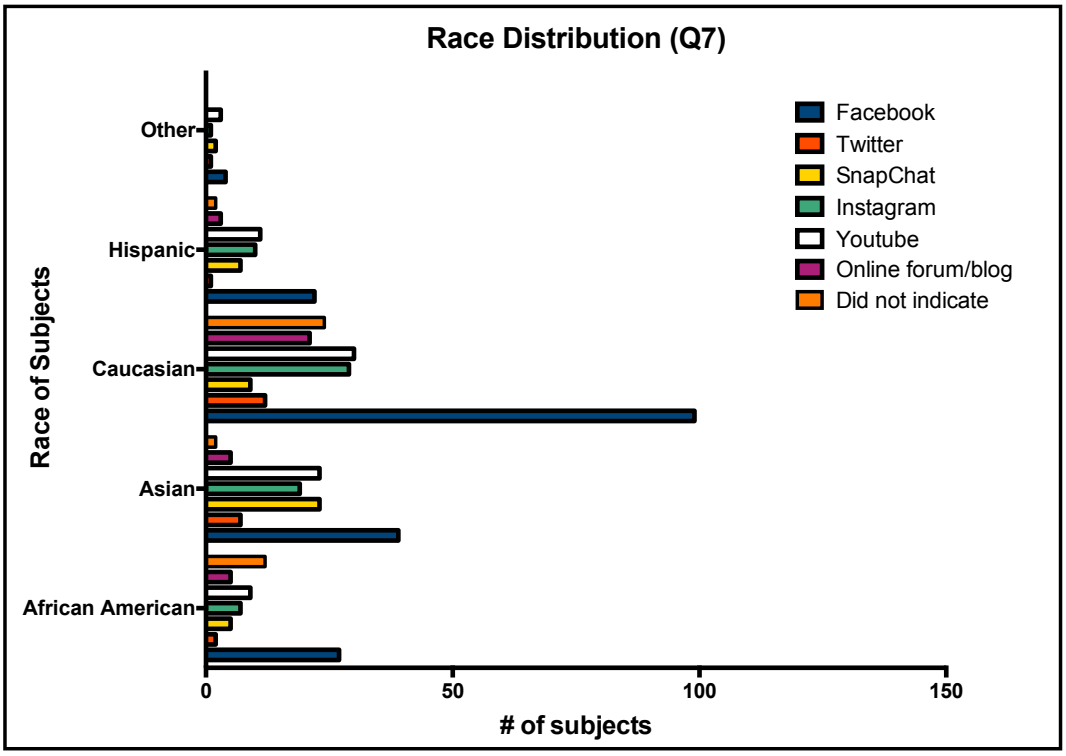


Figure 8.4: Distribution of Race for Question 7

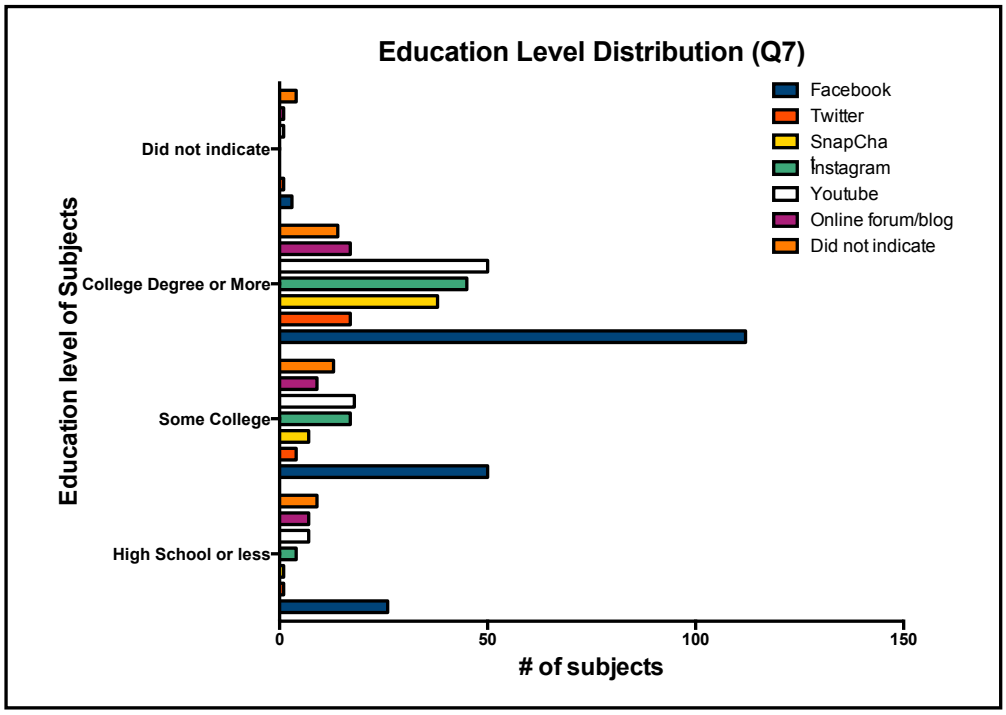


Figure 8.5: Distribution of Education Level for Question 7

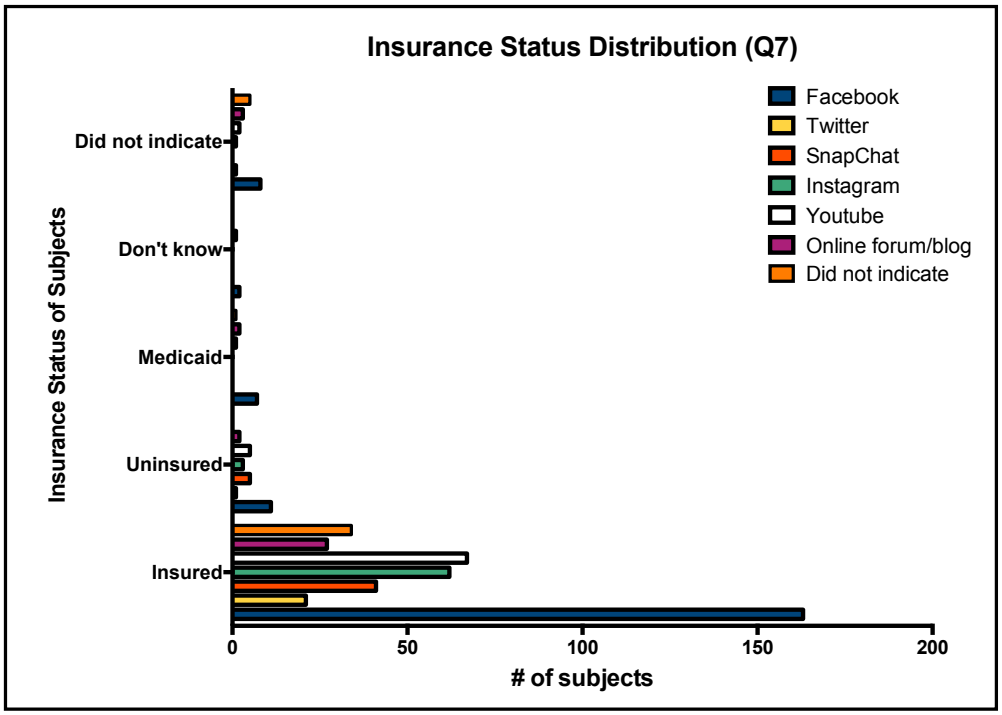


Figure 8.6: Distribution of Insurance Status for Question 7

Question 7 asked participants specifically what types of social media individuals use most often. The reason for choosing these answer choices out of all social media platforms was explained previously with the discussion for question 5. Facebook was the most popular answer choice for the Baylor sites (Figure 8.1). This trend continues throughout the rest of this section. Twitter use was not popular among the older age group. Snapchat was used predominately by 18-29 year olds and 30-49 year olds. Both Twitter and Snapchat experienced decreased use among the older age group, so these may not be the most efficient means to recruit older age groups (Ballve 2014; Duggan et al. 2015a). As is illustrated in Figure 8.2, many individuals in the age group for 50 – 64 years and 65 years and older did not answer this question; this may have to do with the fact that they do not use any of these platforms. The prevalence of the individuals who did not indicate their answer choice for this question increases from the age group starting at 30 – 49 years.

At the Baylor sites, both genders reported that they used Facebook more often than other social media platforms (Figure 8.3). More women than men chose Facebook, which coincides with the previous mentioning of women being more likely to use Facebook compared to men (Duggan et al. 2015a). After Facebook, YouTube and Instagram use is popular among women. Men chose Snapchat more than they chose Instagram, but YouTube was a more popular choice compared to Snapchat and Instagram. Women are reportedly more likely to use Instagram than men, and the results from the survey indicate that as well (Krogstad 2015; Duggan et al. 2015a; Duggan et al. 2015b). Caucasians also showed a high prevalence of Facebook use that far surpasses the use of other forms of social media (Figure 8.4), but Facebook was the most common option for all races. Figure 8.5 shows that those with a college degree or more use

Facebook more often than other forms of social media. The second most chosen answer was YouTube, followed by Instagram (Figure 8.6).

Similar to the Baylor sites, the study participants at UNTHSC chose Facebook more often than the other social media platforms; however, they also chose Snapchat at a higher frequency than the Baylor sites. It is the second most chosen option, followed by YouTube and Instagram. There were higher frequencies in all of these answer choices when comparing the Baylor sites to the UNTHSC site, which is understandable as the majority of those surveyed at UNTHSC were those between the ages of 18 – 29 years.

Table 7.2: Chi-square Results for Question 7

	Age	Gender	Race	Highest Education	Health Insurance
Chi-square	162.1	8.354	52.5	42.83	26.6
Degrees of freedom	18	6	24	18	24
p-value	<0.0001	0.2133	0.0007	0.0008	0.3236

Table 14 illustrates the chi-square analysis of results for question 7. All of the chi-square statistical values are quite high with the exception of gender. The highest chi-square value is for Age and it also has the lowest p-value, followed by race and highest education. This means the relationship between the independent and dependent variable are very strong because the greater the chi-square number, the stronger the relationship between the two variables. Because many of these p-values are less than 0.05, this means that the results for age, race, and education can be generalized from the study population to the general population.

Question 8

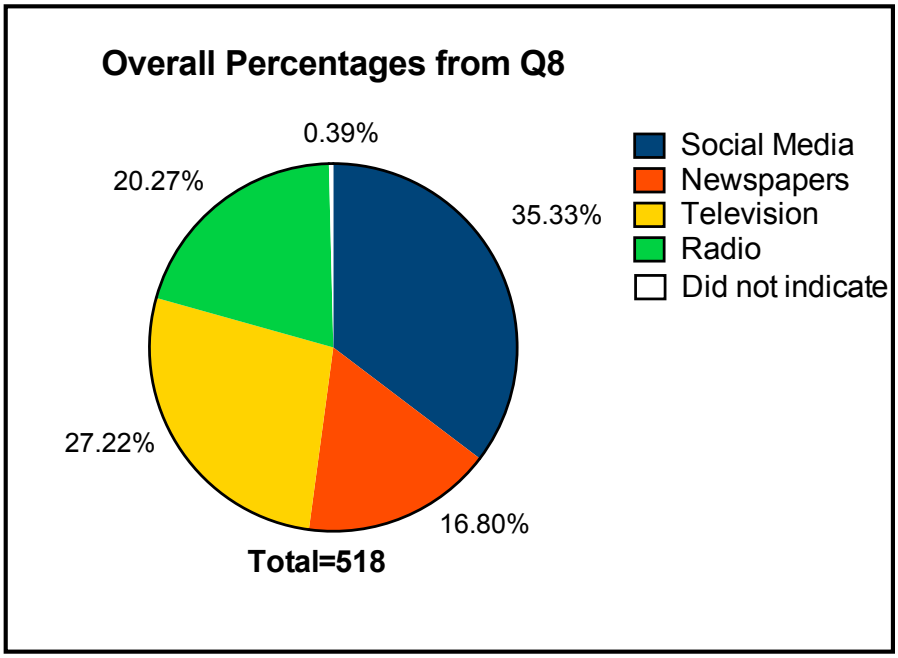


Figure 9.1: Overall Percentages for Question 8: "How do you learn about upcoming events?"

