Reyes, Mario., <u>Use of Social Media and its Potential for Subject Recruitment.</u>

Master of Science (Biomedical Sciences Clinical Research Management), April, 2014, 60 pp., 8 tables, 28 references.

Effective research subject recruitment is crucial for clinical trial success. Low enrollment prolongs clinical trials and delays researchers from determining the safety and efficacy of new medical devices or drugs. The goal of this thesis was to survey the patient community at the University of North Texas Health Science Center to determine their views and knowledge on social media and the effectiveness of social media as a potential platform for subject recruitment. The research questions were aimed at identifying factors that motivate potential research subjects to participate in clinical trials. The results showed individuals were less likely to participate in a clinical trial via social media advertisements. The preferred recruitment method selected was a physician's referral across all of the groups compared. The conclusion proposes that a physician's participation is essential in recruiting subjects for clinical trials. The current study was limited by a single center cohort. Future studies will require a secondary subject pool.

Use of Social Media and its Potential for Subject Recruitment in Clinical Trials Mario Reyes, B.S.

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Use of Social Media and its Potential for Subject Recruitment in Clinical Trials

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the
Graduate school of Biomedical Sciences
University of North Texas
Health Science Center at Fort Worth
In partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE

By

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Fort Worth, Texas
April 2014

AGKNOWLEDGEMENTS

I would like to thank my internship mentor Albert Yurvati, D.O. for guiding me through the entire term of my internship. I would like to extend my heartfelt gratitude to him and his research staff for allowing me the opportunity to work with them. Dr. Yurvati has gone beyond what it means to be a mentor. His guidance and support has been invaluable to me. The qualities he possesses are ones to strive for. He personifies leadership, tenacity, intellect and patience for this I take great pride in being the research intern for Dr. Yurvati. Thank you, Dr. Yurvati for being a true mentor to me. I would like to thank my major professor Jerry Simecka, Ph.D. for his guidance and encouragement through this entire endeavor. I want to thank Patricia Gwirtz, Ph.D. for providing the possibility to intern with Dr. Yurvati and for the support throughout this year. I must recognize and show my appreciation to Srishti Puri Arora, MPH and Isabel Vecino, CCRP and Priyanka Chaudhari, MS and April Bell MS, CCRC for their patience, guidance and kindness in teaching me about clinical research. I must give thanks to Abhilash Vemulapalli and Subhash Aryal, Ph.D. for their help with the statistical analysis. I realize how much I have grown and learned from this experience. I would also like to thank family and friends for supporting me.

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CHAPTER 1

INTRODUCTION

The use of social media has grown exponentially since 2004 with the advent of sites such as MySpace, Facebook, and Twitter. A survey conducted by the Pew Research Center in 2012 reported that approximately 67% of the American population uses social media in their daily life⁴. The Uses and Gratifications theory (U&G) was developed by Katz et al. (1974) to study individuals and traditional mass media. This theory was used by Quan-Haase and Young to identify the incentive behind social media use and determine if various platforms fulfilled different gratifications, such as sociability or entertainment²³. The conclusion made by Quan-Haase was that social media users sought sociability and the ability to maintain relationships.

Social media sites utilize similar domains as their foundation, these domains include: user-generated content, community, and interactive dialogue¹¹. Multiple social media platforms exist because of different communicative practices within each platform. For example Hogan and Quan-Haase assert instant messaging fosters close relationships with dyadic communication (e.g, two individuals communicating ideas, attitudes, etc)¹². Ellison et al found that individuals who frequent Facebook predominantly use it to maintain existing relationships rather than to

initiate new ones⁴. Therefore users keep their circle of friends informed via posts that broadcast information to many users at once. Additionally, Chen found that users of Twitter consistently "tweet"/post to achieve a connection with other Twitter users through "re-tweets" and other interactions². Social media provides the prospect to engage people in conversation about current events, community programs, volunteer opportunities and connecting with friends or family. This gateway has the potential to transcend communication barriers between the community and the medical and research field.

Clinical trials are an essential part of both the medical and research fields. They promote the advancement of scientific observations into medical applications. Clinical trials provide rigorous controlled testing of a new drug and/or medical device on human subjects under the direction of the Food and Drug Administration (FDA)²⁸. Traditionally, subjects are recruited through physician referrals, existing patient database and advertisements. The clinical research staff has the capability to improve recruitment by developing a relationship with potential participants; however, a lack of communication inhibits this process⁹. Eighty percent of clinical trials are prolonged due to low subject recruitment rates 17. Getz notes that the survey by the National Cancer Institute cited lack of awareness of clinical trials, literacy barriers, and prior prejudices of the research field as obstacles toward subject recruitment⁶. A 2008 Center for Information and Study (CIS) on Clinical Research Participation survey found that 75% of the general public surveyed has little or no knowledge about clinical research and the participation process⁸. Research sites should consider increasing pre-clinical trial communication with potential subjects in order to educate them to make a knowledgeable decision. Increasing communication could be accomplished by increasing advertisements, mentioning clinical trials to patients, or applying new platforms for communication, such as social media.

Integrating social media use with clinical trials poses important benefits: potential to increase trial awareness, ability to reach a wider population and a rapid broadcasting of information. Additionally, the use of this platform may allow for improved pre-trial communication, leading to increased awareness and possibly more subjects willing to volunteer. However, combining clinical trials with social media raises concerns over privacy and confidentiality. Social media and its use could potentially violate subjects' privacy including medical information and, therefore, needs addressing¹⁷. In the absence of social media guidance, the Office of Human Research Protections must establish guidelines for the local institutional review board (IRB) to examine communication, content, and protection of subject information⁷.

Definition of Key Terms:

Social Media. The collection of Internet-based programs which allows users to create and exchange dialogue, videos, or pictures, thus, forming user-generated content⁷.

Clinical Trials. Controlled testing of a new drug or medical device using human subjects in order to test efficacy and safety ²⁸.

Human Research Subject. A living individual that a research investigator interacts with to obtain data¹.

Principal Investigator (PI). The individual designated to be responsible for the scientific or technical direction of a project¹.

Clinical Research Coordinator (CRC). A clinical research coordinator facilitates the clinical trial process and serves as a liaison for the PI and subjects. A CRC identifies screens, recruits potential subjects and ensures protocol compliance²¹.

CHAPTER 2

INTERNSHIP SUBJECT

Background and Literature Review:

Low-enrolling clinical research sites have been studied previously and it is understood that poor recruitment strategies are the primary problem that affects enrollment¹⁶. Challenges that limit participation include lack of awareness, understanding study materials, and the increased requirements of the research protocol compared to standard procedures²³. Current literature reveals that a strategy to correct the problem focuses on improving communication between the various parties involved: study sponsor, principal investigators, study coordinators, and the subjects.

The concept behind the strategy for improved communication in the clinical trial process is to improve clinical trial awareness and develop a relationship of trust with potential subjects'. The integration of technology and healthcare has the capability to improve clinic trial enrollment¹⁵. A literature review will illustrate how technology, particularly social media implementation, can be integrated to potentially overcome the challenges of clinical research subject recruitment.

Subject Recruitment

A clinical research trial is deemed a success if it determines the safety and efficacy of a new treatment²⁸. Meeting the enrollment goals set by the study sponsor is crucial to this success. Inefficient recruiting of subjects is widely reported to be the primary factor in prolonging the duration of a clinical trial^{17,26}. The Center for Information and Study on Clinical Research Participation reported that only 6% of clinical trials are completed within the expected timeline ¹⁴. Additionally, Kitterman et al assert that if a study cannot meet enrollment, it fails to provide statistically significant data to meet its intended study purpose 16. However recruiting subjects is not a simple process. Current methods of subject recruitment include searching an existing clinic database, physician referrals, and advertisements on television, radio, newspaper, or internet. Recent literature has explored the different barriers that affect clinical trial recruitment and are broken into 4 categories: subject-related barriers, investigator-related barriers, protocol-related barriers, and other barriers²⁷. In an interview session with clinical researchers, responses revealed differences in subject-related barriers when compared to the literature. Researchers cited comorbidities, age, level of education, social circumstances, language, and culture as possible barriers to recruitment. They failed to mention previously identified barriers, such as the uncertainty associated with clinical research. Sullivan suggests that uncertainty was not mentioned as a barrier because increased access to the internet addresses concerns associated with a lack of information.²⁷. Ross et al reviewed a bibliographic database over a span of 10 years from 1986-1996 to identify different barriers that exist in the clinical trial process²⁵. The results showed that barriers exist on the physicians' side as well as the subjects' side. The barriers from the subjects' aspect are uncertainty of treatment, concerns over information and consent, and the additional demands of the trial such as time constraints. Ross et al concluded

that demands on the research subject should be minimal. Pinnow et al examined at the results of a survey the FDA asked of the members of the Association of Clinical Research Professionals (ACRP) in order to determine obstacles that affect subject recruitment²³. ACRP members were asked several questions: which factors made subject recruitment easier, which barriers were frequently encountered in the recruitment process, and which patient factors contributed as barriers to recruitment. According to clinical research coordinator responses, the top factor that made recruitment easier was when the physician mentioned the study and the potential benefit of the treatment. Seventy-seven percent of responses reported that the major barrier for recruitment was finding suitable volunteers. The concerns of the subject may be addressed by increased contact with the research staff which may help mediate any concerns. A review of the literature reveals how recruiting eligible subjects is a roadblock for clinical trials. The next step in determining a possible solution for clinical trial subject recruitment is to identify the key components of a successful recruitment campaign.

Keown investigated the recruitment strategies that investigators reported as successful in a survey¹⁴. Successful recruitment strategies of research sites tend to incorporate five steps: understanding protocol requirements, assessing existing patients, recruitment initiatives, contingency plan, and commitment¹⁴. Investigators rated knowledge of patient population as the most important along with protocol review, and pre-screening/chart review for subject recruitment purposes. Protocol review is important as investigators often will take on a trial without fully knowing the requirements or the population the study is targeting¹⁴. Identifying if the population needed for a research study will match the population at the research site is crucial for recruiting within the existing patient database. Moreover, Keown proposed recruiting subjects from the existing patient base is the most effective strategy since it may be more

personable and individuals may be more likely to participate¹⁴. Similarly, Getz also reports that the relationship of a subject with the clinical research staff is important as it may influence subject enrollment⁹. Getz further explains that former research subjects emphasized the importance of the research staff because they are the individuals monitoring their well-being. There are four core needs that are important among study participants: being in control of their medical condition and well-being, personal connection to study staff, being treated as human beings, and knowing that their participation will make a difference⁹. An emphasis on pre-trial educational material that is clear, direct, and informative can help a potential research subject make a knowledgeable decision regarding clinical trial participation.

Enrolling participants in a clinical trial requires a targeted approach of the right subjects for the trial. Shewale and Parekh contend that maintaining open communication and distributing information can overcome participation barriers²⁶. Subject education is crucial to clinical trial recruitment. The research of this practicum project examined at how social media can potentially fill in the communication gap between potential subjects and clinical research staff.

Social Media Usage

Much research has been done on social media networks however, Hogan and Quan-Haase contend it is difficult to apply a unified theory of communication and behavior to social media since this medium is fast paced and constantly changing¹². Therefore, a theory that may apply for one social media site may not apply for another site. Across the literature authors have employed the Uses and Gratifications (U&G) Theory developed by Katz et al. (1974) to provide an understanding of why people use social media networks. The U&G theory identifies the user of the media platform as active and motivated. To further address this point an active user is motivated to use different media platforms for specific needs. Additionally, the U&G theory

examines the type of medium and how it can fulfill the need for communication. A central tenet of the U&G theory focuses on what individuals do with media rather than looking at the effects of media on individuals. Furthermore, Katz et al (1974) state that these expectations lead to differing patterns of media use. The U&G theory proposes that the communication in which individuals engage is with purpose, i.e., people choose to communicate based on needs or expectations as influenced by social or psychological factors. Applying the theory through Chen's interpretation states that social media users will form relationships with other users and contends U&G theory is the best method to explore and understand social media use². These relationships are built from the need to connect with others and are influenced by the interactive nature of social media.

Currently, the two major social media platforms are Facebook and Twitter⁴. Ellison et al purports that a positive relationship exists between Facebook use and networking purposes suggesting that its use may extend beyond just a leisurely activity⁴. As social media networks increased in popularity, instant messaging (IM) usage declined. In order to determine the motivation for using instant messaging and Facebook, undergraduate students were surveyed on their usage²⁴. The application of U&G theory made a few key distinctions between the two social media platforms of instant messaging and Facebook. The platform for instant messaging supports engaging in intimate conversations with one user while the Facebook platform is conducive to broadcasting information to many users all at once. This trend was interpreted to signify that one form of social media does not replace another because each form supports a specific communication need²⁴. Moreover, sociability was recognized as the key gratification of the undergraduate students' surveyed²⁴. Quan-Haase and Young emphasize that Facebook and instant messaging create a sense of peer community by staying involved with online

relationships²⁴. These findings support previous work done by Ellison et al which suggests that Facebook aids in sustaining communication with offline relationships⁵. Chen contends that actively using Twitter will fulfill the need to connect with others and develop relationships². Furthermore, Chen's use of U&G theory for Twitter showcases support that social media is not just virtual noise. His study further confirms the works of Ellison et al⁵.