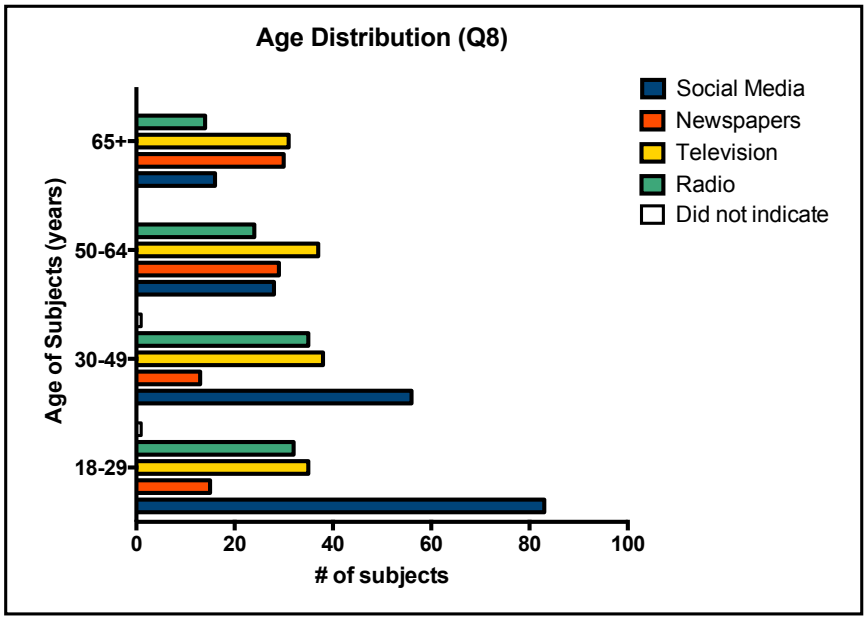


Figure 9.2: Distribution of Age for Question 8

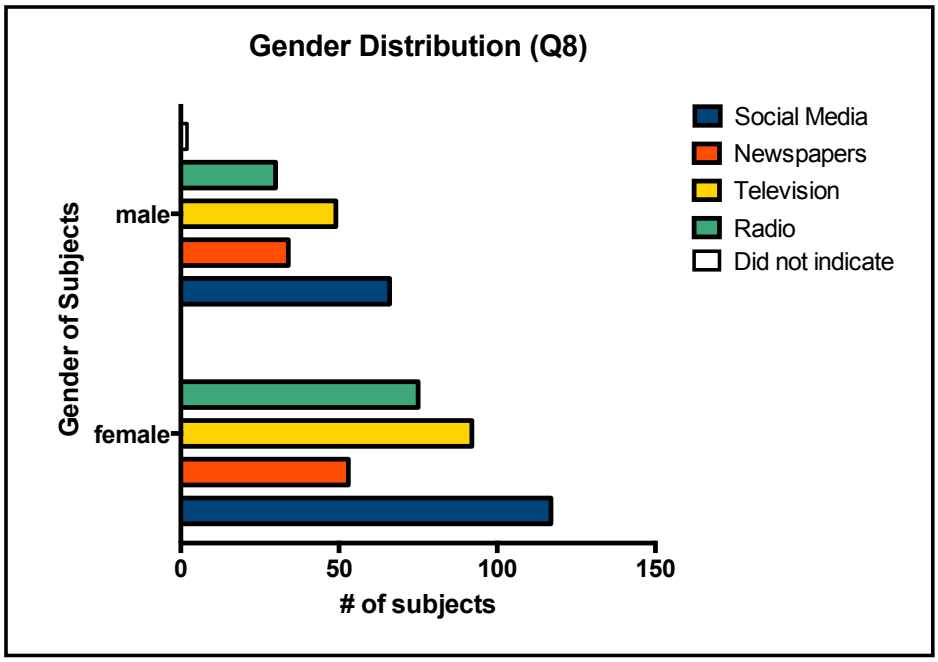


Figure 9.3: Distribution of Gender for Question 8

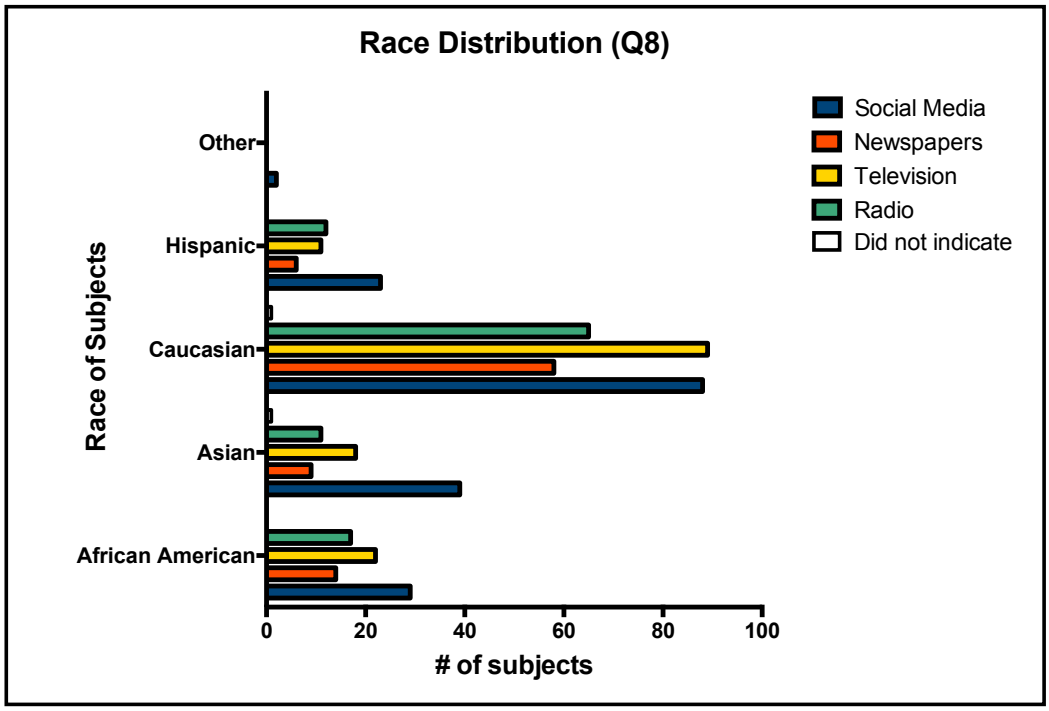


Figure 9.4: Distribution of Race for Question 8

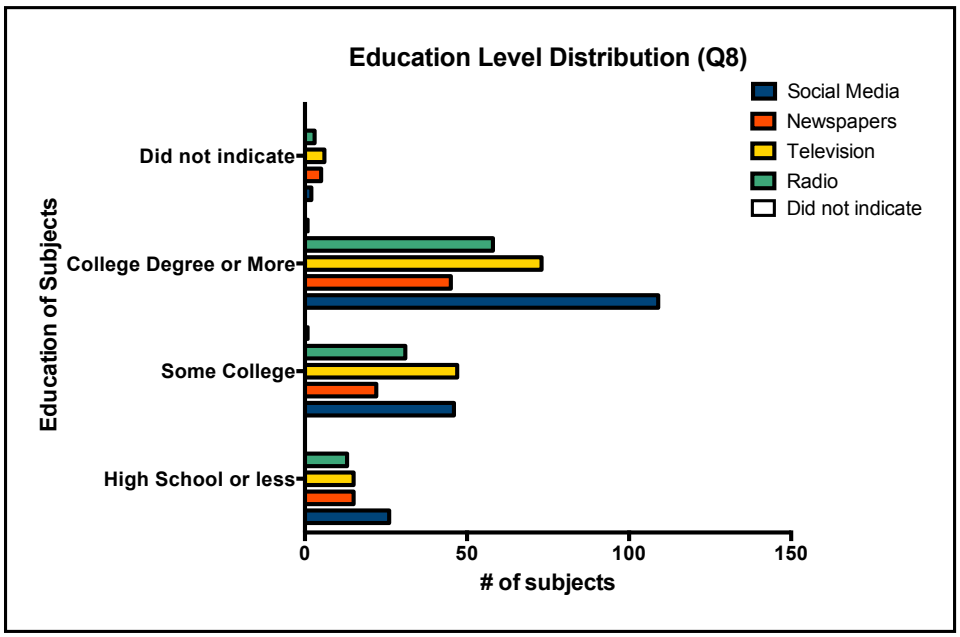


Figure 9.5: Distribution of Education Level for Question 8

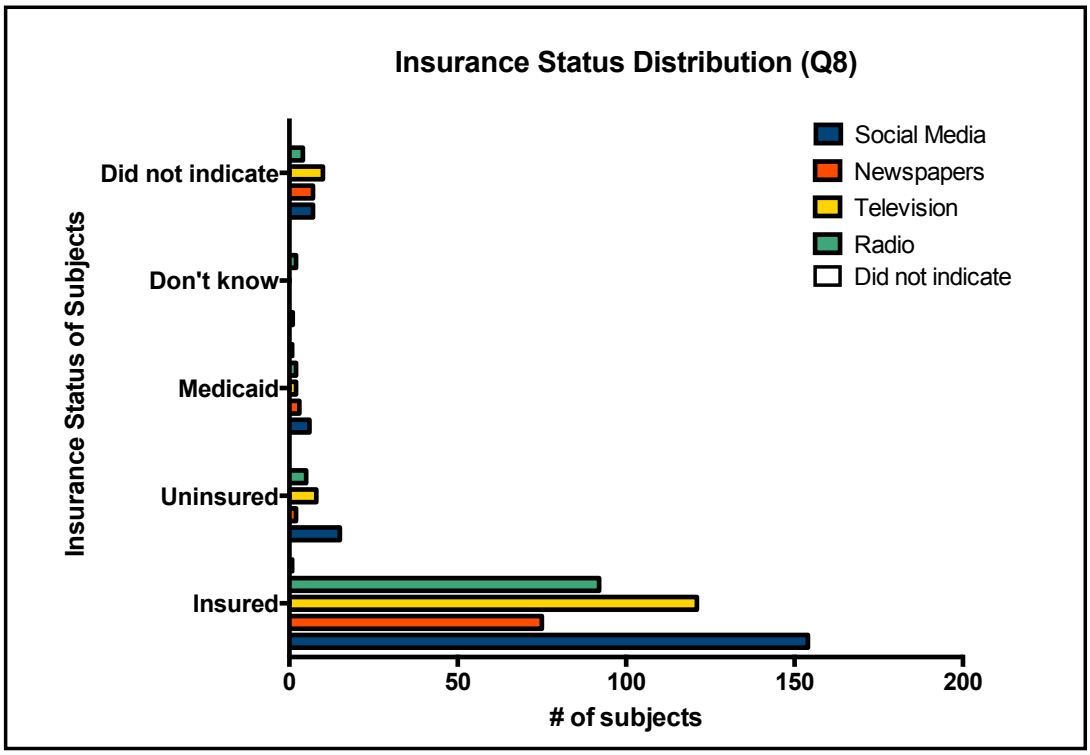


Figure 9.6: Distribution of Insurance Status for Question 8

The final question asked how the subject hears about current and upcoming events. News can be found from a variety of sources, with newspapers, television, and radio being considered more traditional ways to receive information and social media as being an up-and-coming way to stay abreast of upcoming events. For many Americans, it is becoming increasingly common to use social media websites such as Twitter and Facebook as a source of keeping up with current events (Barthel et al. 2015). When comparing how Millennials and Baby Boomers receive their political news, the results were in stark contrast with each other. About 61% of Millennials used Facebook to receive this news, compared to the 39% of Baby Boomers who also relied on Facebook for their political news (Mitchell et al. 2015). According to a study conducted by Pew Research Center in association with the John S. and James L. Knight Foundation, there are 63% of Twitter users and 63% of Facebook users who claim that both of these sites serve as a source to learn about what is happening around the world (Barthel et al. 2015). Of the two, Twitter serves as a way to receive "as-it-happens coverage and commentary on live events," which is why 59% of Twitter users say they follow breaking news on Twitter as opposed to the 31% that say they do that on Facebook (Barthel et al. 2015). Both Twitter and Facebook have made efforts to become providers of news. For example, Facebook implements a "trending" sidebar that shows trending topics in a variety of subjects, while Twitter has been working on several projects with the overarching goal to provide information about live events as they occur in real-time. This rise in those using social media to receive news has been seen across nearly every demographic group. There were increases in both men and women and age groups to their exposure to this new information; however, younger users were more likely to receive news via social media than older users even though the news usage of those under 35 and those over 35 increased at similar rates (Barthel et al. 2015).

According to Figure 7.1, many participants of the survey at the Baylor sites learned about upcoming events and news from social media. The second popular choice was television. Social media was a popular choice among the 18-29 year olds and the 30-49 year olds. The older age groups claim to consult television more often than they use social media to find out about upcoming news (Figure 7.2). Newspapers were the least chosen option and social media, television, and radio were chosen more often.

According to Figure 24.1, survey participants in the age groups of 18 – 29 years and 30 - 49 years chose social media the most. As the age of the participants increases, social media no longer becomes the most popular answer choice. For 50 years and older, television is the most popular answer choice. Second to television are newspapers, followed by social media and then the radio.

The trends for gender, race, highest education level, and insurance status are the same for all participants at the Baylor sites. However, Caucasians did not choose social media as much as they chose television. The study participants at UNTHSC chose social media as their preferred method of receiving information about upcoming events and news. The results for survey participants between the ages of 18 – 29 years at UNTHSC is comparable to those found for the same age group at the Baylor sites.

Table 8.2: Chi-square Results for Question 8

	Age	Gender	Race	Highest Education	Health Insurance
Chi-square	61.14	6.358	21.89	10.96	30.27
Degrees of freedom	12	4	16	12	16
p-value	<0.0001	0.174	0.1467	0.5323	0.0167

Table 16 illustrates the chi-square analysis of results for question 8. The highest chi-square statistical value is for age and it also has the lowest p-value. The p-value for health

insurance was also below 0.05 and it had the second highest chi-square value. This means that the results of both of these demographic categories can be applied to the general population from the study population. It also means that the relationship between the variables is strong.

The results of the chi-square analysis help support that there may be a relationship between some demographic categories and an individual's answer choice in the survey. Some of these relationships are stronger between certain demographics only. There were five questions that resulted in p-values less than 0.05 for age, which made them statistically significant and allowed the opportunity to make the assumption that the results from the survey, in the context of age, could be applied to the general population

The results of the two-way ANOVA statistical test are found in Appendix D. There are similar results from this test as well. The two-way ANOVA test measures if there is variation, but does not necessary tell you where it occurs. There were only a few cases when the results were statistically significant. In question 1 and 3, the results from insurance produced a p-value less than 0.05 for the observations associated with insurance status, but not the answers the subjects chose for these questions. Question 4 had p-values less than 0.05 for education and insurance. In question 2, 5, 6, 7, and 8 there were three demographic categories that produced statistically significant results: race, education, and insurance. Only questions 5, 6, and 7 produced p-values less than 0.05 in for multiple factors. In question 5, 6, and 7, education produced statistically significant results for two factors, one for the demographic category (highest education obtained) and another for the answers chosen by the study participants. For question 7, the same thing occurs for both education and age.

The two-way ANOVA attempts to test three null hypotheses. Some of the data collected for each question was able to reject the null for, at most, two of the null hypotheses, but never for

all three. The p-value was never significant to prove that the interaction between the two factors or variables existed, which means that there is no statistical backing that any of the results from this statistical test prove that the results from this survey are dependent on any of the five demographic categories. Figures 10.1-10.5 (see Appendix D) show comparisons of the overall demographic makeup of the survey participants from UNTHSC and Baylor All Saints. It is apparent that both populations differed greatly. UNTHSC survey participants were mostly between the ages of 18-29, males, Asian, with a college degree or more, and insured. Because variance measures the differences or inconsistencies in the values, this may have influenced the end results of the ANOVA test.

SUMMARY

Clinical research is a necessary and important step in the process of approving investigational drugs, devices, and procedures for market. Without sufficient study subjects there is a risk that the study drug will delay its approval or there will be statistically invalid data due to a small study population. Because clinical trials occupy a major portion of an investigational drug's lifetime, it is important to complete clinical trials quickly and efficiently; however, recruitment can hinder this process. Baylor Research Institute is finding it increasingly difficult to reach out to patients and recruit subjects in a timely manner. In the past, many of their study patients have been referrals from physicians; however, some of the inclusion criteria for studies require finding very specific study subjects.

The results of the survey help illustrate that if the survey subjects had access to more information they would be more likely to consider participating in a clinical trial. It must be recognized that many of the surveyed participants have never been asked to participate in a clinical trial. Social media is an intriguing option to use for recruitment because of its growing popularity among all demographics. Current recruitment efforts involve targeting the specific study subjects based on their demographics, age being a common inclusion or exclusion criteria. Because social media use is becoming increasingly popular among all demographics, this is an interesting option to possibly implement in the future. There is a concern that using social media for recruitment purposes may exclude certain demographics because of trends associated with Internet use, as well as trends associated with participants of clinical trials previously discussed. Many individuals indicated they would be willing to receive information about clinical research

via social media and social media was also how they heard about upcoming events as well; however, there were also individuals that indicated they were uncomfortable with this idea. Moving forward, Baylor Research Institute needs to consider the range of individuals they may be recruiting and make sure they implement strategies that do not exclude groups of people who may be hesitant to adopt more modern ways of communication. Future recruitment strategies will require a combination of different recruitment methods to successfully target individuals. This will depend on the inclusion and exclusion criteria, with age being an example. The statistical results from the chi-square test indicate that in some cases, of all demographic categories, age can be especially associated with use or disuse of social media. The results from the two-way ANOVA test are less conclusive.

LIMITATIONS

Although the results of this study produced informative statistics on the communication habits of the community that choose to receive their healthcare from Baylor All Saints and affiliated sites, there were limitations present.

Limitations Due to Survey

Concerns Regarding Questions

The survey consisted of eight questions that asked a wide range of questions to gauge the community's habits in regards to how they communicate on a daily basis. There was an attempt to amend some portions of the survey because of ill wording and misspelling; however, the Baylor IRB had some delays in approving the changes. The questions of concern were questions 4 and 6. There may have been a higher number of situations where people did not understand these questions and how to answer them. Question 4 asks, "How would you prefer to receive such information?" If the subject indicated that they were not interested in participating in clinical trials, they may have opted not to answer this question, since it did not apply to them. The meaning of this question should have been clarified to ask something like "If you were to receive information about clinical trials, how would you prefer to receive such information?"

Question 6 asks the subject "If you don't feel comfortable receiving clinical trial information from social media, where would you prefer to receive this information?" The same issue exists in this question as it did for question 4. Some individuals who answered that they did not feel comfortable receiving clinical trial information from any of the options in question 5, may have opted to not respond to question 6 due its wording. It should be considered, as well, that the documents are required to use 8th grade level words and grammar, which may complicate certain questions depending on its complexity.

Following question 3 where it asks if the subject would be interested in participating in clinical trials if more information was available, it could be interesting to have had a question that asked why an individual answered "No" to question 3. They may not know what a clinical trial is, they may think that it is not applicable to them, they may be scared for their safety, or they may just not be interested. This would be a topic a future study could explore.

The major professor also suggested that there be a question indicating if the study subject was an employee of the hospital or not. Nurses and physicians have been known to participate in clinical trials as study subjects in the past, which is why this question ended up not being asked. Although this question is only applicable to Baylor All Saints Medical Center and not the affiliated BRI sites, the impact that this question would have is unclear and would be another interesting question to explore.

It would also be interesting for there to be a question that asks the subject why they would be interested in participating in clinical trials that could help inform Baylor Research Institute about what clinical trials they should take on in the future.

Concerns Regarding Answer Choices

Many study subjects were unsure if they could choose multiple answers for this survey because there were no directions indicating if that was allowed or not. Although this is not a problem per say because multiple answer choices may be applicable to many individuals and allowing these individuals to indicate every answer that applies to them gives a more accurate snapshot of community trends, it was difficult to statistically analyze these questions. There were efforts to record and categorize the multiple-choice decisions, but that was something beyond the scope of this study. It would be an interesting topic to explore in the future.

The answer choices presented in the survey were also sometimes too general or did not encompass enough choices. Although research was done before choosing the available answer choices found on the survey, there were some individuals who believed that the questions did not accurately describe their communication habits and they expressed that verbally.

One of the questions from the demographic portion of the survey asks users about their health insurance status. This may have caused some confusion because of the choices available. If someone has Medicaid or Medicare, they are still considered "Insured," which is also its own option. Although there is a Medicaid checkbox, there is not a Medicare box, so it is unclear if all of those who indicate that they had Medicaid may have actually had Medicare or if some of those who checked "Insured" actually had Medicare. A future survey will need a team to help design questions that avoid these problems.

Limitations Due to Demographics

It was only made clear near the end of the internship that the surveys should have been split between Baylor All Saints Medical Center and the two other affiliated sites. This would allow the student to perform a two-way ANOVA and finish the practicum report in the limited timeframe allotted for this program. At the suggestion of the major professor, an amendment was made that would add UNTHSC as a survey site and this change was approved by both the Baylor and the UNTHSC IRBs. By the time it was approved, there were only a few days available for distribution of the survey. The major professor suggested only 50 surveys be distributed to the UNTHSC campus. These 50 surveys resulted in a total of 265 surveys. However, the original intention of the thesis was not to compare an educational facility versus a hospital environment. The goal was to survey individuals that went to Baylor All Saints Medical Center and affiliated sites to have any of their or their family's health care needs met. The population from UNTHSC may have skewed the data and may not give BRI the best data to base their future recruitment strategies off of. For example, the majority of those surveyed happened to be Asian, insured, between the ages 18-29 years, and have a college degree or higher. As with any data, there are multiple statistical tests that can be performed. Some of these tests are better than others, but it is unclear if the ANOVA test was the best fit for the data collected. The amendment was suggested, so that the student would be able to perform a two-way ANOVA statistical analysis, but by doing so the analysis of the data may have been inaccurate and not as useful to BRI's future recruitment efforts. There may be other statistical tests that could have been better, and this may be a point that could be revisited at a later date.

CHAPTER FIVE

INTERNSHIP SITE

The Clinical Trials Office (CTO) is part of the Fort Worth branch of Baylor Research Institute (BRI). CTO handles a wide array of study types ranging from women's studies, cardiovascular disease, and diabetes. The staff that comprises CTO includes: a clinical research manager, clinical research director, administrative assistant, two clinical research nurses, and one clinical research coordinator. Theresa Cheyne served as my on-site mentor for the 6-month internship for partial completion of the Master's program in Clinical Research Management and the clinical research manager of CTO. She also extended her position as being the manager of both CTO and the Transplant team.

JOURNAL SUMMARY

As previously stated, the Clinical Trials Office, a component of the Fort Worth division of Baylor Research Institute, is housed at Baylor All Saints Medical Center. There are several research studies conducted at offsite locations, such as Texas Health Care and the Diabetes and Thyroid Center. Tasks associated with the internship included contacting potential subjects for the SONATA study, updating subjects in the Galen portal, putting together informed consent form packets, drug accountability, and filing of documents back into the regulatory binders. I was able to experience conference calls, site initiation visits, monitor visits, patient visits, and study procedures.

APPENDIX A:

INTERNSHIP JOURNAL

DAILY JOURNAL

Week 1: June 1st – June 5th, 2015

01 Jun 2015

Today was my first day on-site and because I had to do without access to the computer, I had the opportunity to shadow Meagan, a research nurse. Meagan was working on a query that a monitor for a clinical research case had emailed her about. The monitor wanted to check one of the values inputted on the system. The specific question was highlighted in red, and the solution was to clarify what the range for a normal creatine level in males.

Meagan also pulled out one of her newer cases to walk me through the information included in the binder. I saw the various CVs of those working on the case, the delegated tasks, and the informed consent documents. I also asked Meagan about the protocol for sending patient information, to which she replied that it was okay to send patient information over email, but that any identifying information had to be blocked or marked out before it being appropriate to send that kind of information.

Around eleven o'clock, I met with Claudia Matill who is the clinical research director for the Clinical Trials Office (CTO) at Baylor Research Institute (BRI). I signed a confidentiality agreement, so I could receive access to their computer and databases. I was also able to sit through the tracking meetings for Meagan, Theresa (on-site mentor), and Mary (clinical coordinator) where Claudia checked up on the status for the cases, mainly concentrating on their recruitment efforts. There were three main categories of importance: screening, enrolled/consented, and randomized. I learned that screening means that they check to see if the patient meets inclusion requirements based off of their medical history. Enrolled/Consented are

patients that may have already signed the consent form, but there is a possibility that when lab tests are performed they end up not meeting the requirements. All patients have until visit 1b to qualify for inclusion, if the criteria for the study are still not met at 1b then the patient is "Screen failed." Lastly, randomized indicates if the patient was inputted into the IWRS (Interactive Web Response System), which means that the patient was placed into a treatment group and medication was initiated.

Afterwards, I was able to go through the protocol for an ongoing case and compare it to a patient's binder. The company did not provide forms for the patient binders, so Meagan had to make her own using a template from a previous similar study done a few years ago. I then shadowed Meagan as she screened patients for another ongoing case. The private investigator (PI) and sub-PI both sent and gave access to the medical records of patients they thought fit the inclusion and exclusion criteria via Next Gen; however, only one patient fit the criteria exactly and another one could have fit the data pending on what any future lab work would show.

02 Jun 2015

This morning I was able to follow Mary as she went to see if a woman she had screened earlier would be interested in participating in a study. The woman ended up saying she wanted to think about it before agreeing to participate, so Mary gave her the informed consent form and told her that she would ask her at her next visit to check back up on her. For the next hour or so, Mary checked the various doctors who had given her access to their charts to see if any other patients fit the inclusion criteria for the study.

I also accompanied Meagan when she went to drop off a packet to Touchstone. The packet contained a CD and other information so the company would know what to look for.

They will be performing the MRIs for an upcoming study, and they scheduled another meeting to occur during the site initiation visit to update them on the status of the study.

03 Jun 2015

Meagan showed me a study that they had just gotten, but because it was hard to contact the PI it made recruiting difficult. At around 10:30, I left for Dallas to attend a workshop hosted by Medtrials titled "GCP and Sponsor-Investigator Responsibilities." The course had two instructors, one of which happened to be the same instructor for the course we took in the spring for "Intro to Clinical Research Management." I wrote notes in the booklet they gave us, and I learned a lot. Some of it was review from our class, but we went more in depth on certain topics.

I've been thinking about a topic for my thesis, and so far I think the process of recruitment is interesting. There is a current study where the inclusion criteria and the required study activities are difficult for subjects to complete. There were talks about doing outside recruitment, like Facebook and radio ads. My group presentation for our CRM class was actually over using social media as a recruitment method, so it'd be interesting to actually see outside recruitment in effect.

04 Jun 2015

Mary took me, along with a monitor, to closeout a study. The physician had enrolled around twenty-five patients, but he didn't notice anything significant from the results. He decided he wanted to end the study because he wants to work with the company in the future. The monitor later said she respected that about him because that shows that he is responsible

with the money the company gave him and the likelihood they'll work with him again is more likely.

I also talked to Theresa and Meagan about potential thesis topics and we thought that retention would be an interesting topic as well. Currently, I'm doing research on recruitment because it could be something very applicable to how Baylor All Saints focuses their efforts in the recruitment process. At the end of the day, I finally received my login info to do necessary training on the Baylor Learning Network and access to iRIS. I will probably work on this tomorrow.

05 Jun 2015

Today, I assisted Meagan in drafting a script for one of the studies still recruiting patients. We referenced the material the study gave to us, including the study brochure, poster, and consent form. We had to make sure it was 30 seconds so we spent some time rewording the script so it could fit in its timeslot. Then we sent it to the monitor to be approved.

Afterwards, we realized that we were low on brochures, and we thought it would be good to order some more brochures, since the hospital is running a health fair on men's health in the next few weeks. While we were looking for forms to order the brochures, we made copies from the patients' binders that needed to be in regulatory binder.

I also finally started training the training modules on BLN (Baylor Learning Network). From the BLN, I was assigned lessons from the module for BRI Human Research Protection. After lunch, I also saw Meagan input the script to be approved by IRB because the monitor approved it.