Social media use is widespread, with more than half of the population using social media. While the authors provide valuable insight, the limitations of these studies lie in the inability to factor in those individuals who abstain from social media. In the future, social media research should consider the differences between these two population groups. Research on social media patterns is difficult due to the fast pace of technology. However, it is important to continue research in support of the U&G theory to develop long lasting principles that will help understand how individuals continue to use social media networks moving forward. Ellison et al concluded that online interaction does not diminish an individual's real life networks, but serves to aid in supporting these relationships⁵. Clinical research has the potential to positively utilize the human need for connection via social media. This practicum project examined how social media may potentially increase awareness of clinical trials, and if individuals believe social media is a viable media platform to increase subject recruitment.

Integration of Social Media and Clinical Research

Inefficient recruitment has been documented to delay clinical trials²⁰. Current literature has also shown how traditional subject recruitment methods such as searching patient databases, physician referrals, and advertisements are ineffective. Websites revolving around specific diseases have been developed creating niches of online health communities²¹. Furthermore, Gossen reported that 40% of Americans search the internet for health information¹¹. Social

websites have changed how information is spread and consumed. Current events and news can now be instantly obtained from social media posts. Khan et al argue that the popularity of social media platforms offer a new model for finding clinical trial subjects¹⁵. The authors state that through interactions and sharing information via social media, participants have the potential to feel empowered to seek and partake in clinical trials. However, Mousley argues that technology is the most useful for initiating the first line of communication between a potential research subject and a clinical research site. Thus, an individual can browse clinical trial information and pursue additional information if interested²¹. Nonetheless, there are individuals who still prefer traditional media such as a letter or television advertisements, to obtain information. Khan et al assert that there are two fundamental problems that have hindered the use of technology¹⁵. First, the authors contend that until recently, finding research subjects has relied solely on sponsors, investigators and research coordinators. The second problem is that the current tools available, such as clinical trial listings and web based recruiting, fail to engage the user. For example, Khan et al predict how clinical researchers may use Twitter, a social media site, where one can post a message, the message post may gather a following, thereby, bridging the gap between the stakeholders involved15. Whether it is subject to subject or coordinators/investigators and subjects communicating, the authors assert the result will be an increase of clinical trial awareness. Similarly, Gossen suggests that social media is an effortless way for potential subjects to increase communication with clinical research staff early in the recruitment process¹¹. Advertisements for clinical trials on specific social media pages may link subjects to more information regarding trials in the immediate area.

Nickens and Cheng agree that a successful application of social media would incorporate peer to peer communication between online health communities²¹. Additionall,y they contend

that internet and technologically savvy patients tend to communicate within their own health communities and are highly likely to share health information with family, friends, and peers. Gonzalez states that the creation of online health communities has aided in patient networking and has raised awareness for different diseases 10. A growing trend in healthcare is that individuals seek more control of their health and are capable of researching medical information 10. Nickens and Cheng assert that recruiting subjects online requires focused demographic information and credibility²¹. In order to attract subjects, recruiting processes must consider their potential subject's needs. Creating dialogue within online health communities can educate and provide medical alternatives to individuals. However, this form of communication will require constant monitoring of messages in order to prevent any false information from spreading. Gonzalez found this requirement to be the primary challenge of social media adoption since this would require clinical research staff to be trained in social media etiquette and dedicate time to provide feedback¹⁰. The second challenge in adopting social media for subject recruitment is the lack of guidelines from the FDA and Office for Human Research Protection¹⁰. The institutional review board (IRB) is also responsible for overseeing all studies before they can begin at an institution; any study-related communication and its content must be reviewed by the IRB in order to protect the rights and welfare of research subjects⁷. Nickens and Cheng contend that IRB members need to be educated in the way social media works and they must review study communication materials prospectively in order to protect subjects^{7,21}. However, due to the instantaneous nature of social media this type of review limits researchers from engaging with potential participants. Thus, any social network page, advertisement, post, or other form of communication that contains clinical trial related information must be reviewed⁷. This poses a challenge for the IRB to keep up and Gearhart suggests that researchers submit multiple versions

of the proposed messages they may want to post online⁷. Connor states that IRB approved materials for social media platforms undergo further analysis by review committees within the social media company³. These steps may appease concerns over the validity of the message post or advertisement. The biggest challenge for social media and its integration with clinical trial recruitment is the instantaneous nature of social media and the emphasis to protect subjects from being unduly recruited.

A significant majority of clinical research staff members are confident in their abilities to use social media; however, they are not using social media to recruit for clinical trials¹⁰. Mousley examined clinical trial participants' perspective to determine if technology makes the overall experience better. The author asserts that human interaction cannot be replaced by technology, and adds that it is necessary when dealing with sensitive matters²¹. Gearhart suggests clinical trial staff should work directly with IRBs to develop the proper communication practices to avoid violations⁷. Social media is a new and relevant opportunity to address study recruitment in a way that may amplify the results that are currently obtained using traditional media. For example, the Mayo Clinic was able to recruit from an online community of women with heart disease⁷. Researchers were able to meet enrollment goals in less than a week and found more subjects than they needed. The aim of this practicum project was to examine potential subjects' views on social media and its use for clinical trial recruitment. Furthermore, the study planned to identify the motivational factors that encourage subject participation.

Specific Objectives:

- #1. To determine the effectiveness of social media as a potential platform for clinical trial subject recruitment.
- #2. To determine which media platform or recruitment method would be most useful in clinical trial subject recruitment.
- #3. Identify factors that motivate potential research subjects to participate in clinical trials.

Significance:

Clinical researchers continuously try to determine the best method for subject recruitment. Inefficient recruitment due to subject related obstacles prolongs clinical trials and hinders the development and introduction of new therapies²⁰. By addressing the aforementioned specific objectives, researchers may be able to identify subjects' preferred method of current recruitment strategies and compare the usefulness of newer strategies such as social media. Evaluating this information will allow researchers to allocate their resources appropriately. Understanding how to reach participants will inform the research community how to manage recruitment campaigns for the best exposure. These objectives could help researchers determine if it is justifiable to dedicate effort and resources to novel subject recruitment operations on social media or improve current recruitment methods.

Materials and Methods:

The proposed research project was based upon an observational, cross-sectional study.