Week 2: June 8th – June 12th, 2015

08 Jun 2015

I started the morning by finishing my last module for the BLN. I set up my computer, so I could print things on the main printer on this floor. I also was able to log onto iRIS. At noon, Dr. Schetz, my major professor, and Dr. Su, a member of my committee, arrived at Baylor All Saints Medical Center for our scheduled committee meeting. Dr. Patricia Gwirtz was unable to attend due to scheduling conflicts. Theresa and I joined them in a conference room to talk about potential thesis ideas. Dr. Schetz was hoping that we could work on something that already had data, so our next plan of action is to ask the various sponsors that work with BRI to release past data. Recruitment is an ongoing issue and, hopefully, there are some sponsors that are interested and willing to help me with my thesis.

09 Jun 2015

Today I read literature on social media and its use in clinical trials. I also began typing up a proposal, but I won't be able to complete it until we get a reply from the sponsors about whether I can use their data or not.

Later, I helped address huge envelopes to her patients, so she could put gift cards, copies of their labs, and new test strips before sending them to the appropriate recipient.

10 Jun 2015

I watched Meagan address two queries. One was to input lab results for a recent ECG test and the other was to clarify the patient history. I went with Trista and Meagan to the Diabetes and Thyroid Center (DTC), so Trista could drop off her study binders and the information for the

patient she is going to see tomorrow. Meagan had to pick up some test kits because she will need to draw blood for a subject for their "visit 1A." Trista showed me the equipment in their room at DTC and explained to me the process of calibrating the equipment in the room. Signed up for the "Patient Recruitment for Sites: Beyond the Traditional Approach" that is hosted by the ACRP in Dallas. For the rest of the day, I worked on my proposal.

11 Jun 2015

I arrived at the internship early to watch the process for processing a patient's sample. After completing a gentleman's visit 1a, we went into the lab room and centrifuged the specimen. We took the top layer of the separated product and the plan was for the company to send back his results for triglycerides. She showed me how to package the specimen and then we took it into the mailroom to be sent via FedEx. Then she showed me what she did with the patient binder afterwards and began typing notes on what occurred in the visit. These notes would be signed by the PI later and included in the patient binder. Then, I worked on my proposal and questionnaire. I sent both of these documents to Dr. Schetz and Theresa. Before I left for the day, I put stickers with Meagan's information on the brochures that we will be passing out at the upcoming health fair, so they can call her if they're interested in participating in the study.

12 Jun 2015

This morning I attended a lecture that Baylor All Saints hosts every second Friday of even-numbered months called "Grand Rounds." Grand Rounds has speakers that lecture on a variety of topics of interest to all specialties. Today's speaker was Dr. Thomas Busick who is a

practicing dermatologist and came to talk about melanomas. We learned about current and future treatment options, statistics on survival from melanomas, and then answered some questions. I walked to Fort Worth Heart with Meagan, so she could drop off some paperwork and pick some up from the PI that works there. After lunch, Meagan and I put away some items into the storage room that had just been sent to us for a new study starting at our site. We then put together the regulatory binder and made sure we had copies of appropriate documents.

Week 3: June 15th – June 19th, 2015

15 Jun 2015

This past Saturday I went to chapter meeting for the Association of Clinical Research Professionals (ACRP) where the speaker Wade Strzinek, the president of Protenium Clinical Research, discussed strategies for patient recruitment that go beyond the traditional means. His lecture was very interesting, and I was able to hear about some strategies for other sites in the North Texas area that did and did not work. Basically, social media isn't a "solve-all" answer, but it could be used, along with traditional strategies, to educate and reach a greater audience.

Today, I attended a site initiation visit (SIV). We walked through the regulation binders, patient binders, had a demonstration of how the tool works, talked about GCP, received training on their EDC, etc. I also worked on creating an excel sheet with the information of people who had filled out a form indicating they were interested in clinical research.

16 Jun 2015

This morning I finished the excel sheet I created with the information from the recent health fair that listed people interested in clinical research and what types of studies they would be interested in. I also helped Theresa total some values she gave me in excel, as well. For the study that we did the SIV yesterday, Meagan and I started to screen through patients from a previous study to see if they would be good candidates for this new study.

17 Jun 2015

Today I helped Trista with her drug accountability. I matched these insulin pens with their identification number. I also made an excel sheet with this information and included how

many were being returned, used or unused, or had the needle present. Then I sent that information to Trista, so she could look over it and make sure everything matched up. For the rest of the day, I worked on the documents I will need to submit to have IRB approval for both BRI and UNTHSC.

18 Jun 2015

I listened in on a conference call that Theresa had with one of the companies they're working on a new study for. They talked about recruitment. Theresa told them we would be looking at our databases for past patients that might have screen failed for previous studies, but may meet the inclusion criteria for this study. They discussed that our specific site goal was 30 patients. They also talked about external recruitment efforts where they said that because they had experienced some success with Facebook in the past they were going to try to implement Facebook Newsfeed Ads early in the recruitment process. Facebook was a great option for them because it was cost effective, especially for at least a few weeks. They already had their advertisements IRB approved and talked about putting one ad up on Friday and letting it run through the weekend because that was a popular time to generate buzz. I was also added to the Delegate of Authority and iRis for SONATA.

19 Jun 2015

I created an excel sheet for Meagan with information about studies for the transplant department because we are going to help them with some of their studies. I was also assigned to one of the new studies that just started called SONATA, and I had to fill out a conflict of interest questionnaire. I was given access to the database so I can work with some of the informed

consent for patients interested in the SONATA trial. I continued working on the IRB application for Baylor and editing my documents. Later in the afternoon, we got two hits from the Facebook ads. We went ahead and contacted them to see if we could answer any immediate questions. We also asked for certain info that we needed that weren't asked in the survey. Then, Meagan sent them the informed consent form so she could read through it on her own this weekend before Meagan followed up with her next week.

Week 4: June 22nd – 26th, 2015

22 Jun 2015

We had 11 hits from the Facebook ad for the SONATA study. I printed the forms out and Meagan called a few of them that indicated mornings were a good time to reach them. After that we went to DTC to have some forms signed and pick up a testing kit and the packaging material. We continued to call patients that filled out the Facebook survey, and I followed Mary to one of her site visits.

23 Jun 2015

I added onto the excel sheet for Meagan with more transplant studies. I also printed out the screenshots of the people who took the screening survey on Facebook. We had five more from this morning. I have also been looking at this page that has links and quizzes about drug accountability, informed consent and recruitment, medical history and adverse events, PI responsibilities, and source documentation. I updated the patient log on the Galent Gateway. We had a conference meeting in the afternoon, and then I started IATA training. I also called a few people that answered the screening survey in response to the Facebook ad.

24 Jun 2015

I went to Dr. Johns' office with Mary to see a patient, but they ended up not being able to make it for the appointment. When I got back to the office, I called two new referrals from the Facebook ad. Meagan called to follow-up with some of the other potential subjects, and I mailed in a consent form to one of the interested subjects. Then, I updated the patient log for the Sonata

study. In the afternoon, we followed up with several more people and I updated the patient log for them as well.

25 Jun 2015

Arrived on-site early because Meagan had a patient visit (visit 1b). She centrifuged the sample, pipetted the needed portion, packaged it correctly, and then we took it to the mailroom to be sent to the company that performs the tests. I printed off the screen shots of the new referrals off of Galen Gateway. I sent an email to one of them and edited their patient log. I also worked on my proposal and made changes that Dr. Su had emailed me about when he had finished reading it. I also got to see Dr. Johns perform a hysteroscopy where he removed a polyp before implanting an IUD.

After lunch, I called a few new referrals and sent two of them information about the study and gave them my contact info, so they could reach out if they have any questions or if they're interested. We made appointments for two individuals that had contacted us after we had sent them the ICF stating their interest in the study.

26 Jun 2015

There were two new referrals this morning. I called both of them and was able to send an ICF to one individual. The other individual unfortunately did not meet the inclusion/exclusion criteria, so I had to tell her she did not qualify. There was also an individual who emailed me this morning that I had contacted yesterday about the study, and she expressed her interested in the study as well. I updated the patient logs accordingly. Meagan and I put together the screening packets, since we have about four appointments next week for interested individuals.

Week 5: June 29th – July 3rd, 2015

29 Jun 2015

There were eight referrals online, and I printed out the summary forms. I sent emails to two individuals because they noted they would only be available to communicate in the evenings. I updated the patient log. Shortly after updating the patient logs, my computer died. There was a spark and the light flickered. I was unable to turn my computer on, but the screen was still receiving power. I went with Meagan to Dr. Johns' office to consent our first patient. Afterwards, I called IT to report my computer issue. I received a temporary laptop from Shawnta (administrative assistant) to use in the meantime. I called a few more potential subjects and updated the patient log accordingly. I also looked over some of the consent forms the subject signed today to make sure that everything was filled out.

30 Jun 2015

I walked into my office and someone had just finished fixing my computer. Successfully logging in was the final test to see if the computer was working properly. I printed off a referral from the portal system. One of our appointments to consent a patient was cancelled. I went ahead and called the two patient referrals we had and updated the patient logs for them. At around 2:45 PM, Meagan and I headed over to Dr. Johns' office to wait to go through the informed consent with a subject, but she ended up not showing up.

1 July 2015

We had an informed consent meeting at 9:00 AM. Afterwards, I created a patient consenting folder for an appointment we made on July 8th at 2:00 PM. Trista, Meagan, and I

drove over to DTC because they both needed to have things signed by the PIs. Trista also showed me the steps she takes when receiving a new shipment of drugs.

2 July 2015

Meagan and I had an informed consent meeting for a potential subject today. Unfortunately she had previously had a reaction with the contrast dye used for MRI imaging, which is of the exclusion criteria for this study. Meagan called the sponsor to ask if she could still participate. I also received feedback for my proposal from Dr. Schetz, so I started editing my proposal.

3 July 2015

No work today for July 4th weekend!

Week 6: July 6th – July 10th, 2015

06 Jul 2015

I went with Mary to Dr. Johns' office for a patient visit. It was this patient's sixth month follow-up visit and we had her fill out a questionnaire, drew her blood, weighed her, and gave her a gift card. Then Mary filled updated NextGen with the information from the visit and printed out stickers to send off the blood sample. Afterwards, Megan and I followed-up with some potential subjects for SONATA, and I updated the patient log accordingly. Meagan also made an appointment with one individual. I alo worked on editing my proposal.

07 Jul 2015

There was an appointment made for this morning at 9 AM; however, she ended up not showing up. We went back to the office for a little bit. I was able to continue working on the corrections that Dr. Schetz sent me. I also updated the patient log because we had an individual schedule an appointment for next week. At 11 AM we had another appointment. She filled out the informed consent form, and we had her to fill out a questionnaire and tell us her health history.

After lunch, we went through the INDs for a study Meagan is helping with. I also got a call from an interested subject and went ahead and sent her the informed consent document via email. The sponsor called Meagan and they talked about extending the Facebook ad, since it was so successful.

08 Jul 2015

Meagan filled in for Mary today, since she was unable to come into work. She completed a 6-month follow-up visit for a subject in the AEGEA study. Back at the office, we inputted the consented patients into the EDC for the SONATA study. Afterwards, I went with Meagan back to Dr. Johns' office, so she could finish putting in a patient visit in the system. We also attended Dr. Johns' ultrasound training for the SONATA study. Afterwards we consented a patient, but had to screen-fail her because she had no fibroids.

09 Jul 2015

Made a laminated copy of the image of the fibroid locations, so we can have them as references. I also put together two patient folders that we need when we go over the informed consent and health history with them. After lunch we headed over to Touchstone imaging to have MRI training for the SONATA study. We also stopped by the Community Health Clinic, which is a charity clinic, to drop off brochures for the SONATA study and the STRENGTH study because these individuals either don't have insurance or are underinsured. They might be more inclined to participate in a research study if it means they receive free health care services. I also double-checked to make sure I updated the patients that had already been consented on the Galen.

10 Jul 2015

I spent today working on my proposal. I had a conference call with Dr. Schetz about the final changes to my proposal and any other questions I had. I will be going to Dr. Schetz' and Dr. Su's offices to get their signature on the proposal document.

Week 7: July 13th – July 17th, 2015

13 Jul 2015

I updated the patient portal for SONATA by changing the Subject IDs for the subjects that had been consented. I worked on my IRB submission to the Baylor IRB. I just need signatures from Claudia and Dr. Johns before I can submit. I then listened in on a meeting that Theresa had with Mary and Meagan. It was supposed to be a meeting that talked about their goals for this year, but they also talked about how they would split up Trista's work for this week, since she is sick and probably won't be able to come in this week.

14 Jul 2015

We had an informed consent appointment this morning. After signing the informed consent, Dr. Johns performed an ultrasound and unfortunately the subject did not have fibroids. I updated Galen and then I watched Meagan as she updated iRIS, organized the contents of the folders, and inputted them into the study's EDC. I also was able to obtain all the signatures I needed for my IRB submission and sent that to be reviewed. I also helped Sandra put one of her studies into an excel sheet so they could tabulate the costs during the duration of the study in a more efficient and easier manner.

15 Jul 2015

I went with Mary to consent a subject for the SONATA study. Dr. Johns did a sonogram and he found that the subject has two fibroids that can be treated. We did all the required paperwork and had Dr. Johns do his required part. I also updated Galen with her new patient ID. I worked on the spreadsheet that I was helping Sandra with. I also started to format my thesis.

16 Jul 2015

We had an informed consent meeting today. After signing the informed consent, the patient went over her medical history. She told us that she had been previously told she had fibroids. When Dr. Johns did the sonogram her uterine volume was too large and her fibroid was also over the acceptable limit provided to us by the study. We had to screen-fail her. It was sad because we really wanted to help her and she was feeling relieved she might have found a solution to her heavy bleeding and painful cramps. I updated the Galen portal that she screen-failed. In the afternoon, we tried following up with some potential subjects before we reopen the Facebook ad next week. If I couldn't reach them, I updated them as "excluded (pre-consent)" and listed the reason as being unable to contact them.

17 Jul 2015

I made copies of some of the MRI information for the SONATA study, so Theresa could have an extra copy. I also started formatting the document for my practicum report.

Week 8: July 20th – July 24th

20 Jul 2015

When I left Friday, we had just had someone call saying they wanted to make an appointment. I updated that person's information on Galen and will update it again with her new ID number after we consent her on Thursday. I started putting together the UNTHSC IRB packet, so I can send that off when my submission for the Baylor IRB is approved. I also went ahead and started inputting and formatting my journal entries for my thesis.

21 Jul 2015

I went with Mary to one of her follow-up patient visits. When she was inputting the study visit into the computer, one of Meagan's subjects had arrived early thinking she had her consenting appointment today. Her appointment was actually scheduled for tomorrow at 9. Meagan and Trista had gone to DTC, so Mary went ahead and consented her. Dr. Johns did not find any fibroids, so unfortunately she was screen-failed. I also called someone who works for Galen Recruitment and he said he could provide me with some retrospective data about what has worked in the past for recruitment.

22 Jul 2015

I attended a meeting with CTO where they talked about helping Transplant with their studies if they started to get overwhelmed. We also talked about updates within the studies that CTO has and plans for collaborating if the workload became unmanageable.

23 Jul 2015

I shadowed Mary for two patient visits she had today. It was for a study that required one blood draw that filled five tubes, and it was to test if there was any way to detect liver diseases early. There was no immediate benefit to those that participated, but there's an implication that it could help others in the future. I thought it was really awesome how these people wanted to participate just to help others. I also helped put together a patient consent folder for a subject we have scheduled next week.

24 Jul 2015

Today, I helped scan a folder of documents for Sandra in a big pdf file. I also worked on my introduction for my thesis and formatted it. I started rereading articles, so I could start my chapters. I also sent an email to Dr. Schetz to talk about potential dates for my defense.

Week 9: July 27th – July 31st

27 Jul 2015

Sonata had Galen reopen their Facebook ad and I came into work today with seven new referrals. I printed the contact information for those patients. I then when with Meagan on a patient visit to Fort Worth Heart to do a yearly follow-up visit for one of the atrial fibrillation and stroke studies. Meagan performed a quick stroke assessment on her and then she received her gift card. I went with Mary for one of her follow-up visits. She asked her about any updates and drew her blood before the subject received her gift card. I received an email from Bill with some general information they found with their recruitment methods. I also called the referrals from this morning and was able to send a couple of ICFs. I updated the portal accordingly.

28 Jul 2015

There were three new referrals on Galen and most indicated that the best time to reach them would be in the afternoon or evening. I printed those out and called some of them in the late afternoon. We had a subject come in that was one of the first few to consent before Dr. Johns was certified with the sonography training, so we completed several lab tests. Her vitals were recorded, a gonorrhea and chlamydia test was taken, a pelvic exam was done, and a sonogram completed. The sonogram revealed that her uterine volume and fibroid were too large. We unfortunately had to screen-fail her. I also started working on my background and literature review section of my thesis. We had two informed consent meetings for this week be rescheduled for another week.

29 Jul 2015

I started the morning by addressing the stipulations on my IRB submission. There were several spots where I did not adequately answer the question on the application, so I had to go back and elaborate or change certain sections. I also had to reupload the changes to the initial review submission. I helped Trista by downloading updates for the eDiaries for a specific study. Many of them had to be charged and I checked to see that the chargers worked. I called the four new referrals we received today and sent one ICF out to an interested person. The others I was unable to contact.

30 Jul 2015

I printed off four new referrals from Galen this morning. Meagan showed me how to go into iRIS and update the visit details for subjects. I made sure that all the screen fails had their information correctly inputted. Meagan and I went to Dr. Johns to have him sign some forms. I called several new referrals this afternoon. I also did some drug accountability for Trista.

31 Jul 2015

I printed off one new referral from Galen this morning. We had two women interested in the study and request to be scheduled for appointments. This week we received nineteen referrals and were able to contact several interested individuals. I also helped file some forms into the regulatory binder.

Week 10: August 3rd – August 7th

03 Aug 2015

Meagan had left a stack of papers with the patient log information from Galen on my desk from Friday. She had called these subjects last week and I updated Galen with the appropriate information. I updated my journal depository with my week 9 entries and I started a new journal entry for this week. Mary had a "SlieaGen" study visit involving a blood draw, so I went with her to see that. Later, I went with Meagan, while she visited a transplant patient to get his vital signs. We had an informed consent appointment for today at 1, but the patient had a BMI over 40. Therefore, she unfortunately did not qualify for the study.

04 Aug 2015

I read papers for my thesis, so I could work on my second chapter section on literature review. I also helped Trista with patient health reports. Using an excel template, I can put certain information and have it map out the patient's progress throughout the study. Patients may like this because it would allow them to see how they've been doing throughout the study.

05 Aug 2015

I received approval for my IRB submission today, but I have to send a signed financial form for them to release my IRB submission approval letter. In the meantime, I completed the packets for the UNTHSC IRB submission. I also worked on a project that Theresa gave me, which involved looking up some cardiologists and updating their information on her spreadsheet she gave me.

06 Aug 2015

I continued working on the project Theresa gave me yesterday. I also called some potential subjects to follow-up on them and see if they were interested in participating in the SONATA study. I was able to talk to one subject and send her an informed consent form, while I was only able to leave voicemails for the others. I updated their information on the Galen portal.

07 Aug 2015

I made sure Galen was updated because we have a monitor visit next week. I worked on two patient health reports for Trista. I finally received my IRB approval letter and I printed those out and added them to my two packets for the UNTHSC IRB. I emailed Dr. Gwirtz, and she told me I could turn them into her box anytime before Tuesday.

Week 11: August 10th – August 14th

10 Aug 2015

The Facebook ads for the SONATA study started up again and there were seven referrals waiting for me when I arrived at the office. I left around lunchtime to turn in the IRB packets to Dr. Gwirtz' box and I also got a PPD testing. I then called the seven potential subjects and was able to send the ICF to two of them. I updated Galen to reflect that I contacted all of them. Afterwards, Theresa gave me a new project, which involved making an excel sheet with the costs associated with the SONATA study. I was able to look over the contract and the specific costs for each component of the study.

11 Aug 2015

I printed off the four referrals we had today. I called two of them in the morning because they indicated that was the best time to reach them. I was able to contact both of these and send them an ICF. I updated those two patients on Galen and also made sure all of the IDs were correct for those that had been consented. I also continued working on the spreadsheet I made for SONATA. I edited a document for Theresa that they will be using to interview people interested in the position of clinical research assistant. After lunch, I called the other two potential subjects today and sent them the ICF.

12 Aug 2015

I printed out two new referrals and called one at 10 o'clock because that was when she indicated she would be available to reach. She believed her BMI to be over 40, so she went ahead and told me she was not interested. We had an informed consent meeting before that at 9

o'clock. She showed up a little early, but we moved down to a different room to consent her. Unfortunately Dr. Johns has a full schedule today and tomorrow, so we were unable to fit her in for a sonogram. I called the second referral today and sent her an ICF after she called back later in the day. I also worked on a project Theresa gave me about some of the finances of Sandra's studies.

13 Aug 2015

I printed off the two referrals from this morning. I made a patient informed consent binder for an upcoming appointment scheduled for the next few weeks. I also helped file some documents into the regulatory binders for two different studies. I called a potential subject today and sent her an ICF. I also went to the CTO's staff meeting where they talked about concerns and workloads. There was a monitor visit today as well and I printed off my curriculum vitae, so they could have a record of it in the regulatory binder. I made some changes to my introduction of my thesis and worked on the background and literature review portion.

14 Aug 2015

There were four new referrals today. I printed off their information sheets and called them in the afternoon. I was able to reach one patient and send her an ICF. There was a woman who said she wasn't interested previously called back asking me to send her another ICF because she was reconsidering enrolling for the study. I also worked on putting some of the documents in my appendices, such as the BRI IRB documents and questionnaire. I got an email from the UNTHSC IRB asking for more of the study documents, so I sent the forms I attached to my initial application. I updated Galen with all new information we've received.

Week 12: August 17th – August 21st

17 Aug 2015

I printed out six patient summaries from Galen. I started helping Meagan create the informed consent document for a transplant study to be approved by the Baylor IRB after I complete it. I also made another informed consent form for the pregnant partners of those involved in the original study.

18 Aug 2015

We only had one patient referral today, so I printed that out to call them later. I sent two ICFs to some women interested in the study. I also finished the excel sheet that Theresa had assigned me last week. I also completed one of the patient health reports for Trista's study in an excel sheet.

19 Aug 2015

I faxed some medical records forms for Trista. I also worked on various portions of my thesis. I listened in on a conference call for the SONATA study and helped Trista with her patient binders.

20 Aug 2015

Left for interview at MSUCOM.

21 Aug 2015

Interviewed at MSUCOM.

Week 13: August 24th – August 28th

24 Aug 2015

The UNTHSC IRB approved my project last week, so I printed out several copies of my thesis and cover letter to start recruiting. I also started an excel sheet to input my data from the surveys once they are completed. I went to distribute some surveys around 10AM and was able to have twelve of the surveys completed. I realized I might need to change some wording on my survey because some of these subjects marked multiple choices.

25 Aug 2015

I fixed some grammar errors on my survey and I also added an additional question to clarify a response from one question. Later, Theresa helped me resubmit my edited questionnaire to the IRB. In the meantime, I will be using the old survey. We got a call from a woman who was interested in the study, so Meagan spoke with her to schedule an appointment. I also helped Meagan create an excel sheet to keep track of the subjects for one of her studies she's working on. I updated Galen with the subjects that Meagan called last week.

26 Aug 2015

I continued to put in the information I got from the surveys I passed out on Monday and Tuesday into an excel sheet. I went with Mary, while she completed a patient visit for SlieaGen. I got a couple more surveys completed and put those into my excel sheet as well. I received my copy of the UNTHSC IRB submission that was accepted last week and uploaded the images to the appropriate appendix of my thesis. I also submitted the new questionnaire to iRIS.

27 Aug 2015

I attended phone training for SONATA because they changed their protocol recently. I also helped Susan with the language in the informed consent form she is working on. Later, I tagged along with Theresa during her site selection visit (SSV) for a new fibroid study. The SSV took place at our site and Dr. Johns' office. They also talked about another study the sponsor was interested in having us help with. In the afternoon, we had the second part of a screening visit for a SONATA subject. The information we collected was her vitals, blood draw for creatine, pregnancy test, gonorrhea and chlamydia test, hysteroscope, endometrial biopsy, and a sonogram to confirm measurements. I also got several people to complete some surveys for me, so I spent the rest of my day inputting that information.

28 Aug 2015

We got a patient referral from another source other than Galen. I sent the woman an ICF via email. I looked over my data from my excel sheets to confirm I had the right numbers. Later, Theresa had me fill some information on IND reports and then scan those files to her. I also helped transfer some files from one of Dr. Johns' binders to another new binder. Afterwards, I worked on three ICFs for Theresa, but there were about four more left. I sent my work to Meagan, so she could look over it because I was unsure how to transfer all the information from the sponsor to our ICF template. I was also able to have a few subjects fill out my survey for me.

Week 14: August 31st – September 4th

31 Aug 2015

I collected some surveys and inputted that information once I got back to my desk. I also helped Meagan call back some potential subjects for the SONATA study. Unfortunately, many of them we were unable to contact, so we had to move them to a different folder. I also updated my journal entries in my thesis documents.

01 Sep 2015

I continued to collect surveys from people at the hospital. I inputted that information into my excel sheet. Someone called in response to the calls I made yesterday saying she was interested in receiving more information on the SONATA study, so I sent her the ICF for the study and provided our contact information to her.

02 Sep 2015

I went with Meagan to Dr. Johns' office to schedule some subject visits and have him sign some documents. Later, I shadowed Mary, while she did a patient visit for the Slieagen study. I worked on revising another informed consent for a transplant study, which I sent to Meagan to proofread. I was able to get several surveys today and quickly put that information into my excel sheet. Afterwards, Meagan had an informed consent meeting in our office. After she was finished, we went to Dr. Johns' office to do the subject's her sonogram.

03 Sep 2015

I received more completed surveys and inputted that information into my excel sheet. I then attended a joint CTO and transplant meeting where we talked about the current status of both divisions.

04 Sep 2015

I went around the hospital to find more subjects for my surveys. I also decided to retract my IRB submission to Baylor with the changes to the survey because it had still not been accepted. I also considered the fact that after getting Baylor's IRB approval I would have to get UNTHSC's IRB approval, which would mean that by the time everything was approved I wouldn't really have enough of a sample for those questions anyways. I ended today with 92 surveys. I also worked on documenting INDs for Susan on a word document.

Week 15: September 7th – September 11th

07 Sep 2015

Labor Day

08 Sep 2015

I went with Mary for a follow-up visit she did for Aegea. Then I finished working on Susan's IND document. Afterwards, I went to collect more surveys and my total number of surveys became 103. I spent the majority of my day inputting survey data into excel, and then Meagan and I had an informed consent meeting with a Sonata subject at 3 PM.

09 Sep 2015

I finished the rest of my data input into my excel file. I printed off new referrals for SONATA and updated the woman I called yesterday. I had called her at an inconvenient time, so she asked me to call back in 30 minutes. I left her a voicemail 30 minutes later, which I indicated in the comment section on the portal website. I also attended a Research and Evidence Based Practice Council with Theresa and Adrienne. There was one group who wanted approval for their study that involved NICU babies and breastfeeding. We also heard a presentation about data storage.

10 Sep 2015

I got some surveys completed and put those into my excel sheet. I also went with Mary as she consented a patient for SONATA. Dr. Johns couldn't decide if she screen failed today because she was about to start her period and her endometrium was thickened because of that.

He recommended she come in another day. Then I made some copies for Theresa and called some interested potential subjects for the SONATA study.

11 Sep 2015

I called a potential SONATA subject this morning because she indicated mornings were best for her. I also printed out the summary sheets for two other interested subjects. I went with Trista to DTC to try to figure out the eDiary and tablet for an upcoming consenting on Monday. I was also able to go with Meagan to complete the last follow-up visit for a subject. I called several more interested potential subjects for the SONATA study and updated Galen with their current status. I then worked on my thesis and sent my intro to Dr. Schetz to proofread.

Week 16: September 14th- September 18th

14 Sep 2015

There were seven entries on the Galen portal. I printed out all of those and immediately emailed the two that indicated the best time to contact them would be in the evening. Then I went to DTC with Trista for her first consenting visit for BIPI. For the consenting visit we had to have them sign the ICF, register the patient for the eDiary, have her take some tests, and take vital signs. Because of the inclusion of technology in this study, this visit took a while. I called some interested subjects and sent a few ICFs and voicemails before leaving for the day.

15 Sep 2015

Left for my interview and received a call that I was accepted into MSUCOM!

16 Sep 2015

Interview day at KCUMB.

17 Sep 2015

I updated Galen with potential subjects that Meagan had called when I wasn't on-site. I updated my excel sheet with the surveys. Then I went with Meagan to DTC to see her consent a patient for the STRENGTH study.

18 Sep 2015

I made an IND table for Alexion and then scanned the individual INDs to my email. I don't have complete access to the F drive, so I wasn't able to upload them to update the Transplant folders. I also emailed a potential subject today.

Week 17: September 21st – September 25th

21 Sep 2015

I spent the first part of the morning double checking all the files that I scanned on Friday and transferred them to a folder until I have access to Transplant shared drive. I also watched a blood draw for a diabetes study. I updated my excel sheet with new surveys and I continued working on my thesis. Meagan followed-up with some potential subjects and I updated that information into the Galen portal.

22 Sep 2015

Meagan consented a subject in the morning for SONATA and then we walked over to Dr. Johns' office to complete her sonogram. I got several surveys completed and input those results into my excel sheet. I also went with Mary for a Slieagen patient visit. Then, I worked on a subject enrollment log for Transplant.

23 Sep 2015

I went with Meagan to complete visit 2 for a patient in the Strength study. I saw her do the patient's EKG and blood draws. This was the first randomization for a drug that I've seen. Later, I updated my excel sheet with new surveys. I also worked on my thesis.

24 Sep 2015

The Facebook ads were put up again one more time. I printed out the four hits we had since yesterday and emailed one of the interested subjects who indicated the best time to contact her was in the evening. I finally got access to the F drive and transferred all of the IND reports

that I scanned into an appropriate file. I went with Meagan for two 3-year follow-up patient visits for the Canopy study. I also called interested subjects for the SONATA study. I updated my excel sheet with new surveys from today.

25 Sep 2016

I helped Theresa empty out old binders and put their contents into the "to be shredded" bin. I also printed out potential subject summaries for SONATA. I had a conference call with Dr. Schetz to discuss the progress of my thesis. I also inputted new survey results into my excel sheet.

Week 18: September 28th – October 2nd

28 Sep 2015

I printed off the patient summaries for interested SONATA subjects. There were 11 waiting for us when we came into work today. Meagan had called some individuals on Friday, so I updated Galen to reflect those changes. I was able to contact two individuals in the morning and sent both of them ICFs. Theresa gave me a project that involved updating an excel sheet that I had made at the beginning of the summer. I also updated my journal entries in my thesis. I had some surveys that were filled out today and also updated my excel sheet with that information. I called all of the interested potential SONATA subjects and updated their information on the portal.

29 Sep 2015

There were three interested subjects in Galen and I printed their information out, so I could call them in the afternoon. I completed surveys and updated that info into my excel sheet. I also received an email from Bill who works with Galen. I emailed him yesterday on the behalf of Dr. Schetz who told me he wanted data that I could do statistical analysis on.

30 Sep 2015

I worked on the project that Theresa had given me a few days ago. I updated the excel sheet for Cumberland with the invoice items. I also called interested subjects for SONATA and sent ICFs. I got a few surveys completed and inputted those into my excel sheet as well. We were supposed to go to Dallas for the course "Advanced GCP," but it was cancelled last minute.

01 Oct 2015

We had a couple of interested subjects today and I printed off their information summaries. I also had Theresa and Dr. Su sign the "intent to defend" form. I made final changes to the excel document for Cumberland and sent that to Theresa.

02 Oct 2015

Meagan and I called all the patients we've contacted in the past for the SONATA study to make sure that everyone has received information. There were several individuals that were still interested and we also scheduled some women for upcoming appointments. I finally reached my goal of 200 surveys today and I put that information into my excel sheet. I also helped Trista sort some files into her regulatory binders.

Week 19: October 5th – October 9th

05 Oct 2015

I had a meeting with Dr. Schetz this morning where we discussed my data and how I should type my specific aims. Dr. Schetz told me that I cannot do statistical analysis on my, so he suggested I extend my survey to UNTHSC. This is because he wants me to do a two-way ANOVA test. I started a project for Jennifer by scanning W9 forms and consent forms and then adding those to the Transplant shared drive. I also shadowed Mary as she completed a patient visit for Slieagen.

06 Oct 2015

I continued working on Jennifer's project. I also called several locations to see if they would allow me to pass my surveys out. I talked to Susan and Jennifer to see if they could take me to the Transplant Clinic and Liver Consultants of Texas offices, so I could talk to their managers about getting approval for my survey. Deborah said I could go with her to a Breast Cancer Convention to pass out my surveys whenever I get IRB approval. Touchstone said they would not allow me to pass out my survey. I prepped the required forms to update iRIS and plan to have Theresa sign off on that tomorrow, since she was out-of-office today and yesterday.

07 Oct 2015

Theresa signed Form 35 and I was able to submit my IRB submission with the required explanation of changes. I also shadowed Mary for her Slieagen study visit and then watched how she centrifuged and then separated the plasma into an appropriate tube for shipping and storing. She put that in the refrigerator, where Jennifer was responsible for the rest of the process (i.e.

sending it off to the appropriate party). I went with Deborah, Shawnta, Mary, and Meagan to a Breast Cancer Convention where they talked about specific cases. It was a really interesting experience and very cool to see the collaborative process between different professionals and what they saw as acceptable approaches to these specific cases.

08 Oct 2015

I checked the status of my submission and its present status hasn't changed from yesterday. I worked on creating the graphs for my thesis, and I also worked on refining previous sections of my thesis. I helped Shawnta relocate office things to other rooms because we're in the process of moving things around to make room for more patient rooms and office space.

09 Oct 2015

I attended a Grand Rounds seminar where Dr. Erwin talked about how there may be an alternative to pap smears in HPV testing because it would give a more definitive test. I shadowed Mary as she did a patient visit for Sliagen. I also helped Sandra by scanning and sending her some documents specific for a study. I had a meeting with Dr. Gwirtz to talk about the progress of my thesis.

Week 20: October 12th – October 16th

12 Oct 2015

Interview Day at CUSOM

13 Oct 2015

Travelling back to and from Dallas

14 Oct 2015

There was a pre-review action that needed to be addressed for the proposed changes to my study with the Baylor IRB. They requested I put a date in the header. I completed that and turned that in. I helped Jack, the new CRA, by showing him how to fill in the IND reports. I shadowed Mary for a Slieagen visit. I also went to another Breast Cancer Conference today and they talked about more cases. I still think it is awesome that I've taken histology and I can recognize some of the structures. Some of the topics are over my head, but the meetings are very interesting. I helped Mary alphabetize subjects' information sheets she had already called for Sliagen.

15 Oct 2015

The Baylor IRB approved my proposed changes to site location and sent me an approval letter. I sent the required documents to Dr. Gwirtz and she said she was going to start working on it tomorrow. I went with Meagan to drop off the CD for a subject's MRI scan. I also shadowed Mary for a little bit for Slieagen. I made a checklist for our floor to put into the break room.

16 Oct 2015

I worked on figuring out how to statistically analyze my data and continued to work on the parts of my thesis I had the information to work on. Dr. Gwirtz sent the signed memo to Dr. Brian Gladue, the head of the UNTHSC IRB for approval. I worked on locating files to update Theresa's Standard Operating Procedures (SOPs), but I could not locate the file online. For the time being, I do not have to worry about finding these documents.

Week 21: October 19th – October 23rd

19 Oct 2015

I shadowed Mary as she completed an Aegea follow-up visit. There was a blood draw involved, gift card distribution, and then writing notes on the visit in the patient portal. Meagan had a consenting appointment for a potential patient for the SONATA study. When she went to complete her sonogram, the subject screen-failed because she didn't have clinically significant fibroids. Afterwards, I updated subject information in the Galen portal. I helped Meagan update the screen-fail binder for Sonata. I added two patients to the binder and made sure everything was in the order that Meagan specified.

20 Oct 2015

I shadowed Mary for a Slieagen visit in the morning. It was her 6-month follow-up visit and she had to answer a few questions and have her blood drawn. The materials for her 12-month office visit were distributed and then Mary updated her information in the patient portal. Afterwards, Mary sent me the documents for another study and I helped with the informed consent form.

21 Oct 2015

The UNTHSC IRB was approved, so I updated my appendix section for my IRB documents and included those documents. I am making plans to collect surveys. I went to DTC with Meagan, Theresa, and Trista for a Diabetes meeting where they talked about ongoing trials, upcoming/future trials, finances, and then other concerns they had. CTO had a staff meeting where everyone updated Theresa with the current progress with ongoing studies.

22 Oct 2015

I took a half day today because I need to travel to New Orleans for a funeral. I resent an ICF to an individual that said she never received her email with the ICF attached to it. I also worked on the graphs for my thesis. I plan on finishing my thesis as much as I can this weekend.

23 Oct 2015

Not in office for funeral.

Week 22: October 26th – October 30th

26 Oct 2015

SONATA is rerunning their Facebook ads, so I printed off the new entries. I also made a cleaning list to go into the break room. I called potential patients today and sent out some ICFs. I also worked on an excel workbook with information about transplant studies. I listed all of the transplant studies and included information about the purpose, number of subjects enrolled, subjects needed, time spent in study, and the PIs for each.

27 Oct 2015

I printed off new potential patient summaries. I also sent an ICF to an individual for the SONATA study who had called earlier in the morning. I finished the excel sheet with the Transplant studies and sent that to Theresa. In the afternoon, I called a couple of interested subjects and was able to talk to one of them. I sent her an ICF and updated information to the Galen Portal.

28 Oct 2015

I printed off new potential patient summaries again. I went with Meagan and Theresa to watch a procedure for the SONATA study. I saw the preparation that went into the procedure and then what happens afterwards. There's a lot that needs to be documented. All together, the whole process took us the majority of the day. I sent some ICFs after we got back and called a potential patient.

29 Oct 2015

I printed off a patient summary for SONATA and emailed the individual because she indicated she wanted to be contacted via email. I finished the project that Theresa and Michelle assigned to me regarding the timesheets and editing its contents to make it more current. Michelle also assigned me the task of creating an organization chart for her power point presentation. Theresa also gave me another project involving the financial binders. Michelle sent me another project involving double-checking an excel sheet to make sure the total values matched up.

30 Oct 2015

I came in early today to work on my thesis. I worked on inputting data and finishing the last sections of my thesis. I stayed late hoping that I'd finish before I left for the day. Unfortunately, this did not happen. I did continue to work on it at home, but I realized it didn't send to Dr. Gwirtz until extremely late in the evening because it was stuck in the outbox. Earlier today, I printed out a patient summary and called her before 9AM like she indicated, but she told me she was busy and hung up before I could get her information down. I did email her an ICF for the study. I went with Meagan to retrieve the sterilized device for the SONATA study. It was sent to be sterilized after the procedure on Wednesday. We also dropped off some paper work at Fort Worth Heart. I sent another ICF to a woman who called in the afternoon. For the rest of the day, I worked on my thesis.

APPENDIX B:

QUESTIONNAIRE

QUESTIONNAIRE

Age: ☐ 18 – 29 ☐30 – 49 ☐ 50-64 ☐65+
Gender: ☐Male ☐Female
Race: ☐African American ☐Asian ☐Caucasian ☐Hispanic ☐Other
Education: ☐High School or less ☐Some college ☐College degree or more
Health Insurance: ☐Insured ☐ Uninsured ☐Medicaid ☐Don't know

Q1. Have you taken part/been asked to take part in clinical trials before?

☐ YES

☐ NO

Q2. If you answered "YES" to the last question, how were you approached to take part?

☐Doctor

☐Brochure/pamphlet

☐Poster/flyer

☐Radio or TV ad

☐ Social Media (Facebook, Twitter, Online forums, Blog, etc)

Q3. Would you be interested in taking part in clinical trials if more information was available to you/easier to access?

☐ YES

☐ NO

Q4. How would you prefer to receive such information?

□ Social Media (Facebook, Twitter, YouTube, Online forums, Blog)

□ Print Media (Newspaper Ads, Brochures, Pamphlets, Posters)

□ Mass Media (Television and Radio Ads)

Q5. What form of social media would you like or would prefer to receive information about clinical trials from?