The study utilized a sixteen question survey targeted towards the patient population at the

University of North Texas Health Science Center (UNTHSC) and the UNT Bone and Joint

Institute at Ben Hogan Sports Medicine Center. The questionnaire was developed by compiling questions that would gauge the views and knowledge of the potential subject on social media and clinical trials. The study utilized a design that identified the barriers that prolong subject recruitment and the factors that motivate subjects to participate in clinical trials. Subject participation was entirely voluntary and anonymous. Subjects were recruited by the clinic staff at the front desk of the respective clinic they visited. Subjects were informed that the study would take less than five minutes to complete. In lieu of written informed consent, a request for a waiver was submitted to the UNTHSC IRB. A cover letter was used to explain the purpose of the study and the risks of the study. The subject completed the survey and submitted it which ended their participation in the study. The data collected did not contain any identifying information and was stored in a folder by staff until collected. No other recruitment methods were utilized for this project. The subject age range of this research project consisted of 18 years through 65+ years, and consisted of both male and female subjects. Children and other at risk populations were excluded from this study.

The first two questions of the questionnaire were related to age group and gender which aimed to identify what age groups use social media more frequently. Responses also aimed to show the difference between gender and social media use. Question 1 incorporated age ranges that relate to generational groups: Millennial, Generation X, Baby Boomers, and Silent. According to the Pew Research Center, eighty-three percent (83%) of the Millennial generation, which ranges from the age of 18 years to 29 years, participate in social media⁴. Pew Research Center had shown that females use social media more frequently than males⁴. Questions 3 through 6 identified the social media habits of participants. Participants who did not use any social media platform were asked to skip to a further question. Questions 7 through 13 identified

participant awareness of clinical trials and likelihood of participating in a clinical trial. This question set also examined motivational factors and barriers for possible differences amongst demographics. Questions 14 through 16 documented participant attitudes of clinical trial recruitment communication methods. This set of questions showed whether participants preferred traditional recruitment methods or are open to social media platforms.

Based on an equation to calculate sample size this project needed to survey approximately 96 subjects. However, to account for non-responders and incomplete surveys, 160 surveys were distributed, of these 102 surveys were completed and returned. Data was input onto an online survey tool to store responses and exported to the Statistical Package for the Social Sciences (SPSS) software. SPSS was used to manage data and determine descriptive statistics of participant responses. Additionally, 2x2 Contingency Tables were used to determine any significant correlations by stratifying by different data sets and determining any significance using the χ^2 test. Logistic regression analysis was used to determine if there was any significance between motivational factors, barriers, current recruiting methods and future participation. Statistically significant values were determined by *p-values* less than 0.05 for the different statistical tests.

Results:

SPSS was used to determine the demographics of 102 participants. There were 71 women and 30 men participants. One individual failed to answer the gender question. The data were also separated by age groups. The data were grouped into age ranges that correlate to the following generational groups: Millennial, Generation X, Baby Boomers, and Silent. The age ranges were as follows; 18-29 (n=25), 30-45 (n=20), 46-64 (n=36), 65+ (n=21). In order to satisfy the goals of this study, data was also grouped into users and non-users of social media. Of the 102

responses, 77 participants (75.5%) admitted to being social media users while 25 responses (24.5%) were not on social media as seen in Table 1. Of those who indicated they were social media users, 42 participants (41.2%) specified they were daily users. These 3 groups were then used to stratify the data and determine any differences amongst groups. The questionnaire addressed subject awareness of clinical trials. The first question in this set was to determine if participants knew the definition of a clinical trial. Of the 98 responses, 88.8% (n=87) of participants knew the exact definition of a clinical trial (Table 3). The participant was then asked if they were aware of clinical trials in the area, past clinical trial participation, and possible future participation. Of 100 responses, 58% said they were not aware of clinical trials in the area (Table 3), and 78% indicated they had not participated in clinical trials in the past. However, when asked about future participation, 51.5% (n=52) indicated they would participate. Furthermore, participants were asked if they had ever seen a clinical trial advertisement on a social media network, 59.4% (n=57) indicated they had not seen an advertisement. These results can be seen in Table 3.

To assess specific aim #1, results were analyzed to view social media patterns of subjects, such as which social media platform was most used, social media concerns, and motivating factors for using social media. The most used social media network across all participants was Facebook, 97.4% (n=75). Additionally, Facebook was the most popular social media platform across age groups and gender. Staying connected with friends was the main motivational factor for using social media as cited by 97.3% (n=73) of individuals surveyed. This matched previous literature that sociability was the main reason to use social media 24 . Privacy was the prevalent concern by 80.8% (n=80) of participants. Additionally, this was also noticed across the three groups of gender, age group, and social media users and non-users as shown in Table 7. χ^2

analysis predictably showed that Facebook as a recruiting platform did differ amongst users of social media and non-users.

In order to fully address specific aim #1, several questions addressed the potential of social media to determine its effectiveness. Two questions compared traditional media (newspaper, radio, or TV) and social media. The questions were re-coded from a 4 tier response Likert scale (i.e., very likely, somewhat likely, not likely, would not participate) into two responses consisting of: would participate and would not participate. This technique was completed due to a low number of responses for the selections "very likely" and "would not participate." Re-coding process simplified the data and it offered further analysis possibilities for the results, however, those possibilities were found to be out of scope. Of the data collected, 55% indicated they would not participate in a clinical trial if they learned about it via a social media network (Table 3). Some respondents left comments and addressed the issue of the advertisements credibility. Conversely, 58% cited they would participate if they learned about it via traditional media methods (Table 3). However, χ^2 analysis revealed a relationship among social media users and likeliness to participate in a clinical trial with a statistically significant *p-value* of 0.043.

The last question of the questionnaire assessed the second aim of this study, participants were asked to choose which platforms would work best in recruiting subjects. Analyzing the responses revealed that 78.2% participants overwhelmingly chose physician's referral as the best recruiting platform. Traditional media platforms, such as television advertisement (27.7%) and letters (23.8%), were the most preferred recruiting platforms over social media platforms. Logistic regression was also used to identify any relationships between future participation and

current recruitment methods. A *p-value* of 0.028 was statistically significant showing that willingness to participate in future clinical trials was associated with a physician's referral.

In order to address the third objective of this project respondents were asked to choose the factors that would motivate them to participate in a clinical trial. Respondents were also asked to identify barriers that would discourage them from participating in clinical trials. The question was a multiple response. Of the 97 participants that answered which motivational factors were more likely to encourage participation, 59.8% (n=58) cited that "hoping to improve their current medical condition" as the most frequently chosen response. Furthermore the 2nd and 3rd chosen motivational factors were altruism (44.3%) and physician recommended (41.2%). Table 5 lists all the motivational factors from the survey. When comparing motivational factors across age groups, hoping to improve current medical condition was the top motivational factor for all groups except Millenials. This group cited the desire to help others as a top motivational factor. Across genders, both males (35.4%) and females (27.2%) noted that hoping to improve current medical condition as main factor. The third comparison of these factors was done across the group of social media users and non-users. Again, both sets of groups found that hoping to improve current medical condition was an important motivational factor. Further breakdown of motivational factors by gender, age groups, and social media use can be seen in Table 5. Further analysis showed that payment was statistically significant among genders with a p-value of 0.042 (p<.05) indicating that there is a potential relationship between them. The desire to help others was statistically significant (p-value of .034) among users of social media and non-users. The second portion of specific aim #3 assessed the barriers that would discourage participation in a clinical trial. Of the 101 participants that answered which barriers were least likely to encourage participation, 61.4% (n=62) indicated side effects as a barrier. Thirty-two percent of respondents

indicated the secondary barrier was time commitment. Across all age groups the main barrier indicated was the possibility of side effects. This trend continued between genders as well as social media users and non-users as seen in Table 6. χ^2 analysis did not show any statistically significant differences amongst the groupings. Logistic regression analysis failed to show significant differences for barriers and willingness to participate in future trials.

Summary:

The purpose of the first objective was to explore the possibility of social media as a platform and its effectiveness in subject recruitment. The views that were collected from respondents indicated that social media was not a favorable option for participation. Additionally, social media platforms were not frequently identified to be potential platforms for recruitment. The majority of respondents said they would not participate in a clinical trial via a social media advertisement. Interestingly, some respondents left comments indicating a sense of distrust with this type of communication. However, traditional media such as television and radio were viewed favorably with the majority of respondents indicating their possible participation. The main concerns of using social media were noted to be privacy and identity theft suggesting that maintaining privacy is important to potential subjects. In addition, credibility of the advertisement seems to be an important issue. Future studies may need to address these types of questions.

The results from this report that address specific aim #2 revealed that overwhelmingly the preferred recruitment method is predicated on the physician being involved to promote the possibility of a research study. These results revealed that resources should be allocated to improve physician involvement. Potentially increasing physician awareness of clinical trials may help eliminate subject-related recruitment issues. The literature identified physician barriers in

the clinical trial recruitment process, such as lack of time, resources, and referrals. Increasing communication or the use of informative materials about available clinical trials among physicians or between physicians and a research site may be an initial step to improving subject recruitment. Explaining the potential benefits for physicians who participate in clinical trials, such as giving input on the future direction of therapeutics, should be emphasized to those physicians that are not participating. Evaluating different strategies to recruit physicians to dedicate their time to clinical trials is an avenue for further research.

The third objective addressed what motivates people to participate in a research study as well as the factors that discourage them. In addition, these motivational factors and barriers were analyzed to determine if they differ by gender, age groups, and social media use. Understanding these factors can help researchers determine the best approach. For example, improving a current medical condition was discovered to be the main motivational factor for participation, therefore research staff should fully educate subjects on the potential benefit of the treatment. The same strategy can be applied to the barriers that affect participation. The concern of side effects was shown to be the main barrier that discourages subjects, emphasizing the low risk of side effects and continuance of care may appease concerns of subjects.

Discussion:

Clinical trials provide a controlled method to test the efficacy and safety of new medical devices and/or drugs. Inefficient subject recruitment hinders the entire clinical trial process. The purpose of this study was to determine the effectiveness of social media as a potential platform for clinical trial subject recruitment. Determining which platform would be most useful in clinical trial subject recruitment was another goal of the study. Lastly, the research project aimed to identify factors that motivate potential research subjects to participate in clinical trials. The

participant was asked about demographics that were then used to analyze data and form comparisons across generational groups, gender, and usage of social media. Furthermore previous studies on research participation identified which factors motivate and detract subjects from participating in a clinical trial⁶. These factors were used to design the questionnaire in this study. Some of the data trends observed during the course of this study supports previously published information. Recent literature discusses how different subject-related barriers impact research participation²³. However, very little information on the role social media use by subjects may play for increasing clinical trial awareness. Gonzalez mentions some clinical trial companies are using social media to directly connect with subjects, for example, "ClinicalConnection" posts recruitment messages on Twitter for its followers¹⁰. As Gonzalez notes in her findings, most adoption of social media is occurring within smaller medical organizations such as community health centers and specialty treatment centers. A key advantage of social media as identified by clinical researchers was the ability to target specific groups¹³.

Social media may not be the singular tool to increase subject recruitment but instead must be used synergistically with other recruitment tools¹³. The majority responses indicated that the best platform to reach potential subjects would be a physician's referral thereby suggesting potential participation depends on physician involvement which supports the literature¹³. Resources should be distributed in order to improve physician participation in clinical trials. As mentioned, increasing physician awareness of clinical trials could eliminate recruitment issues. Fifty-five percent of responses noted they would not participate in a clinical trial advertised on social media suggesting that those surveyed may not trust the advertisement. Additionally 46.2% of those surveyed marked privacy as a concern of their social media use. Clinical research sites may want to begin a social media presence to develop trust with potential participants as seen in

the literature¹⁰. However, awareness of clinical trials is still very low among the population surveyed. It's been reported that clinical researchers see social media as a tool to reach the Millenial generation to search for new participants¹³. Researchers should be optimistic as the majority of all responses stated they would consider participating in a clinical trial. The factor most likely to motivate an individual to participate in a clinical trial across all groups is the need to improve their own medical condition. However, most people indicate they would be less likely to participate due to the potential of side effects. This supports the previously reported view that the risk of side effects reduced willingness to participate among individuals¹⁸. Using this information can be helpful to address the issue of low subject recruitment rates in clinical trials. In order to improve subject recruitment it is necessary to understand the target population. For example, trials looking for individuals with osteoporosis via social media advertisements are less likely to be successful⁴. As noted by Howe, a younger population uses social media more frequently and trials should target this demographic 13. Further studies may want to look at the type of information individuals are more likely to respond to online. In addition, a study that looked at physician willingness to participate via a social media recruitment campaign should be researched.

The limitations of this study included the method of distributing the surveys. The two survey sites in Fort Worth limited the number of potential participants as well. A broad distribution of age groups was achieved. However, there was a gender gap present. According to Pew Research, females use social media more than males, which may be a possible explanation why more females responded to the questionnaire⁴. Expanding the sampling location would show a more diverse population to increase the scope of further studies. An additional limitation included the structure of the survey which could be improved to avoid any confusion by the

subjects and consequently their answer choices. In conclusion, increasing subject awareness of clinical trial opportunities may increase subject participation. Social media may increase awareness but may not increase participation as reported. However a majority of responses did indicate interest in future participation. It is clear that subject recruitment needs multiple approaches to reach individuals, and clinical researchers must examine how social media can be best applied in this regard. Furthermore, physician awareness and participation in clinical trials must be improved as subjects reported that this was the preferred recruitment method. By improving low subject recruitment rates, researchers will have the statistically significant data needed to show if treatments are efficacious and safe.