☐Facebook

☐Twitter

☐ YouTube

☐Online forum / Blog

☐I don't feel comfortable receiving clinical trial information from any of these options

Q6. If you don't feel comfortable receiving clinical trial information from social media, where would you prefer to receive this information?

☐Doctor referral

☐Flyers

☐Brochure

☐Radio ad

Q7. What forms of social media do you use most often?

☐Facebook

☐Twitter

☐Snapchat

☐Instagram

☐ YouTube

☐Online forum / Blog

Q8. How do you learn about upcoming events?

☐Social media (Facebook, Twitter, YouTube, Forums)

☐Newspapers

☐Television

☐Radio

APPENDIX C:

IRB DOCUMENTS

IRB Approval – Expedited Review of New Study

To: Theresa Cheyne, RN

Copy to: Claudia Mattil, Theresa Cheyne, RN

Date: August 04, 2015

Re: 015-182
Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials
Reference Number: 088829

Your new proposal was reviewed by a designated member of Baylor IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following category(ies) from the 1998 approved list:
Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

This review included the following components:

Study Application	
Form Name	**Outcome**
Study Application - Review by BRI IRB	Approved as Presented

Study Document			
Title	**Version Number**	**Version Date**	**Outcome**
Supplemental application Form 1	Version 1.1	07/29/2015	Approved
Form 18 - signed	Version 1.0	07/14/2015	Approved
Form 34-signed	Version 1.0	07/14/2015	Approved
Form 35 - signed	Version 1.0	07/13/2015	Approved
proposal	Version 1.0	07/13/2015	Approved

Questionnaire	Version 1.0	06/19/2015	Approved

Study Consent Form			
Title	**Version Number**	**Version Date**	**Outcome**
Cover Letter 7_13	Version 1.1	07/13/2015	Approved

Your submission has been approved. The approval period begins on 08/04/2015 and expires on 08/03/2016. Your next continuing review is scheduled for 06/22/2016.

This study is approved to be conducted at the following locations:
Baylor All Saints Medical Center at Fort Worth, Main, BASMC-Transplant Clinic
Other Non-Baylor Facility - Diabetes and Thyroid Center
Other Non-Baylor Facility - Texas Health Care, PLLC

The following individuals are approved as key study personnel (research team members & administrative support):
Cheyne, Theresa, RN; Mattil, Claudia; Nguyen, Denise Thi

Based on the information as provided in your application, the IRB has determined that this study qualifies for a waiver of documentation of informed consent in accordance with 45 CFR 46.117.

This means that while you are required to obtain consent, written documentation of such is not required. This should be done utilizing the IRB approved method as listed above. This is either a cover letter, telephone script or other specific tool as approved by the IRB.

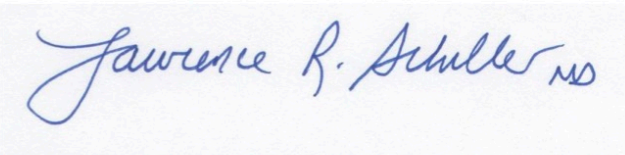
All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Research Institute prior to beginning your study.

If you need additional assistance, please contact the IRB Specialist at 214-820-9989.

Sincerely,



Signature applied by Lawrence R. Schiller on 08/05/2015 01:16:25 AM CDT

1.0 General Information

*** Please enter the full title of your study:**

Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials

*** Please enter the Study Nickname you would like to use to reference the study:**

Potential for Social Media in Clinical Research Trials

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Is this Study using Subject Management?

○ Yes ◉ No

2.0 Add Department(s)

2.1 List departments associated with this study:

Primary Dept?	Department Name
☑	**BRI** - CLINICAL RESEARCH - ONCOLOGY

3.0 Assign key project personnel(KSP) access to the project
*** The current project status does not allow for changes to the Key Study Personnel. If you wish to change the Key Study Personnel, please contact the IRB.**

3.1 * Please add a Principal Investigator for the project:

Cheyne, Theresa, RN

Select if applicable

☐ Student ☐ Department Chair

☐ Resident ☐ Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Nguyen, Denise Thi
Co-Investigator

B) Research Support Staff

Cheyne, Theresa, RN
Research Coordinator

3.3 * Please add a Project Contact:

Cheyne, Theresa, RN
Mattil, Claudia

The Project Contact(s) will receive all important system notifications along with the Principal Investigator (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please add a Faculty Advisor:

3.5 If applicable, please select the Designated Department Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e g the Department Chair or Dean).

3.6 If applicable, please select the Administrative Assistant(s):

Administrative Assistant Note

4.0 TYPE OF APPLICATION

4.1 Is this a one time Emergency Use only application?

○ Yes ◉ No

5.0 TYPE OF PROJECT

5.1 Type of Project (Please choose the one category that best fits your project):

○ Research Determination Decisions
◉ Minimal Risk Possible Expeditable/Exempt Projects
○ Clinical and/or Other Greater than Minimal Risk Projects

If Research Determination Decisions:

○ Case Reports (1 or 2 patients only)
○ Preparatory to Research HIPAA Only Review (not to be used to collect data or recruit subjects)

If Minimal Risk Possible Expeditable/Exempt Projects is selected then:

☐ Review of Existing Medical Information (Clinical Chart or Database) Only
☐ Blood collected solely
☐ Secondary use of Blood/Tissue
☐ Database (Research)
☐ Tissue/Blood Bank
☐ Exercise
☑ Survey Procedures/Focus
☐ Registry

If Clinical and/or Other Greater than Minimal Risk Projects is selected then:

☐ Drug Study. Only Approved Drugs Used in Accordance with current FDA Approval
☐ Drug Study: Phase I
☐ Drug Study. Phase II
☐ Drug Study: Phase IIa
☐ Drug Study: Phase IIb
☐ Drug Study: Phase III
☐ Drug Study: Phase IIIa
☐ Drug Study: Phase IIIb
☐ Drug Study: Phase IV
☐ Medical Device: PMA Approved (used in accordance with approval)
☐ Medical Device Investigational (IDE)
☐ Medical Device: Humanitarian Use (HDE)
☐ Medical Device: 510K Approved (used in accordance with approval)
☐ Clinical Trial/Feasibility Study
☐ Other Greater than Minimal Risk Study (please specify type)

Specify Other:

5.2 Study Subjects

Indicate number of subjects projected to be enrolled in study:

Locally:
300.0
Nationally/Internationally (if multi-center trial)
0.00

6.0 FUNDING INFORMATION

6.1

Identify funding sources for this study:

Additional review is required by Baylor Research Institute, Office of Sponsored Research. This includes negotiation of your contract or submission of your grant for externally funded studies. Studies funded solely by Baylor (either through the entity or one of the Foundations) require completion of either a Departmental or Foundation Funding Form.

These forms can be found at:

https://www.mybaylor.com/BRI/Forms/BHCS DEPARTMENTAL RESEARCH SUPPORT FORM - 052914.xlsx

and should be submitted directly to Ashley.Dowell@baylorhealth.edu

Your IRB Approval letter will not be released until all financial paperwork is completed.

Do Not include these forms with your IRB submission.

View Details	Sponsor Name	Sponsor Type	Funding Through	Contract Type:	Project Number	Award Number
⊞	Baylor Research Institute	Internal Baylor Funding				

6.2 Are resources for conducting this study being provided from other sources?

○ Yes ◉ No

If yes, please specify what resources are being provided

6.3 Does this project involve testing of a product or service that is not owned by the sponsor/funding source as listed above (i.e. approved drug, investigational product, clinical procedure):

○ Yes ◉ No

If yes, please list the name of the product or service:

If yes, please list the owner of the product or service:

6.4 Please list the Protocol Number as issued by Sponsor (if none, list N/A):

N/A

6.5 Is the Principal Investigator or any Baylor owned subsidiary the IND/IDE holder for this study?

○ Yes ◉ No

7.0 SCIENTIFIC/SCHOLARLY REVIEW

7.1 Who (group or individual) has conducted the scientific review for this study?

* One or more check boxes in first column must be checked.

	Check all that apply	Provide Sponsor/Manufacturer or Other
☑ Project has received scientific evaluation from an independent source(s)	☐ FDA ☐ NIH ☐ Sponsor/Manufacturer ☑ Other	Dr. Alan Johns

☐ Project has received scientific evaluation from BHCS representative (s)

Check all that apply

☐ Department Chair
☐ Department Committee
☐ Other Representative

Department Chair

Department Committee

Other Representative

Study Classification
Non-Investigator Initiated

8.0 RESEARCH TEAM MEMBERS

8.1 Do all members of the research team hold appropriate medical staff and/or allied health professional credentials required to perform any standard procedures that are being done as a part of this study?

◉ Yes ○ No

If no, please explain:

9.0 ADMINISTRATIVE/CLINICAL OVERSIGHT

9.1 Location of Research Activities:

Please choose all locations where research activities will take place. This should include study related procedures, obtaining informed consent, data collections, etc.

Locations

Facility. Baylor All Saints Medical Center at Fort Worth

Building: Main

Location: BASMC-Transplant Clinic

Facility: Other Non-Baylor Facility

Facility: Other Non-Baylor Facility

9.2 If Location is Other Non-Baylor or Other Baylor Facility, please specify where.

Diabetes and Thyroid Center - 7801 Oakmont Blvd # 101, Fort Worth, TX 76132
Texas Health Care, PLLC - 1250 8th Avenue Suite 330, Fort Worth, TX 76104

9.3 Clinical Division(s):

Please identify the Clinical Division(s) involved in this study:

Other Non-Clinical

10.0 USE OF FDA REGULATED PRODUCTS

10.1 Does this study involve the use FDA regulated drugs (approved or investigational)?

○ Yes ◉ No

10.2 Does this study involve the use of FDA regulated medical devices?

○ Yes ◉ No

11.0 SUBJECT RECRUITMENT

11.1 Subjects will be recruited from the following sources (check all that apply):

Note: The IRB must approve all recruitment materials prior to use.

- ☐ My Private Practice
- ☐ Physician Referral Sources
- ☐ Advertising currently available for IRB Review (Posters, Newspaper, Radio, Television, Internet, etc.)
- ☐ Advertising not currently available for IRB Review but to be submitted prior to use (Posters, Newspaper, Radio, Television, Internet, etc.)
- ☐ Listing on Baylor Internet site
- ☐ Listing on www.clinicaltrials.gov
- ☑ Other

Please specify Other Source:

Baylor All Saints Medical Center, DTC, Texas Health Care

11.2 Describe methods that will be used to identify potential subjects, obtain and record subject PHI (i.e. BCON search, medical records query, database query, etc). This section should specifically state what records will be searched, who will conduct the search, what (if any) data will be recorded for future contact with subjects, what relationship the individuals who review the data have with the potential subject:

The population sampled will be individuals that come into the hospital or select medical clinics associated with the Clinical Trials Office at Baylor All Saints Medical Center in Fort Worth that come in during the time the survey is distributed, which will be about 2-3 months. Exclusions will include individuals who are younger than 18 years of agea nd those that cannot read English. There will be no relationship between the individual who reviews the data and the potential subject. The subjects will not be contacted after the duration of the study as it is an anonymous survey and there will not include any personal identifying information on the questionnaire.

11.3 Do you plan to offer a stipend/payment to subject who take part in the study?

○ Yes ◉ No

If yes, please provide the amount. This can be the overall total, per visit total, or any other combination which provides the IRB with the necessary information. Please specify which method is being used (i.e. overall or per visit):

Provide additional details such as how often payments will be made, how much per visit (if not listed above) and timing (at the visit? by mail afterwards? at the next visit?, etc.)

Keep in mind that payments must be made as frequently as possible and bonus payments cannot be given for the completion of the study.

Method of payment?

☐ Bank of America Visa Gift Cards provided by BRI
☐ Gift Card provided by the Sponsor
☐ Other

Please specify Other Method of Payment:

12.0 DATA SAFETY MONITORING BOARD

12.1 The IRB requires that all studies involving greater than minimal risk include provisions for monitoring of the data to assure the protection of the rights, welfare and safety of the research subjects. This would include (but is not limited to) such information as protocol compliance, adverse events, serious adverse events, complaints by subjects, unanticipated problems and other risks to subjects.

Please answer the following questions to address these issues for this study:

12.2 Has a Data Safety Monitoring Board been established for your study?

○ Yes ◉ No

If yes, please provide the reference in the protocol for reporting information to the IRB:

If no, please check any/all of the following that apply:

☐ Phase III clinical trial
☐ Phase I or II clinical trial where subjects are being enrolled at more than one location
☐ Phase I or II clinical trial that includes a blinding component
☐ Phase I or II clinical trial that includes a vulnerable population
☐ Phase I or II clinical trial that involves randomization
☐ Study involves gene transfer or gene modification therapy
☐ The IND/IDE application is made by the PI or another Investigator at Baylor
☑ None of the following apply

12.3 Has another type of Data Monitoring Committee/other committee been established by sponsor?

○ Yes ◉ No

If yes, please provide the reference in the protocol for reporting information to the IRB:

12.4 Has an independent Medical Monitor, Data Monitor, or other data review process been

established by sponsor?

○ Yes ◉ No

If yes, please provide the reference in the protocol for reporting information to the IRB:

12.5 If none of the above has been established, please provide a process for monitoring of this information. While in some cases, this may be acceptable to be handled only by the PI, ideally, this process should include someone independent of the study execution when at all possible.

PI and sub-investigator will monitor.

13.0 USE OF RADIATION

13.1 Does study involve radiation exposure for any of the following purposes? Research or Diagnostic or Therapeutic

(If you check any of the boxes below, then you must also submit your application to the Baylor Committee on Radiation Safety and Radioisotopes. See instructions on this MyBaylor web site: https://www.mybaylor.com/opera tions/radiation_safety/BUMC/Pages/CRSR-Review-of-IRB-Protocols-with-Radiati on.aspx /> or call 214-820-7133 or email medical.physics@baylorhealth .edu)

○ Yes ◉ No

13.2 If yes, what type of radiation exposure procedure is involved?

Select **all** that apply:

Radiation Safety Review: The subsequent questions should be answered if the procedure is being done for diagnostic or therapeutic purposes.

- ☐ Diagnostic X-Ray
- ☐ CT Scanning
- ☐ Fluoroscopy
- ☐ Radionuclide Studies
- ☐ Therapeutic Radiation (external beam or other)
- ☐ Other Administration or use of Radioactive Substances

14.0 SUPPLEMENTAL REVIEW REQUIRED

14.1 Radiation Safety Review continued:

Will women of child-bearing potential be exposed to radiation (including any diagnostic or therapeutic radiology or nuclear medicine procedure) as part of this study?

○ Yes ◉ No

If YES, then pregnancy status must be evaluated prior to each radiation procedure. Please indicate what provisions for evaluating pregnancy status are proposed for your study. This should include (but is not limited to) such information as when study required pregancy tests are done and what type of birth control is required per protocol.

14.2 Institutional BioSafety Committee:

Does this study involve the use of recombinant DNA?

○ Yes ◉ No

Does this study involve the use of Select Agents?

○ Yes ◉ No

Does this study involve the use of Select Agent Toxins*?

○ Yes ◉ No

If you answered "YES" to any of the questions above, your study must be submitted to the Institutional Biosafety Committee (IBC) for review. Send a copy of the protocol and IRB Application to: Steven J. Phillips, Ph.D , BRI Biosafety Officer, Baylor Research Institute 214-820-9993 (Phone) 214-820-4952 (Fax) steveph@baylorhealth.edu

14.3 Nursing Research Committee:

Does this project study nursing in the area of practice, professional issues, education, or management?

○ Yes ◉ No

If yes, this must be submitted to Susan Houston, PhD, Director of Nursing Research for Baylor Health Care System.

14.4 Cancer Center/Oncology:

Does this project involve cancer patients?

This question applies to studies conducted by any department (nursing, surgery, pastoral care, social work, etc.) if the subjects in the study are chosen because they are cancer patients.

○ Yes ◉ No

14.5 Pathology/Tissue Committee:

Does this research involve the use of human tissue that has been removed from a patient at a Baylor facility?

○ Yes ◉ No

STATEMENT OF CHIEF OF SERVICE/CHIEF SCIENTIFIC OFFICER

(*This person can be anyone who has the scientific knowledge to approve the validity of the proposed study The PI is not authorized to sign this form as this creates a conflict of interest*)

Project Title: Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials

IRB # 015-182

Principal Investigator Theresa Cheyne

Name and Title of Scientific Review Delegate Dr. Alan Johns, Medical Director

I have reviewed this proposed research project and my signature below certifies that this project has scientific and scholarly validity. My signature also certifies that this project has undergone scientific and scholarly review to determine that it has scientific of scholarly validity. I also certify that conduct of this project is in compliance with the mission and goals of Baylor Health Care System and this service

Signature of Chief of Service/Medical Staff Delegate/Chief Scientific Officer — Date of Signature: 7/18/15

STATEMENT OF BAYLOR ADMINISTRATOR:

(*This person can be anyone who is in an upper administrative position overseeing the daily operations where the proposed study will take place The PI is not authorized to sign this form as this creates a conflict of interest*)

Project Title Analysis of Current Recruitment Methods. Measuring the Potential of Social Media in Clinical Research Trials

IRB Number. 615-182

Principal Investigator Theresa Cheyne

Name and Title of Baylor Administrator Claudia Mattil, Clinical Research Director

I have reviewed the proposal to be submitted to Baylor Research Institute and understand that by signing below I have committed the resources needed by my department to conduct this study It is my responsibility to assure that budget issues related to this study are resolved If this study involves the resources of another Baylor department, I have contacted that department administrator for input regarding their department If applicable, I will ask the investigator to obtain a second signature for said department administrator

Signature of Baylor Administrator

7-14-15
Date of Signature

Project Title: Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials

IRB Number: 015-182

Type of Review: (Circle One) **New Study**
Continuing Review
Revision
Event (SAE, Protocol Deviation, etc)

INVESTIGATOR COMMITMENT:

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to the IRB approved protocol and any additional stipulations imposed by the IRB I assure the IRB that I have sufficient time to conduct and complete the research in accordance with IRB guidelines I agree to comply with all Baylor Research Institute IRB policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research I certify that no similar proposal has been disapproved by another IRB. I agree to maintain strict confidence of information that may be disclosed including subject/patient, data, employee, institution proprietary, industry trade secrets, and any other form of confidential information

I agree to report immediately to the IRB any non-compliance, unanticipated problems involving risks to subjects or others, complications or adverse incidents with respect to human subjects

I agree to perform the project with qualified personnel according to the approved protocol I agree that I am to implement no changes in the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects) I agree to obtain the legally effective informed consent from human subjects or their legally responsible representative, and use only the currently approved, date-stamped consent form I agree to evaluate on an individual subject basis, whether or not an individual subject understands the information presented during the informed consent process. I agree that informed consent is an ongoing process and it is my responsibility to determine over a period of time that all research subjects continue to be willing to participate

I understand that I have the responsibility to make the Department Administrator aware of all protocols that are submitted to the IRB.

I understand that the electronic submission includes documents that may have been completed by a delegate on my behalf My signature indicates that I have reviewed the information and am in agreement with the information as provided to the IRB

The Institutional Review Board of the Baylor Research Institute will suspend approval of all research projects of investigators who are non-compliant with the above requirements The Chief-of-Service will be notified of the suspension as will the Chairman of the Medical Board and other Institutional Officials Non-compliance of IRB requirements could result in Institutional Officials reporting these actions to the Office of Human Research Protections, the US Food and Drug Administration, the Study Sponsor or other agencies

Signature of Principal Investigator

7/13/15
Date of Signature

IRB# 015-182

Baylor Research Institute
Baylor All Saints Medical Center
Diabetes and Thyroid Center
Texas Health Care, PLLC

I am a student intern at Baylor Research Institute and we are conducting a research project to determine the best strategies to recruit interested individuals about upcoming clinical research trials in this particular community. Currently, it is very difficult to recruit interested individuals by traditional methods (such as radio, TV, brochures, flyers, etc.), so this research project would study the methods of communication that this community uses most often. You are invited to take part in this research study survey because you are a member of this community and are using the Baylor All Saints Medical Center and associated clinics for your health care needs.