CHAPTER 3

INTERNSHIP EXPERIENCE

My internship was conducted at UNT Health Science Center in the Department of Surgery. My internship mentor Dr. Albert Yurvati is currently involved in several clinical research trials in his role as a Principal Investigator and Sub-Investigator. The difficulties of recruiting subjects for trials led to the topic of interest, "Social Media Use and its Potential for Clinical Trial Subject Recruitment." During my internship I worked with multiple clinical trials and luckily was able to see a clinical trial from its beginning to the end. The most memorable experience with a clinical trial was the Finish-3 study, a phase 3 clinical trial that looked at intra-operative hemostasis after topical application of fibrocaps (study treatment) or hemostatic sponges that are the standard of care. The purpose of this study is to determine if the investigational study treatment achieved hemostasis faster. The treatment was composed of human fibrinogen and thrombin mixed as a powder that once applied polymerizes to decrease clotting time. I was able to observe 15 vascular surgeries, specifically 10 femoral-popliteal, 3

femoral-femoral bypasses and two carotid endarterectomies. Witnessing the surgeries was a great experience for me and will always remain truly memorable.

Working as an intern with Department of Surgery allowed me to participate in various aspects of a clinical trial. While working with the Venous Leg Ulcer trial, I was able to participate in subject recruitment, screening, enrollment, and randomization. During my internship I have learned these phases vary from one trial to another. In some trials, screening a subject may not mean they are enrolled. The randomization phase is one of the most important visits because if all criteria are met the subject will be receiving study treatment or standard of care. The most important aspects of clinical trials are the subject inclusion/exclusion criteria, as it will ultimately determine if the subject is enrolled. Unfortunately, I have seen instances where a subject failed to meet criteria and could not participate in the trial. It is difficult to see an individual leave especially when they truly could benefit from the care, however, one has to understand the strict nature of clinical trials is meant for subject safety and to minimize scientific error.

For the venous leg ulcer studies, I organized subject source documents and arranged them according to the study visit. I have also been able to learn how to use a digital camera that calculates depth, volume and area of an ulcer. I assisted my clinical coordinator supervisors in applying compression treatment to research subjects. If a shipment of study medication needed to be received, I learned how to document receipt and properly store the medication. During my internship, I learned how to process lab specimen and submit for diagnostic work-ups to Quest Diagnostics and LabCorp.

As part of both studies that investigate the effect of the use of Botulinum toxin A on subject spasticity on upper and lower limbs, I documented the study examinations via film, as per the protocol. From this study, I learned how an electrocardiogram examination is performed and how to correctly place the leads in order to accurately determine the electrical activity of the heart. I observed the physician administer electro-magnetically guided (EMG) injections for subjects with spasticity. These EMG injections allow for determination of the adequate dosage and into the correct muscle area.

During my internship my activities included seeing subjects during all the phases of clinical trials. I also assisted with medical procedures such as taking blood pressure, calculating heart rate, and respiratory rate. My responsibilities as a student intern have varied among trials. My internship supervisor taught me how to submit documents to the IRB for conflict of interest, serious adverse events (SAE), continuing review, protocol amendments, and study closures. This helped me learn how to submit my exempt review application to the IRB for my internship project. I also learned how data was input into the electronic case report forms from the source documents so that the sponsor may monitor data. In addition, I was able to learn how to prepare for a monitoring visit and how to address the queries the monitor makes. I prepared for at least twenty monitoring visits during my internship. The experiences in this internship have taught me a lot about the sector of clinical trials and a great deal about myself and my abilities. I have learned the importance of clinical trials for the advancement of medicine and I know that I aim to have a career in clinical trials.

APPENDIX A

IRB Approval

UNIVERSITY of NORTH TEXAS HEALTH SCIENCE CENTER OFFICE for the PROTECTION of HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD

Request for Waiver of Documentation of Informed Consent Form A

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fuvestigator's Name: Jerry Simecka, Ph.D.

Title of Project: Use of Social Media and its Potential for Subject Recruitment in Clinical Trials

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

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

(initial)	consent document are, the principal the breach of confidentiality. This	ng the participant and the research would be I risk would be the potential harm resulting fi- refers to instances where participants could be in that they were participants in the research.	our
Explanation:			
<u>OR</u>			
(initial)	Condition 2 The research presents and involves no procedures for whithe research context.	no more than minimal risk of harm to partie? ch written consent is normally required outsi	pants de of
Explanation:			
Investigator's Signa	ture fue of	Date 7-23-/3	_
IRB Chair's Signatu	пе	Date	

Informed Consent Waiser Amelication From A session (19/39)



DATE:

September 27, 2013

TO:

Jerry Simecka, PhD (with Mario Reves)

Molecular Biology and Immunology

FROM:

Brian A. Gladue, PhD, CIP

Executive Director, Office of Research Compliance

PROTOCOL: # 2013-154

Use of Social Media and its Potential for Subject Recrultment in Clinical Trials

Halee

NOTICE OF DETERMINATION / APPROVAL

The Office of Research Compliance, on behalf of the Institutional Review Board (IRB) of the University of North Texas Health Science Center (UNTHSC), has reviewed your protocol and has determined this protocol to meet criteria for **EXEMPT** status, as specified in Federal Regulations 45 CFR 46.101(b) in one or more of the following categories, as initialed below:

(1) Research Conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of... Instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, againate, achievement), survey protections; interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any cisclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- ______(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, incerview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office...
- (4) Research involving the collection or study of existing data, documents, records, pethological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through stertifiers linked to the subjects.
 - . (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs...
 - (6) Taste and food quality evaluation and consumer acceptance studies...

You are responsible for complying with all UNTHSC policies, decisions, conditions and requirements regarding projects involving human subjects. You are responsible for insuring that the research is implemented as specified in the protocol. In addition, you are required to use ONLY the reviewed and approved documents, materials and/or procedures designated for this protocol that were acknowledged by the Office of Research Compliance.

You must report to the Office of Research Compliance any changes affecting the protocol upon which this certification is based. No changes may be made without prior approvat, except those necessary to eliminate immediate hazards.