This survey will indicate your preferred methods of communication, as well as gauge your interest in clinical research trials. The survey will take no more than 10 minutes. You will not be asked for your name or any other identifying information on the survey. If you choose to do so, complete the survey and send it back to me. Do not write your name on the survey. I do not need to know who you are. The results of this study would then be used to implement more efficient means of recruitment. Since the survey does not ask for any person information that could identify you, there will be no way to withdraw from the study once you complete and return the survey directly to me or staff.

There are no foreseeable risks associated with taking part in this survey. You may receive no direct benefit from taking part in this study. The benefits of this survey/interview will allow us to evaluate the most efficient way to reach out to interested individuals for clinical research trials. You have the option to not complete the survey and not be in the study. By choosing to fill out the attached survey and returning it to me, you are saying that you are willing to take part in this study.

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

- Principal Investigator: Theresa Cheyne
  - Email: Theresa.Cheyne@baylorhealth.edu
  - Phone: 817-922-2579
- Co-Investigator: Denise Nguyen
  - Email: Denise.Nguyen@baylorhealth.edu
  - Phone: 817-922-2588

If you have any questions about your rights as a research subject, please contact Lawrence Schiller, MD at 214-820-2687.

Thank you for your interest in taking part of this project and I hope you will take a few minutes to complete the survey and return it to me. Without the help of people like you, this research would not be conducted.

Sincerely,

Denise Nguyen

UNT | HEALTH SCIENCE CENTER

Institutional Review Board

DATE: August 19, 2015

TO: Patricia Gwirtz, PhD (with Clinical Research Management Student: Denise Nguyen)
Clinical Research Management

FROM: Scott Penzak, PharmD
UNTHSC Institutional Review Board (IRB) Vice Chair

PROTOCOL: # 2015-138

Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials

IRB BOARD ACTION AND NOTICE OF APPROVAL

This project is a clinical research management project of Denise Nguyen, who is key personnel on an existing protocol approved by Institutional Review Board (IRB) at Baylor Research Institute. The IRB at Baylor Research Institute approved the protocol on 08/04/15 as an Expedited category project [Baylor IRB 015-182]. The University of North Texas Health Science Center (UNTHSC) IRB has reviewed the protocol and accepts and concurs with the Baylor IRB findings and approves the protocol under Expedited review procedures [45 CFR 46.110 (b) (1), category (7)].

Approval is effective August 19, 2015 through **August 3, 2016.**

Please Note: The protocol's expiration date is aligned with the expiration date of the Baylor IRB-approved protocol.

Remember that you are responsible for complying with all UNTHSC requirements regarding projects involving human subjects and ensuring that the research is conducted as specified in the approved protocol. It is important that you use only the latest approved versions of all study documents and that all changes be approved by the IRB before they are implemented.

Any changes affecting the protocol upon which this certification is based must be reported to the Office of Research Compliance. **No changes may be made without prior approval by the IRB** except those necessary to eliminate immediate hazards.

Should your project period extend beyond this expiration date, you must submit a Progress Report for Continuing Review to the IRB. You must allow sufficient time for the renewal request to be reviewed and approved **before expiration of the current approval.** Be sure to *prepare for a renewal 2 months prior to the protocol expiration date.* If the project is finished before the approval expiration date, you may submit a final Progress Report (Continuing Review) either at the time the project is completed or before the expiration.

The Office of Research Compliance does their best to send out a reminder notice to send in your Progress Report (Continuing Review), but it is your responsibility to prepare such a report in order for continuing review to occur before the expiration date.

If you have any questions, please contact the Office of Research Compliance at 817-735-0409.

Board Action-page 2

PI: Patricia Gwirtz, PhD

IRB Project #: 2015-138

Date: 08/19/2015

SPECIAL FINDINGS:

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

☐ **45 CFR** ☐ **21 CFR**

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

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

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

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

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

☐ OTHER:

OTHER

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

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

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

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

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

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

survey instrument

☑ **Other Comments:**

The UNTHSC IRB Chair concurs with the Baylor IRB's finding that this study qualifies for a waiver of documentation of informed consent in accordance with 45 CFR 46.117.
Please note: the protocol's expiration date (08/03/16) is aligned with the expiration date of the Baylor IRB-approved protocol.

UNT Health Science Center
Office of Research Compliance
Institutional Review Board
BOARD ACTION

IRB Project #: 2015-138 Date Submitted: August 14, 2015

Principal Investigator: Patricia Gwirtz, PhD (with Clinical Research Management Student: Denise Nguyen)

Project Title: Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials

Sponsor Protocol #: N/A

Department: Clinical Research Management Contact Info: patricia.gwirtz@unthsc.edu

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

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

☑ Project has received approval through: **August 3, 2016**

☑ Informed consent(s*) approved as submitted on : **August 19, 2015**

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

*Including: Cover Letter

☐ Study Protocol dated _____ approved as submitted.

☐ Investigator's Brochure _____ approved as submitted.

☑ Protocol Synopsis approved as submitted on: **August 19, 2015**

☐ Amendment _____ to the protocol approved as submitted.

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

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

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

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

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

☑ Special Findings/Other

Clinical Research Management Project of Denise Nguyen who is key personnel on an existing Baylor IRB-approved protocol. Protocol approved by the Baylor Research Institute IRB on 08/04/15 as an Expedited category project[Baylor IRB 015-182]. Dr. Gwirtz serves as PI of record for UNTHSC. The UNTHSC IRB Chair accepts and concurs with the Baylor IRB's findings. See p. 2.

Chair / Vice Chair, Institutional Review Board

August 19, 2015
Date

IRB Form 2 (revised March2015)

University of North Texas Health Science Center

Office for the Protection of Human Subjects (OPHS) / Institutional Review Board (IRB)

Request for Review of Expedited Category Research Project

IRB # 2015-139
(Staff Use Only)

Research activities that (1) present **no more than minimal risk** to human subjects and (2) involve **only** procedures listed in one or more of the categories below in Section One may be reviewed by the IRB through the expedited review procedure. *Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

If you believe that your research falls into one of the following categories, please indicate which category or categories you believe is or are appropriate. The IRB Chairperson (or designee) will review your research to determine if expedited review is warranted and if approval can be granted. If you have any questions, you may contact the OPHS Office at 817-735-0409.

Title of Research Activity: ANALYSIS OF CURRENT RECRUITMENT METHODS: MEASURING THE POTENTIAL OF SOCIAL MEDIA IN CLINICAL RESEARCH TRIALS

Name of Principal Investigator (Faculty Member): Dr. Patricia Gwirtz, Ph.D, FACC

Department/Program: Integrative Physiology and Anatomy

RECEIVED
AUG 13 2015
UNTHSC
Research Compliance

Categories Eligible for Expedited Review: (You can check more than one category, as needed.)

Category 1:	**Check if applicable:**	**Check if applicable:**	
☐ **Clinical studies of drugs and medical devices ONLY when condition (a) or (b) is met:** →	☐ (a) Research on drugs for which an investigational new drug application is not required.	☐ (b) Research on medical devices for which: (i) an investigational device exemption application is NOT required **OR** (ii) medical device is **cleared/ approved** for marketing and it is being used in accordance with its cleared/approved labeling.	**Note:** Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is **NOT** eligible for expedited review.
Category 2:	**Check applicable biance Center**	☐ (b) Other adults and children*, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.	**Indicate volume and frequency of blood draws.**
☐ **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:** →	☐ (a) Healthy, non-pregnant adults who weigh at least 110 pounds. **Contact OPHS Staff for criteria**	**Contact OPHS Staff for criteria**	_____ _____ _____
Category 3:	**Check all that apply:**	☐ Amniotic fluid obtained at the time of membrane rupture prior to or during labor	☐ Hair and nail clippings in a non-disfiguring manner
☐ **Prospective collection of biological specimens for research purposes by noninvasive means.** →	☐ Placenta removed at delivery ☐ Deciduous teeth taken during exfoliation or routine patient care ☐ Permanent teeth if routine patient care indicates a need for extraction ☐ Excreta and external secretions (including sweat) ☐ Uncannulated saliva	☐ Supra- and subgingival dental plaque and calculus. [Collection is not more invasive than routine prophylactic teeth scaling and it is done according to accepted techniques] ☐ Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings	☐ Sputum collected after saline mist nebulization **If research does not include any of the given specimen collections, give a brief description:** _____ _____
Category 4:	**Check all that apply:**	☐ Magnetic resonance imaging (MRI)	**NOTE:** *Studies intended to evaluate the safety and effectiveness of a medical device are **NOT** eligible for expedited review, including studies of cleared medical devices for new indications.*
☐ **Collection of data through noninvasive procedures routinely done in clinical practice. Where medical devices are employed, they must be cleared/approved for marketing.** →	☐ Physical sensors applied to the body surface or at a distance AND do not involve input of significant amounts of energy into the subject or an invasion of subject's privacy ☐ Weighing or testing sensory acuity ☐ Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography	☐ Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing (appropriate to age, weight, and health of the individual) **If research procedures do not include any of the given procedures, please enclose a brief description:** _____ _____ _____	*To qualify for this subcategory, the study **CANNOT** involve general anesthesia, sedation or procedures with X-rays or microwaves (such as CT/CAT Scan, etc).*

IRB APPROVED
AUG 19 2015
University of North Texas Health Science Center

Category 5: ☐ **Research involving materials (data, documents, records, or specimens) that:** →	**Check if applicable:** ☐ (a) Have already been collected for some **other purpose,**	**Check if applicable:** ☐ (b) Will be collected for **non-research** purposes (such as medical treatment or diagnosis)	**Does the research protocol fit under this category and is condition (a) or (b) met?** ☐ Yes ☐ No
Category 6: ☐ **Collection of data from voice, video, digital, or image recordings made for research purposes** →	**Check all those applied for research study:** ☐ **Voice** ☐ **Video** ☐ **Digital** ☐ **Image**	**Will subjects be informed about the recordings?** ☐ Yes ☐ No	**Include in the protocol a detailed description of how, when and what extent subjects will be recorded. In addition, describe data storage and confidentiality of the recorded data.**
Category 7: ☑ **Research where condition (a) or (b) is applicable:** →	**Check if applicable:** ☑ (a) Individual or group characteristics or behavior (research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior)	**Check if applicable:** ☑ (b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.	**Does the research protocol fit under this category?** ☑ Yes ☐ No

Recall: 'Children' in (b) above is defined in the HHS regulations as "persons who have not attained the legal age for consent for treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" [45 CFR 46.402(a)].In Texas, this is typically under 18 years old.

Does the study involve storage or banking of human specimens or identifiable private information for use in future studies?

Yes ☐ No ☑

Does the study involve genetic testing or DNA/RNA extraction? Yes ☐ No ☑

If any of the answers to the above questions are yes, please ensure that this information is discussed in the informed consent form (if applicable).

Maximum number of subjects recruited for participation: 300-350 Age range of the subjects recruited: 18 and up

Will this study include any of the following subject pools?

☑ Pregnant Women ☐ Cognitively Impaired ☐ Prisoners ☐ Genetics ☐ Military Personnel
☐ Minors (<18) ☐ UNTHSC employees ☐ Fetuses ☐ UNTHSC students ☑ Patients
☑ Economically Disadvantaged (homeless, evacuees)

How will you recruit and correspond with subjects for this study?

☐ Telephone (please submit telephone script with your submission) ☐ Referrals
☐ Advertising (newspaper, email, Daily News, website, brochure, radio, etc.) ☑ Other

Will subjects be compensated for their participation? Yes ☐ No ☑

Document payment schedule in the protocol synopsis, and if applicable, the informed consent.

Will any of the following instruments or methods be used? ***Check all that apply. Include copies of these materials with your submission:***

☐ Interview (attach script/guide) ☑ Surveys/Questionnaires
☐ Standardized (published) tests or assessments ☐ Focus Group (attach guide)

Does the study involve (**check all that apply**):

☐ Painful or aversive stimuli ☐ False Feedback ☐ Emotional Stress
☐ Withholding of critical information ☐ Deception ☐ False Information

List all OTHER KEY PERSONNEL associated with this project (co-investigators, study coordinator, study physician, etc.)

Is there a **STUDENT INVESTIGATOR** associated with this project? ☑ Yes ☐ No

Name of student investigator: Denise Nguyen

Email address of student investigator: Denise.Nguyen@baylorhealth.edu Contact number of student investigator: 817-922-2588

Role/ Responsibilities: Consenting subjects, handing out and collecting questionnaires, analyzing data

CO-INVESTIGATOR:

Name & Degree: Dr. Patricia Gwirtz, Ph.D., FACC Department: Integrative Physiology and Anato

Role/ Responsibilities: _____

CO-INVESTIGATOR:

Name & Degree: _____ Department: _____

Role/ Responsibilities: _____

STUDY COORDINATOR:

Name & Degree: _____ Department: _____

Role/ Responsibilities: _____

When submitting your Expedited research to the OPHS Office, please submit 2 complete packets with the following information contained within EACH packet.

If the IRB materials you submit fail to capture the most necessary information for a complete/thorough review, or if the application packet is incomplete, your IRB materials will be sent immediately back to you. Please ensure that the following information is submitted in each packet for a more streamlined "speedy" review of your research project. In addition, please keep in mind that the review process takes time, and research may not be initiated until the application has been approved.

(1) IRB Application Form (with original PI signature on one copy)
(2) Protocol Synopsis
(3) Informed Consent Form (if applicable)
(4) Conflict of Interest Form
(5) CITI Training Certificates

If applicable:

(6) Grant Application
(7) Recruitment Materials (flyers, emails, advertisements, etc.)
(8) Surveys/Questionnaires
(9) Telephone scripts/oral scripts
(10) Assent Forms/Parental Permission Forms
(11) Research Agreements
(12) Letters of permission/cooperation, and/or approvals from other IRBs

Patricia A Gwirtz
Principal Investigator Signature

8/12/2015
Date

BAYLOR Research Institute
Affiliated with Baylor Health Care System

IRB Approval – Expedited Review of Revision

To: Theresa Cheyne, RN

Copy to: Claudia Mattil, Theresa Cheyne, RN

Date: October 14, 2015

Re: 015-182
Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials
Reference Number: 093570

Your proposed revision was reviewed by a designated member of Baylor IRB Red via expedited review.

This review included the following components:

Submission Form	
Form Name	Outcome
Revision Form	Approved as Presented

Study Application	
Form Name	Outcome
Study Application - Review by BRI IRB	Approved as Presented

Study Consent Form			
Title	Version Number	Version Date	Outcome
Cover Letter 14Oct2015	Version 1.2	10/14/2015	Approved

This revision was determined to be eligible for expedited review as it is a minor change to previously approved research, during the period (no more than one year) for which the research is approved. Further we have determined that this change does not present an increase in risk or a significant change to the overall risk to benefit ratio.

Your submission has been approved. This approval is effective on 10/15/2015. Any aspect of your previously submitted project that is not specifically addressed in this submission remains approved as previously presented. Your expiration date and scheduled continuing review are unchanged.

If this submission includes changes to the informed consent document(s), re-consent is required in accordance with the plan as outlined in the revision request form. If re-consent is not appropriate for some of the subjects involved in the study, this would have been documented in this section of the form.

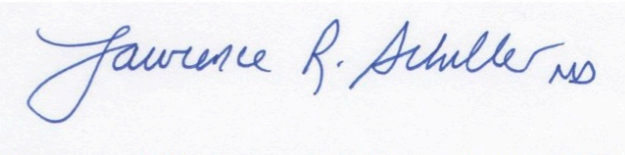
All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Research Institute prior to beginning your study.

If you need additional assistance, please contact the IRB Specialist at 214-820-9989.

Sincerely,



Signature applied by Lawrence R. Schiller on 10/14/2015 10:25:23 PM CDT

Project Title: Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials

IRB Number: 015-182

Type of Review: (Circle One)

New Study
Continuing Review
Revision
Event (SAE, Protocol Deviation, etc)

INVESTIGATOR COMMITMENT:

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to the IRB approved protocol and any additional stipulations imposed by the IRB I assure the IRB that I have sufficient time to conduct and complete the research in accordance with IRB guidelines I agree to comply with all Baylor Research Institute IRB policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research I certify that no similar proposal has been disapproved by another IRB I agree to maintain strict confidence of information that may be disclosed including subject/patient, data, employee, institution proprietary, industry trade secrets, and any other form of confidential information

I agree to report immediately to the IRB any non-compliance, unanticipated problems involving risks to subjects or others, complications or adverse incidents with respect to human subjects

I agree to perform the project with qualified personnel according to the approved protocol I agree that I am to implement no changes in the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects) I agree to obtain the legally effective informed consent from human subjects or their legally responsible representative, and use only the currently approved, date-stamped consent form I agree to evaluate on an individual subject basis, whether or not an individual subject understands the information presented during the informed consent process I agree that informed consent is an ongoing process and it is my responsibility to determine over a period of time that all research subjects continue to be willing to participate

I understand that I have the responsibility to make the Department Administrator aware of all protocols that are submitted to the IRB

I understand that the electronic submission includes documents that may have been completed by a delegate on my behalf My signature indicates that I have reviewed the information and am in agreement with the information as provided to the IRB

The Institutional Review Board of the Baylor Research Institute will suspend approval of all research projects of investigators who are non-compliant with the above requirements The Chief-of-Service will be notified of the suspension as will the Chairman of the Medical Board and other Institutional Officials Non-compliance of IRB requirements could result in Institutional Officials reporting these actions to the Office of Human Research Protections, the US Food and Drug Administration, the Study Sponsor or other agencies

Signature of Principal Investigator

10/7/15
Date of Signature

UNT Health Science Center

Office for the Protection of Human Subjects
Institutional Review Board
BOARD ACTION

IRB Project #: 2015-138 Date Submitted: 10-16-15

Principal Investigator: Patricia Gwirtz, PhD (with Denise Nguyen and John Schetz)

Project Title: Analysis of Current Recruitment Methods: Measuring the Potential of Social Media in Clinical Research Trials

Sponsor Protocol #:

Department: Clinical Research Management / GSBS Contact Info: x 2079

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

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

☐ Project has received approval through: _____

☐ Informed consent(s*) approved as submitted on : _____

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

*Including:

☐ Study Protocol dated _____ approved as submitted.

☐ Investigator's Brochure _____ approved as submitted.

☐ Protocol Synopsis approved as submitted on: _____

☑ Amendment **Amendment 1 : 10/16/15** to the protocol approved as submitted.

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

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

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

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

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

☑ Special Findings/Other

see page 2

Chairman, Institutional Review Board

10/16/2015
Date

IRB Form 2 (revised March 2011)

Board Action-page 2

PI: Patricia Gwirtz, PhD

IRB Project #: 2015-138

Date: 10-16-2015

SPECIAL FINDINGS:

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

☐ **45 CFR 46.404** ☐ **21 CFR**

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

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

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

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

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

☐ OTHER:

OTHER

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

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

Survey research with identifiers

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

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

☐ **Informed Consent Waiver:** The Board finds this project qualifies for a _____ under the provisions of _____

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

☐ **Other Comments:**

IRB# 015-182 14-Oct-2015

Baylor Research Institute
Baylor All Saints Medical Center
Diabetes and Thyroid Center
Texas Health Care, PLLC
University of North Texas Health Science Center
Joan Katz Breast Center

I am a student intern at Baylor Research Institute and we are conducting a research project to determine the best strategies to recruit interested individuals about upcoming clinical research trials in this particular community. Currently, it is very difficult to recruit interested individuals by traditional methods (such as radio, TV, brochures, flyers, etc.), so this research project would study the methods of communication that this community uses most often. You are invited to take part in this research study survey because you are a member of this community and are using the Baylor All Saints Medical Center and associated clinics for your health care needs.

This survey will indicate your preferred methods of communication, as well as gauge your interest in clinical research trials. The survey will take no more than 10 minutes. You will not be asked for your name or any other identifying information on the survey. If you choose to do so, complete the survey and send it back to me. Do not write your name on the survey. I do not need to know who you are. The results of this study would then be used to implement more efficient means of recruitment. Since the survey does not ask for any person information that could identify you, there will be no way to withdraw from the study once you complete and return the survey directly to me or staff.

There are no foreseeable risks associated with taking part in this survey. You may receive no direct benefit from taking part in this study. The benefits of this survey/interview will allow us to evaluate the most efficient way to reach out to interested individuals for clinical research trials. You have the option to not complete the survey and not be in the study. By choosing to fill out the attached survey and returning it to me, you are saying that you are willing to take part in this study.