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



DATÉ:

October 17, 2013

TO:

Jerry Simecka

Molecular Biology and Immunology

FROM:

Brian Gladue, PhD, CIP

Executive Director, Office of Research Compliance

PROTOCOL: #2013-154

Use of Social Media and its Potential for Subject Recruitment in Clinical Trials

IRB BOARD ACTION AND NOTICE OF APPROVAL: MODIFICATION TO PROTOCOL

The Office of Research Compliance, on behalf of the Institutional Review Board (IRB) of the University of North Texas Health Science Center (UNTHSC), has reviewed and approved the following modification(s) to your protocol: minor, non-significant changes to the survey instrument (e.g., rewording and rephrasing of questions and enswer options). The protocol continues to qualify for **EXEMPT** status as specified in Federal Regulations 45 CFR 46.101 (b), category (2).

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

You must report to the Office of Research Compliance any changes affecting the protocol upon which this certification is based. No changes may be made without prior approval, except those necessary to eliminate immediate hazards.

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

APPENDIX B

Survey Instrument

Use of Social Media and its Potential for Subject Recruitment in Clinical Trials

Principal Investigator: Jerry Simecka, Ph.D.

Co-Investigator: Mario Reyes, B.S.

Institution: University of North Texas Health Science Center at Fort Worth

introduction:

We are conducting a research project to determine whether social media would effectively increase subject recraitment in clinical trials.

You are invited to participate in this research study survey because your feedback is important to us. This servey will take no more than 5 minutes to complete.

Risk/Benefit:

There are no foreseeable risks associated with participating in this survey. You may receive no direct benefit from participating in this study. The benefits of this survey will allow us to evaluate the opinions of individuals visiting the UNT Health Science Center and UNT Bone and Joint Institute.

Agreement to Participate:

Participation in the study is completely voluntary. Your decision to participate (or to not participate) in this research project will in no way affect the clinical cure you receive as a patient in this clinic. Should you decide to participate, please complete and return the survey to the front desk.

Confidentiality:

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

Leaving the Study:

Since the survey is not identifiable, there will be no way to withdraw from the study once you complete and return the survey.

Questions/Concerns:

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

Principal Investigator: Jerry Simecka, Ph.D.

817-735-2366

Co-investigator: Mario Reyes, B.S.

210-355-7083

If you have any questions about your rights as a research subject, please contact the UNT Health Science Center Institutional Review Board at (817) 735-0409

Thank you for participating in this study.

ACKNOWLEDGED

Research Compliance

Social Media and Clinical Trials Survey

1.	What a	age group do you belong to?
	63	18-29 years
	9	30-45 years
	55	46-64 years
	\mathbf{E}	65+ years
2.	Gende	r?
	П	Female
	13	Male
3.	Do you	use ANY of these social media platforms? *Check all that apply*
	Ü	Facehook
	\Box	Twitter
	П	LinkedIn
	D	Other
		None (Skip to question 6)
4.	How r	nany days a week do you use any of the prior social media sites?
	13	Daily
	Æ	2 times/week
	П	3 times/week
	E.	4 times/week
	U	5 times/week
		Not often
5.		motivates you to use these social media sites? *Check all that apply*
	□	Staying connected with friends
	Е	
	C	Learning about career opportunities
		Staying informed about current events
	U	Learning of research opportunities ACKNOWLEDGED
		OCT 17-2013

6. What	concerns you about social media sites? *Check all that apply*
Ξ	Privacy
U	Identity Theft
15	Victimization (bullying, harassment, etc)
E	No Concerns
П	Indifferent
7. Do yo	u know what a clinical trial is?
ü	Experimental research on animals
	Controlled testing of a new drug or medical device
U	Laboratory testing with new chemicals
D	A court trial against a physician
8. IJow	aware are you of any clinical trials in your area?
В	Very aware
Ü	Somewhat aware
Ц	Not aware
9. Have	you ever participated in a clinical trial?
ū	Yes
0	No
0	Not sure
10. Wou	ld you ever consider participating in a clinical trial?
П	Yes
	No
-	Not sure
11. Have	e you ever seen a clinical trial advertisement on a social media site?
0	Yes
	No
L	Not sure
	APPROXIT
	ACKNOWLEDGED

HNTHSC Research Compliance

12. Which	of the following would make you least likely t	to participate in a clinical trial?
	Uncertainty of treatment	
Ш	Confidentiality	
1	Possibility of side effects	
Ð	Time commitment	
Ti.	Travel	
13. Which trial?	of the following would make you more lil	kely to participate in a clinical
13	Desire to help others	
Е	Hope to improve current medical condition	
U	Access to new medical treatments	
	If recommended by physician	
a	Payment	
	likely are you to participate in a clinical trial media site?	should you tearn about it on a
E	Very Likely	
	Somewhat Likely	
	Not Likely	
	Would Not Participate	
15. How tradit	likely are you to participate in a clinical tri ional media such as a <i>newspaper, radio, or TV a</i>	al should you learn about it on advertisement?
ı.	Would Not Participate	
<u> </u>	Not Likely	
E.	Somewhat Likely	
n	Very Likely	
16. Base findir	d on your opinion, which of the following ag clinical trial research subjects?	platforms would work best in
12	Facebook	□ Radio ad
C	Twitter	□ Newspaper ad
Ü	LinkedIn	Physician's referral
Ε.	Letter	ACKNOWLEDGED
13	TV ad	ore, is how
		172 File
		SNTHSC Permarch Compliance
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APPENDIX C

Survey Responses

Table 1. Demographics of Responses	
Response	Percentage
Gender	
Female	70.3
Male	29.7
Age Groups	
18-29	24.5
30-45	19.6
46-64	35.3
65+	20.6
Social Media Use	
Yes, I use social media	75.5
Daily Use	41.2
No, I do not use social media	24.5

Table 2. Participant Awareness of Clinical Trials	
Response	Percentage
Clinical Trial Awareness	
Very Aware	6.0
Somewhat Aware	36.0
Not Aware	58.0
Past Participation	
Yes	20.0
Not Aware	78.0
Not Sure	2.0
Future Participation	
Yes	51.5
No	10.1
Not Sure	38.4
Clinical Trial Advertisement Awareness	
Yes	32.3
No	59.4
Not Sure	8.3
Clinical Trial Definition Awareness	
Experimental Research on Animals	3.1
Controlled Testing of a new medical drug or device	88.8
Laboratory testing with chemicals	8.2

Table 3. Likeliness to Participate in a Clinical Trial:	
Response	Percentage
Via a social media adverstistment	
Would Participate	44.4
Would Not Participate	55.6
Via a traditional media advertisement	
Would Participate	58.0
Would Not Participate	41.8