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

- Principal Investigator: Theresa Cheyne
  - Email: Theresa.Cheyne@baylorhealth.edu
  - Phone: 817-922-2579
- Co-Investigator: Denise Nguyen
  - Email: Denise.Nguyen@baylorhealth.edu
  - Phone: 817-922-2588

If you have any questions about your rights as a research subject, please contact Lawrence Schiller, MD at 214-820-2687.

Thank you for your interest in taking part of this project and I hope you will take a few minutes to complete the survey and return it to me. Without the help of people like you, this research would not be conducted.

Sincerely,

Denise Nguyen

IRB# 015-182 14-Oct-2015

Baylor Research Institute
Baylor All Saints Medical Center
Diabetes and Thyroid Center
Texas Health Care, PLLC
University of North Texas Health Science Center
Joan Katz Breast Center

I am a student intern at Baylor Research Institute and we are conducting a research project to determine the best strategies to recruit interested individuals about upcoming clinical research trials in this particular community. Currently, it is very difficult to recruit interested individuals by traditional methods (such as radio, TV, brochures, flyers, etc.), so this research project would study the methods of communication that this community uses most often. You are invited to take part in this research study survey because you are a member of this community and are using the Baylor All Saints Medical Center and associated clinics for your health care needs.

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Sincerely,

Denise Nguyen

Page 1 of 1

APPENDIX D

STATISTICAL TABLES

Table 1.1: Have you taken part/been asked to take part in clinical trials before?				
		Yes	No	Total
Age (years)	18-29	19	72	91
	30-49	19	51	70
	50-64	18	39	57
	65+	10	37	47
	Total	66	199	**265**
Gender	Male	26	69	95
	Female	40	130	170
	Total	66	199	**265**
Race	African American	9	38	47
	Asian	15	29	44
	Caucasian	38	106	144
	Hispanic	4	22	26
	Other	0	4	4
	Total	66	199	**265**
Highest Education	High School or Less	6	37	43
	Some College	18	54	72
	College Degree or More	39	104	143
	Did not indicate	3	4	7
	Total	66	199	**265**
Health Insurance	Insured	55	166	221
	Uninsured	5	12	17
	Medicaid	1	9	10
	Don't know	1	2	3
	Did not indicate	4	10	14
	Total	66	199	**265**

Table 2.1: If you answered "YES" to the last question, how were you approached to take part?							
		Doctor	Brochure/ pamphlet	Poster/ Flyer	Radio or TV ad	Social Media	Total
Age (years)	18-29	5	6	8	0	10	29
	30-49	8	1	0	4	7	20
	50-64	14	2	0	2	1	19
	65+	7	1	1	0	1	10
	Total	34	10	9	6	19	78
Gender	Male	17	4	4	0	4	29
	Female	17	6	5	6	15	49
	Total	34	10	9	6	19	78
Race	African American	6	0	1	1	2	10
	Asian	4	2	3	0	8	17
	Caucasian	21	5	4	5	9	44
	Hispanic	3	3	1	0	0	7
	Other	0	0	0	0	0	0
	Total	34	10	9	6	19	78
Highest Education	High School or Less	4	1	1	1	1	8
	Some College	10	3	1	2	4	20
	College Degree or More	18	6	7	3	13	47
	Did not indicate	2	0	0	0	1	3
	Total	34	10	9	6	19	78
Health Insurance	Insured	31	7	7	5	14	64
	Uninsured	0	1	1	1	3	6
	Medicaid	1	1	0	0	0	2
	Don't know	0	0	1	0	1	2
	Did not indicate	2	1	0	0	1	4
	Total	34	10	9	6	19	78

Table 3.1: Would you be interested in taking part in clinical trials if more information was available to you/easier to access?				
		Yes	No	Total
Age (years)	18-29	67	24	91
	30-49	51	19	70
	50-64	37	20	57
	65+	26	21	47
	Total	181	84	**265**
Gender	Male	66	29	95
	Female	115	55	170
	Total	181	84	**265**
Race	African American	26	21	47
	Asian	33	11	44
	Caucasian	102	42	144
	Hispanic	17	9	26
	Other	3	1	4
	Total	181	84	**265**
Highest Education	High School or Less	17	26	43
	Some College	52	20	72
	College Degree or More	107	36	143
	Did not indicate	5	2	7
	Total	181	84	**265**
Health Insurance	Insured	155	66	221
	Uninsured	11	6	17
	Medicaid	6	4	10
	Don't know	1	2	3
	Did not indicate	8	6	14
	Total	181	84	**265**

Table 4.1: How would you prefer to receive such information?						
		Social Media	Print Media	Mass Media	Did not indicate	Total
Age (years)	18-29	60	27	14	11	112
	30-49	43	23	17	8	91
	50-64	25	28	19	2	74
	65+	14	24	13	5	56
	Total	142	102	63	26	333
Gender	Male	48	32	23	15	118
	Female	94	70	40	11	215
	Total	142	102	63	26	333
Race	African American	21	19	9	6	55
	Asian	28	11	8	8	55
	Caucasian	70	62	43	11	186
	Hispanic	20	9	3	1	33
	Other	3	1	0	0	4
	Total	142	102	63	26	333
Highest Education	High School or Less	19	16	10	4	49
	Some College	40	33	23	5	101
	College Degree or More	81	49	28	16	174
	Did not indicate	2	4	2	1	9
	Total	142	102	63	26	333
Health Insurance	Insured	120	85	55	22	282
	Uninsured	10	4	3	1	18
	Medicaid	6	3	3	2	14
	Don't know	1	2	0	0	3
	Did not indicate	5	8	2	1	16
	Total	142	102	63	26	333

Table 5.1: What form of social media would you like or prefer to receive information about clinical trials from?

		Facebook	Twitter	Youtube	Online Forum/ Blog	I don't feel comfortable with these options	Did not indicate	Total
Age (years)	18-29	50	13	15	30	19	6	133
	30-49	34	6	7	17	20	1	85
	50-64	24	3	4	9	23	1	64
	65+	10	0	0	4	31	3	48
	Total	118	22	26	60	93	11	330
Gender	Male	34	12	12	24	34	7	123
	Female	84	10	14	36	59	4	207
	Total	118	22	26	60	93	11	330
Race	African American	18	3	5	4	17	5	52
	Asian	21	6	7	13	15	2	64
	Caucasian	62	9	12	33	53	4	173
	Hispanic	14	3	1	10	7	0	35
	Other	3	1	1	0	1	0	6
	Total	118	22	26	60	93	11	330
Highest Education	High School or Less	15	3	2	7	19	1	47
	Some College	36	4	8	13	24	4	89
	College Degree or More	65	15	16	40	45	6	187
	Did not indicate	2	0	0	0	5	0	7
	Total	118	22	26	60	93	11	330
Health Insurance	Insured	97	19	21	53	80	7	277
	Uninsured	9	3	4	5	2	1	24
	Medicaid	5	0	0	1	3	2	11
	Don't know	2	0	0	0	1	0	3
	Did not indicate	5	0	1	1	7	1	15
	Total	118	22	26	60	93	11	330

Table 6.1: If you don't feel comfortable receiving clinical trial information from social media, where would you prefer to receive this information?

		Doctor referral	Flyers	Brochure	Radio ad	Did not indicate	Total
Age (years)	18-29	53	16	24	9	19	121
	30-49	37	9	18	6	17	87
	50-64	32	9	16	8	11	76
	65+	27	8	15	6	9	65
	Total	149	42	73	29	56	349
Gender	Male	59	15	17	13	21	125
	Female	90	27	56	16	35	224
	Total	149	42	73	29	56	349
Race	African American	22	5	9	5	8	49
	Asian	34	11	11	3	3	62
	Caucasian	77	20	40	20	40	197
	Hispanic	14	6	11	1	4	36
	Other	2	0	2	0	1	5
	Total	149	42	73	29	56	349
Highest Education	High School or Less	23	5	13	5	6	52
	Some College	38	11	31	11	12	103
	College Degree or More	82	24	27	12	37	182
	Did not indicate	6	2	2	1	1	12
	Total	149	42	73	29	56	349
Health Insurance	Insured	125	36	63	24	47	295
	Uninsured	7	3	4	2	5	21
	Medicaid	6	1	1	1	2	11
	Don't know	1	0	1	1	0	3
	Did not indicate	10	2	4	1	2	19
	Total	149	42	73	29	56	349

Table 7.1: What forms of social media do you use most often?

		Facebook	Twitter	Snapchat	Instagram	Youtube	Online Forum/blog	Did not indicate	Total
Age (years)	18-29	80	9	43	39	43	11	0	225
	30-49	58	10	3	19	17	10	5	122
	50-64	34	4	0	8	13	5	15	79
	65+	19	0	0	0	3	8	20	50
	Total	191	23	46	66	76	34	40	476
Gend	Male	64	11	24	20	29	14	16	178
	Female	127	12	22	46	47	20	24	298
	Total	191	23	46	66	76	34	40	476
Race	African American	27	2	5	7	9	5	12	67
	Asian	39	7	23	19	23	5	2	118
	Caucasian	99	12	9	29	30	21	24	224
	Hispanic	22	1	7	10	11	3	2	56
	Other	4	1	2	1	3	0	0	11
	Total	191	23	46	66	76	34	40	476
Highest Education	High School or Less	26	1	1	4	7	7	9	55
	Some College	50	4	7	17	18	9	13	118
	College Degree or More	112	17	38	45	50	17	14	293
	Did not indicate	3	1	0	0	1	1	4	10
	Total	191	23	46	66	76	34	40	476
Health Insurance	Insured	163	21	41	62	67	27	34	415
	Uninsured	11	1	5	3	5	2	0	27
	Medicaid	7	0	0	0	1	2	1	11
	Don't know	2	0	0	0	1	0	0	3
	Did not indicate	8	1	0	1	2	3	5	20
	Total	191	23	46	66	76	34	40	476

Table 8.1: How do you learn about upcoming events?

		Social Media	Newspaper	Television	Radio	Did not indicate	Total
Age (years)	18-29	83	15	35	32	1	166
	30-49	56	13	38	35	1	143
	50-64	28	29	37	24	0	118
	65+	16	30	31	14	0	91
	Total	183	87	141	105	2	518
Gender	Male	66	34	49	30	2	181
	Female	117	53	92	75	0	337
	Total	183	87	141	105	2	518
Race	African American	29	14	22	17	0	82
	Asian	39	9	18	11	1	78
	Caucasian	88	58	89	65	1	301
	Hispanic	23	6	11	12	0	52
	Other	4	0	1	0	0	5
	Total	183	87	141	105	2	518
Highest Education	High School or Less	26	15	15	13	0	69
	Some College	46	22	47	31	1	147
	College Degree or More	109	45	73	58	1	286
	Did not indicate	2	5	6	3	0	16
	Total	183	87	141	105	2	518
Health Insurance	Insured	154	75	121	92	1	443
	Uninsured	15	2	8	5	0	30
	Medicaid	6	3	2	2	1	14
	Don't know	1	0	0	2	0	3
	Did not indicate	7	7	10	4	0	28
	Total	183	87	141	105	2	518

Table 9.1: ANOVA results for Question 1

Age		
Source of Variation	% of total variation	P value
Interaction	3.071	0.9433
Age	6.612	0.8476
Participating in Clinical Research	24.23	0.1251
Gender		
Source of Variation	% of total variation	P value
Interaction	3.383	0.6732
Gender	7.317	0.5407
Participation in Clinical Research	23.71	0.2955
Race		
Source of Variation	% of total variation	P value
Interaction	6.545	0.8679
Race	30.42	0.2968
Participating in Clinical Research	9.459	0.2135
Education		
Source of Variation	% of total variation	P value
Interaction	7.692	0.6837
Education Status	36.38	0.14
Participation in Clinical Research	16.06	0.1104
Insurance		
Source of Variation	% of total variation	P value
Interaction	13.23	0.414
Insurance	51.21	**0.0298**
Participation in Clinical Research	5.091	0.2252

Table 10.1: ANOVA results for Question 2

Age		
Source of Variation	% of total variation	P value
Interaction	20.22	0.8164
Age	5.611	0.5818
Recruitment Methods	18.13	0.2087
Gender		
Source of Variation	% of total variation	P value
Interaction	4.564	0.9428
Gender	3.171	0.4938
Recruitment Method	29.4	0.3808
Race		
Source of Variation	% of total variation	P value
Interaction	14.42	0.9532
Race	24.87	**0.0356**
Recruitment Methods	9.713	0.3394
Education		
Source of Variation	% of total variation	P value
Interaction	10.09	0.9469
Education Status	31.04	**0.0101**
Recruitment Method	16.82	0.1333
Insurance		
Source of Variation	% of total variation	P value
Interaction	23.4	0.4922
Insurance Status	33.07	**0.0023**
Recruitment Method	6.736	0.3588

Table 11.1: ANOVA results for Question 3		
Age		
Source of Variation	% of total variat	P value
Interaction	5.789	0.8834
Age	7.438	0.8412
Potential for Future Research	14.92	0.2335
Gender		
Source of Variation	% of total variat	P value
Interaction	1.254	0.8046
Gender	10.74	0.4826
Potential for Future Research	16.18	0.3962
Race		
Source of Variation	% of total variat	P value
Interaction	7.302	0.8425
Race	34.21	0.2463
Potential for Future Research	5.382	0.3378
Education		
Source of Variation	% of total variat	P value
Interaction	14.63	0.4276
Education	38.84	0.1124
Potential for Future Research	8.851	0.2077
Insurance		
Source of Variation	% of total variat	P value
Interaction	9.909	0.5227
Insurance	58.12	**0.0177**
Potential for Future Research	2.983	0.3343

Table 12.1: ANOVA results for Question 4		
Age		
Source of Variation	% of total variat	P value
Interaction	10.11	0.9687
Age	5.136	0.7295
Different Medias	22.07	0.174
Gender		
Source of Variation	% of total variat	P value
Interaction	4.316	0.9068
Gender	7.904	0.3488
Different Medias	23.94	0.4411
Race		
Source of Variation	% of total variat	P value
Interaction	8.366	0.9896
Race	29.16	0.0576
Different Medias	9.204	0.3526
Education		
Source of Variation	% of total variat	P value
Interaction	12.54	0.7726
Education	34.13	**0.0126**
Different Medias	16.7	0.1029
Insurance		
Source of Variation	% of total variat	P value
Interaction	13.22	0.7187
Insurance	50.79	**0.0004**
Different Medias	5.307	0.3522

Table 13.1: ANOVA results for Question 5		
Age		
Source of Variation	% of total variat	P value
Interaction	10.54	0.986
Age	8.299	0.303
Social Media Recruitment	29.38	**0.0437**
Gender		
Source of Variation	% of total variat	P value
Interaction	7.211	0.8948
Gender	4.346	0.3495
Social Media Recruitment	33.43	0.2735
Race		
Source of Variation	% of total variat	P value
Interaction	13.81	0.9816
Race	20.61	**0.0341**
Social Media Recruitment	14.02	0.1821
Education		
Source of Variation	% of total variat	P value
Interaction	12.16	0.8704
Education	30.33	**0.0014**
Social Media Recruitment	23.29	**0.0216**
Insurance		
Source of Variation	% of total variat	P value
Interaction	23.43	0.2827
Insurance	39.86	**< 0.0001**
Social Media Recruitment	8.635	0.134

Table 14.1: ANOVA results for Question 6		
Age		
Source of Variation	% of total variat	P value
Interaction	3.01	> 0.9999
Age	4.537	0.702
Other Recruitment Methods	29	0.0959
Gender		
Source of Variation	% of total variat	P value
Interaction	3.292	0.9619
Gender	7.437	0.2817
Other Recruitment Methods	31.84	0.3068
Race		
Source of Variation	% of total variat	P value
Interaction	9.2	0.9922
Race	30.53	**0.0123**
Other Recruitment Methods	12.45	0.1988
Education		
Source of Variation	% of total variat	P value
Interaction	15.58	0.6597
Education	31.17	**0.0035**
Other Recruitment Methods	20.2	**0.0406**
Insurance		
Source of Variation	% of total variat	P value
Interaction	17.69	0.4022
Insurance	50.41	**< 0.0001**
Other Recruitment Methods	6.825	0.1812

Table 15.1: ANOVA results for Question 7		
Age		
Source of Variation	% of total variat	P value
Interaction	17.65	0.791
Age	14.22	**0.0333**
Social Media Use	28.43	**0.0131**
Gender		
Source of Variation	% of total variat	P value
Interaction	5.441	0.9482
Gender	4.049	0.3024
Social Media Use	41.07	0.1442
Race		
Source of Variation	% of total variat	P value
Interaction	16.6	0.958
Race	17.66	**0.0235**
Social Media Use	17.88	0.0686
Education		
Source of Variation	% of total variat	P value
Interaction	20.66	0.1917
Education	34.76	**< 0.0001**
Social Media Use	22.15	**0.0023**
Insurance		
Source of Variation	% of total variat	P value
Interaction	11.87	0.3959
Insurance	66.05	**< 0.0001**
Social Media Use	6.259	0.0554

Table 16.1: ANOVA results for Question 8		
Age		
Source of Variation	% of total variat	P value
Interaction	13.66	0.9567
Age	2.785	0.8194
News Source	23.25	0.1452
Gender		
Source of Variation	% of total variat	P value
Interaction	3.161	0.9699
Gender	10.72	0.2213
News Source	23.12	0.4906
Race		
Source of Variation	% of total variat	P value
Interaction	8.156	0.9979
Race	28.55	**0.0264**
News Source	9.309	0.3885
Education		
Source of Variation	% of total variat	P value
Interaction	13.29	0.8267
Education	32.08	**0.0056**
News Source	16.99	0.0992
Insurance		
Source of Variation	% of total variat	P value
Interaction	15.71	0.6876
Insurance	47.16	**< 0.0001**
News Source	5.871	0.3462

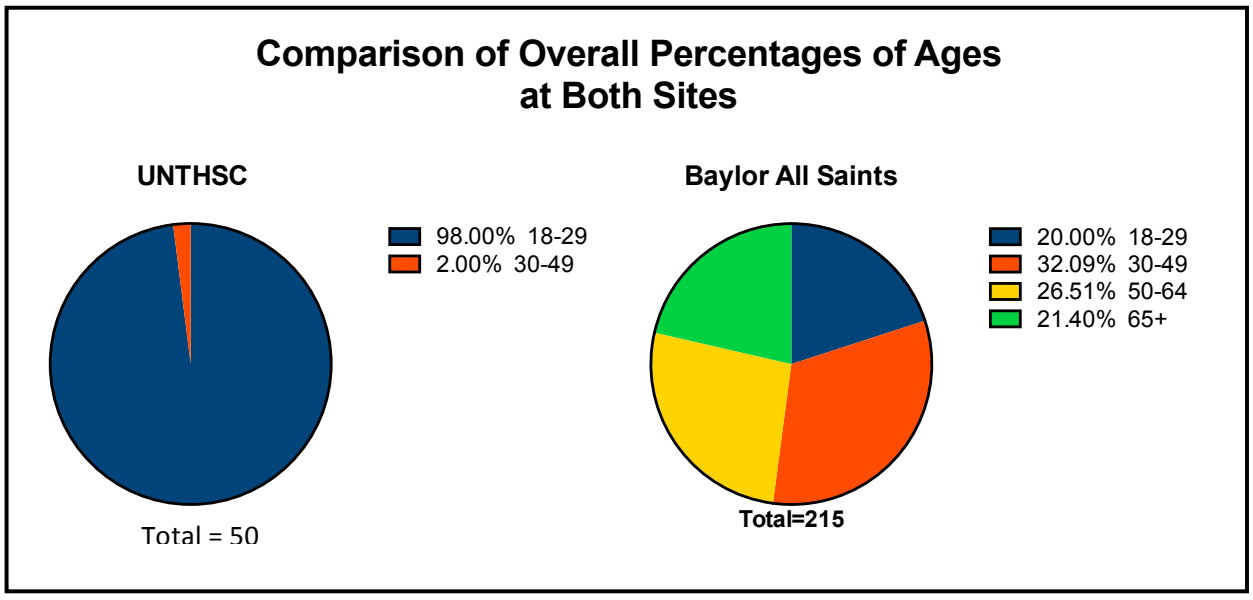

Figure 10.1

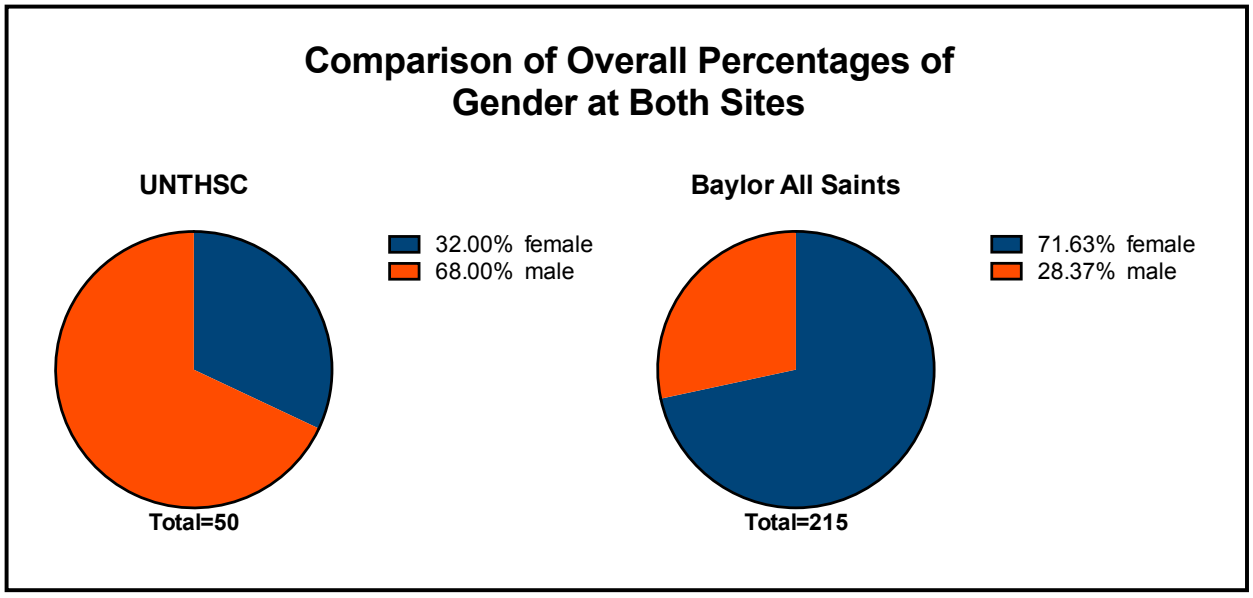

Figure 10.2

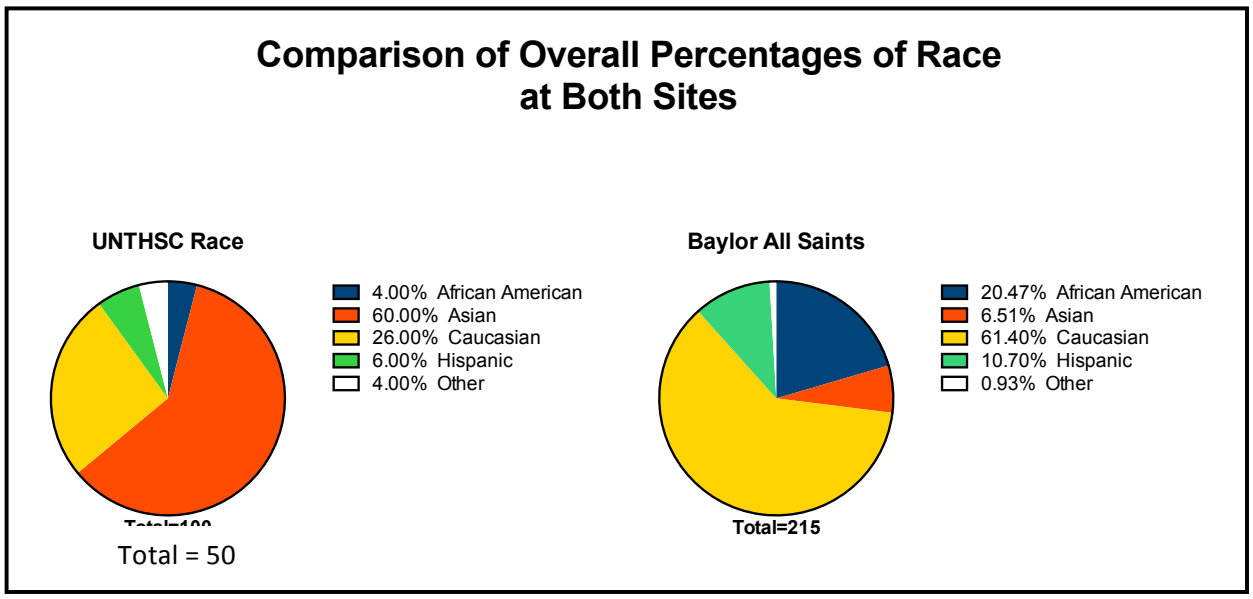

Figure 10.3

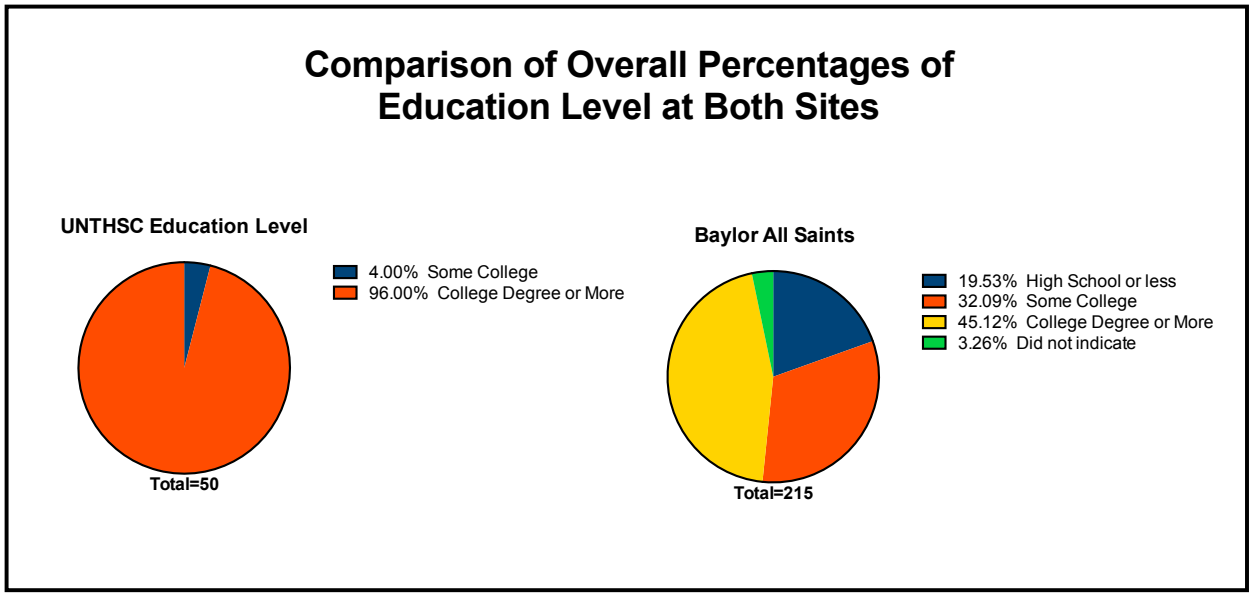

Figure 10.4

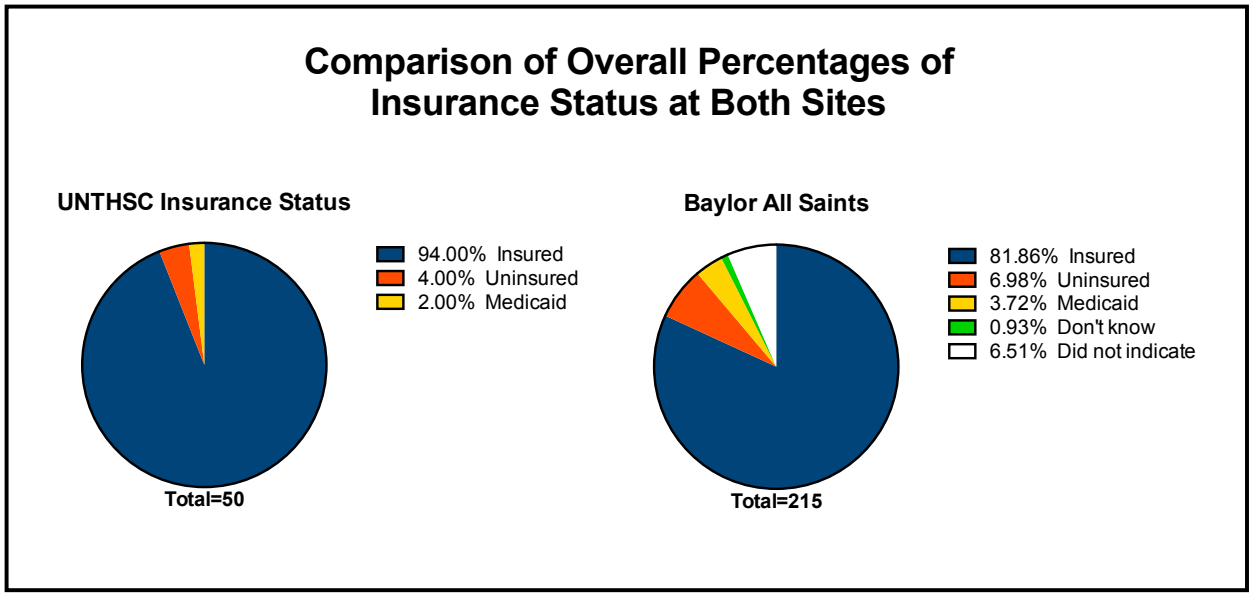

Figure 10.5

Table 17.1: Comparison between Baylor and UNTHSC (Q1)				
	Yes		No	
Age (years)	BRI	UNTHSC	BRI	UNTHSC
18-29	6	14	37	36
30-49	19	0	50	1
50-64	18	0	39	0
65+	9	0	37	0
Gender				
Female	35	4	119	13
Male	17	10	44	25
Race				
African American	8	0	36	1
Asian	5	10	9	21
Caucasian	35	3	97	10
Hispanic	4	0	19	3
Other	0	0	2	2
Education Level				
High School or less	5	0	37	0
Some College	17	1	52	1
College Degree or More	27	12	70	36
Did not indicate	3	0	4	0
Insurance Status				
Insured	42	13	134	35
Uninsured	5	0	10	1
Medicaid	1	0	7	1
Don't know	0	0	2	0
Did not indicate	4	0	10	0

Table 18.1: Comparison between Baylor and UNTHSC (Q2)										
	Doctor		Brochure/pamphlet		Poster/flyer		Radio or TV ad		Social Media	
Age (years)	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC
18-29	2	3	2	2	4	5	0	0	4	5
30-49	8	0	1	0	1	0	4	0	7	0
50-64	14	0	2	0	0	0	2	0	1	0
65+	6	0	1	0	0	0	0	0	1	0
Gender										
Female	17	0	4	1	3	1	6	0	12	2
Male	14	3	2	1	1	4	0	0	1	3
Race										
African American	6	0	0	0	0	0	1	0	1	0
Asian	2	2	0	1	1	3	0	0	3	5
Caucasian	20	1	4	1	4	2	5	0	9	0
Hispanic	3	0	2	0	1	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0
Education Level										
High School or less	4	0	0	0	0	0	1	0	0	0
Some College	9	1	3	0	1	0	2	0	4	0
College Degree or More	16	2	3	2	3	5	3	0	8	5
Did not indicate	2	0	0	0	0	0	0	0	1	0
Insurance Status										
Insured	28	3	4	2	8	5	0	0	9	5
Uninsured	0	0	1	0	1	0	1	0	3	0
Medicaid	1	0	0	0	0	0	0	0	0	0
Don't know	0	0	0	0	0	0	0	0	0	0
Did not indicate	2	0	1	0	0	0	0	0	1	0

Table 19.1 Comparison between Baylor and UNTHSC (Q3)				
	Yes		No	
Age (years)	BRI	UNTHSC	BRI	UNTHSC
18-29	30	38	13	11
30-49	50	1	19	0
50-64	37	0	20	0
65+	25	0	21	0
Gender				
Female	101	16	54	1
Male	41	23	19	10
Race				
African American	24	0	20	1
Asian	9	25	5	6
Caucasian	92	12	40	2
Hispanic	15	1	8	1
Other	2	1	0	1
Education Level				
High School or less	16	0	26	0
Some College	50	2	19	0
College Degree or More	71	37	26	11
Did not indicate	5	0	2	0
Insurance Status				
Insured	120	37	56	11
Uninsured	9	1	6	0
Medicaid	5	1	3	0
Don't know	0	0	2	0
Did not indicate	8	0	6	0

Table 20.1: Table Comparison between Baylor and UNTHSC (Q4)								
	Social Media		Print Media		Mass Media		Did not indicate	
Age (years)	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC
18-29	30	30	14	14	3	11	1	9
30-49	43	0	22	1	16	1	8	0
50-64	25	0	28	0	19	0	2	0
65+	14	0	23	0	13	0	5	0
Gender								
Female	86	9	63	7	34	6	9	3
Male	27	21	24	8	17	6	7	6
Race								
African American	20	0	18	0	9	0	5	1
Asian	8	21	4	7	0	8	2	7
Caucasian	66	5	57	6	39	4	8	1
Hispanic	17	3	8	1	3	0	1	0
Other	2	1	0	1	0	0	0	0
Education Level								
High School or less	19	0	15	0	10	0	4	0
Some College	40	0	30	2	22	1	4	0
College Degree or More	42	40	38	13	17	11	7	9
Did not indicate	2	0	4	0	2	0	1	0
Insurance Status								
Insured	93	29	72	13	45	10	14	9
Uninsured	9	1	3	1	2	1	1	0
Medicaid	6	0	2	1	2	1	0	0
Don't know	1	0	1	0	0	0	0	0
Did not indicate	5	0	8	0	2	0	1	0

Table 21.1 Comparison between Baylor and UNTHSC (Q5)												
	Facebook		Twitter		Youtube		Online forum/blog		Not Comfortable		Did not indicate	
Age (years)	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC
18-29	27	23	6	7	8	7	14	16	6	14	1	3
30-49	34	0	5	0	7	0	17	0	19	1	1	0
50-64	24	0	4	0	4	0	9	0	23	0	1	0
65+	10	0	0	0	0	0	4	0	30	0	3	0
Gender												
Female	75	9	8	2	12	2	32	4	53	6	4	0
Male	20	14	7	5	7	5	12	12	25	9	2	3
Race												
African American	17	0	3	0	5	0	4	0	16	0	4	1
Asian	5	17	1	5	1	6	2	10	7	8	0	2
Caucasian	59	3	7	2	11	1	29	4	48	5	3	0
Hispanic	11	2	3	0	1	0	7	2	6	1	0	0
Other	2	1	1	0	1	0	0	0	0	1	0	0
Education Level												
High School or less	15	0	3	0	2	0	7	0	18	0	1	0
Some College	35	0	4	0	8	0	11	1	22	1	3	0
College Degree or More	32	23	8	7	9	7	25	14	33	15	2	3
Did not indicate	2	0	0	0	0	0	0	0	5	0	0	0
Insurance Status												
Insured	76	22	12	5	14	5	38	13	67	16	3	3
Uninsured	8	1	2	1	3	1	4	1	2	0	1	0
Medicaid	5	0	0	0	0	0	0	1	2	0	1	0
Don't know	2	0	0	0	0	0	0	0	0	0	0	0
Did not indicate	5	0	0	0	1	0	1	0	7	0	1	0

Table 22.1 Comparison between Baylor and UNTHSC (Q6)										
	Doctor Referral		Flyer		Brochure		Radio Ad		Did not indicate	
Age (years)	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC
18-29	18	35	4	11	12	12	3	6	11	11
30-49	45	1	9	0	17	1	6	0	17	0
50-64	32	0	9	0	13	0	11	0	11	0
65+	27	0	8	0	15	0	5	0	9	0
Gender										
Female	81	10	23	4	49	8	13	2	33	5
Male	33	26	8	7	12	5	9	4	15	6
Race										
African American	21	0	5	0	9	0	4	0	7	1
Asian	13	22	4	7	4	7	0	3	0	8
Caucasian	68	10	16	4	33	4	19	3	37	2
Hispanic	12	2	6	0	10	1	1	0	3	1
Other	0	2	0	0	1	1	0	0	1	0
Education Level										
High School or less	23	0	5	0	13	0	4	0	6	0
Some College	35	2	11	0	30	1	10	1	11	0
College Degree or More	50	34	13	11	16	12	7	5	30	11
Did not indicate	6	0	2	0	2	0	1	0	1	0
Insurance Status										
Insured	94	33	25	11	52	12	18	6	40	11
Uninsured	5	2	3	0	3	1	2	0	5	0
Medicaid	4	1	1	0	1	0	1	0	1	0
Don't know	1	0	0	0	1	0	0	0	0	0
Did not indicate	10	0	2	0	4	0	1	0	1	0

Table 23.1: Comparison between Baylor and UNTHSC (Q7)														
	Facebook		Twitter		SnapChat		Instagram		Youtube		Online forum/blog		Did not indicate	
Age (years)	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC
18-29	36	45	2	7	14	29	17	22	19	24	2	9	0	0
30-49	59	1	10	0	3	0	20	1	16	1	10	0	4	0
50-64	34	0	4	0	0	0	8	0	14	0	5	0	15	0
65+	19	0	0	0	0	0	0	0	2	0	7	0	21	0
Gender														
Female	106	16	10	2	17	10	28	9	38	7	18	1	24	0
Male	34	29	6	5	5	18	6	13	11	17	6	8	16	0
Race														
African American	24	1	2	0	3	1	6	0	8	0	5	0	12	0
Asian	9	30	1	6	3	20	7	15	4	15	2	3	2	0
Caucasian	91	9	11	1	6	3	25	4	23	6	15	6	24	0
Hispanic	19	3	1	0	5	2	8	2	10	1	3	0	2	0
Other	2	2	1	0	0	2	0	1	1	2	0	0	0	0
Education Level														
High School or less	26	0	1	0	1	0	4	0	6	0	7	0	9	0
Some College	38	1	4	0	7	0	17	0	15	2	6	2	13	0
College Degree or More	68	43	10	8	9	28	19	22	31	22	11	7	14	0
Did not indicate	3	0	1	0	0	0	0	0	1	0	1	0	4	0
Insurance Status														
Insured	46	34	14	7	13	27	30	20	43	22	18	8	35	0
Uninsured	10	1	1	0	3	2	1	2	4	1	2	0	0	0
Medicaid	7	0	0	0	0	0	0	0	0	1	0	1	1	0
Don't know	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Did not indicate	8	0	1	0	0	0	1	0	2	0	3	0	5	0

Table 24.1: Comparison between Baylor and UNTHSC (Q8)										
	Social Media		Newspapers		Television		Radio		Did not indicate	
Age (years)	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC	BRI	UNTHSC
18-29	37	46	5	9	19	15	17	14	0	1
30-49	55	1	12	1	37	1	35	0	1	0
50-64	28	0	29	0	47	0	24	0	0	0
65+	16	0	30	0	31	0	13	0	0	0
Gender										
Female	103	15	67	4	85	7	69	5	0	0
Male	28	32	24	6	32	9	16	9	1	1
Race										
African American	28	0	12	1	22	0	16	0	0	0
Asian	9	31	1	7	7	12	2	9	1	0
Caucasian	78	11	68	1	85	4	58	4	0	1
Hispanic	20	3	6	0	11	0	11	1	0	0
Other	2	2	0	0	0	1	0	0	0	0
Education Level										
High School or less	26	0	15	0	15	0	12	0	0	0
Some College	44	1	21	0	46	0	30	1	0	1
College Degree or More	65	46	36	10	58	16	45	16	1	0
Did not indicate	2	0	5	0	6	0	3	0	0	0
Insurance Status										
Insured	110	45	66	10	105	16	78	16	1	0
Uninsured	13	2	2	0	8	0	5	0	0	0
Medicaid	6	0	2	0	2	0	2	0	0	1
Don't know	1	0	0	0	0	0	1	0	0	0
Did not indicate	7	0	7	0	9	0	4	0	0	0

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