Table 4. Cur	Table 4. Current Recruitment Methods											
Response	Total	Female	Male	18-29	30-45	46-64	65+	Social Media User	Social Media Non- User	X ² p- value	Reg. p- value	
Facebook	17.8	10.7	4.2	10.7	10.0	11.3	0.0	10.5	2.8	0.039	0.346	
Twitter	5.9	3.4	4.2	7.1	2.5	2.8	0.0	4.3	0	0.118	0.859	
LinkedIn	5.9	2.7	4.2	5.4	0.0	2.8	3.2	3.7	0	0.150	0.841	
Letter	23.8	12.1	12.5	8.9	15	11.3	16.1	11.1	16.7	0.949	0.311	
TV ad	27.7	15.4	10.4	16.1	15	12.7	12.9	14.8	11.1	0.14	0.096	
Radio ad	20.8	10.1	12.5	10.7	10	9.9	12.9	11.1	8.3	0.222	0.43	
Newspaper ad	14.9	8.1	6.3	3.6	10	8.5	9.7	6.8	11.1	0.833	0.757	
Physician's Referral	78.2	37.6	45.8	37.5	37.5	40.8	45.2	37.7	50.0	0.453	0.028	

Table 5. Motivational Factors for Clinical Trial Participation												
Response	Total	Female	Male	X ² p- value	18- 29	30- 45	46-64	65+	Social Media User	Social Media Non- User	X ² p- value	Reg. p- value
Desire to help others	44.3	21.8	22.9	0.435	28.3	16.2	19.2	23.8	23.4	15.0	0.034	0.391
Hope to improve current medical condition	59.8	27.2	35.4	0.976	23.9	35.1	32.9	23.8	28.5	32.5	0.572	0.233
Access to new medical treatments	39.2	20.4	14.6	0.071	17.4	18.9	19.2	21.4	18.4	22.5	0.881	0.493
If recommended by physician	41.2	19.0	22.9	0.794	21.7	18.9	19.2	21.4	20.3	20.0	0.395	0.920
Payment	19.6	11.6	4.2	0.042	8.7	10.8	9.6	9.5	9.5	10.0	0.698	0.999

Table 6. Barriers Identified for Clinical Trial Participation Response Total		Female	Male	18-29	30-45	46- 64	65+	Social Media User	Social Media Non- User	Reg. p- value
Uncertainty of	29.7	19.8	21.1	21.1	18.5	15.1	26.5	16.7	28.9	
Treatment										0.980
Confidentiality	5.0	2.7	2.6	0.0	3.7	7.5	0.0	3.5	2.6	0.999
Possibility of side	61.4	37.8	50.0	52.6	33.3	35.8	41.2	41.2	39.5	
effects										0.559
Time commitment	31.7	22.5	15.8	18.4	25.9	22.6	17.6	21.9	18.4	0.950
Travel	22.8	17.1	10.5	7.9	18.5	18.9	14.7	16.7	10.5	0.856

Table 7. Social	Media (Concerns							
Response	Total	Female	Male	18-29	30-45	46- 64	65+	Social Media User	Social Media Non- User
Privacy	80.8	45.1	46.2	50.0	48.6	38.7	48.6	46.2	43.5
Identity Theft	56.6	32.0	32.7	23.8	25.7	37.1	37.8	30.8	34.8
Victimization	24.2	14.8	9.6	16.7	17.1	14.5	5.4	13.8	13.0
No Concerns	8.1	4.9	3.8	4.8	5.7	4.8	2.7	5.4	2.2
Indifferent	8.1	3.3	7.7	4.8	2.9	4.8	5.4	3.8	6.5

Table 8. Motivational Factors for Social Media Response	Total	Female	Male	18-29	30-45	46-64	65+
Staying Connected with Friends	97.3	55.7	50.0	44.2	51.9	65.1	53.3
Meeting new people	13.3	6.8	6.5	9.6	3.7	7.0	6.7
Learning about career opportunities	12.0	4.5	8.7	9.6	7.4	2.3	6.7
Staying informed about current events	52.0	29.5	28.3	32.7	29.6	25.6	20.0
Learning of research opportunities	8.0	3.4	6.5	3.8	7.4	0.0	13.3

APPENDIX D

Daily Journal

Internship Journal

Wednesday, August 21, 2013

- Email Amanda Oglesby to discuss hold up from IRB
 - o Clear all issues
 - o Review underway as of this date

Friday, August 30, 2013

- Meet with committee members to discuss status of project
 - Make changes to questionnaire wording
 - o Discuss delays with the IRB submission from 7/25/13

Friday, August 30, 2013

- Meet with committee members to discuss status of project
 - o Make changes to questionnaire wording
 - o Discuss delays with the IRB

Monday, September 16, 2013

• Meet with Srishti to discuss last committee meeting findings

Tuesday, September 17, 2013

- Assist with Oasis screening Visits (April)
- Assist with DermaScience

Wednesday, September 18, 2013

• Assist with a 2 study visits for Large Ulcer study at PCC (Srishti)

Thursday, September 19, 2013

• Assist with screening visits for Oasis at Ben Hogan (April)

Friday, September 20, 2013

• Work on research project

Monday, September 23, 2013

• Talk to IRB to discuss hold up with project submission

Tuesday, September 24, 2013

- Assist with Oasis screening Visits (April)
- Assist with DermaScience

Wednesday, September 25, 2013

• Assist with a 2 study visits for Large Ulcer study at PCC (Srishti)

Thursday, September 26, 2013

• Assist with screening visits for Oasis at Ben Hogan (April)

Friday, September 27, 2013

- Work on research project
- Approval of IRB submission

Monday, September 30, 2013

- Meet with Srishti
 - o Discuss changes to survey questionnaire

Tuesday, October 01, 2013

- Assist with Oasis Screening/Randomization Visits (April)
- Assist follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Wednesday, October 02, 2013

• Assist with a 2 study visits (Follow-up and Randomization) for Large Ulcer study at PCC (Srishti)

Thursday, October 03, 2013

- Assist with randomization and follow-up visits for Oasis at Ben Hogan (April)
- Assist with follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Friday, October 04, 2013

• Work on research project

Monday, October 7, 2013

- Research project
- Submit changes to Survey Questionnaire to the IRB

Tuesday, October 8, 2013

- Assist with Oasis Follow-Up Visits (April)
- Assist with a randomization visit for small ulcer as well as follow up visits
 - Learn to perform an Ankle Brachial Index

Wednesday, October 9, 2013

• Assist with a 2 study visits for Large Ulcer study at PCC (Srishti)

Thursday, October 10, 2013

- Assist with follow-up visits for Oasis at Ben Hogan (April)
- Assist with follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Friday, October 11, 2013

Work on research project

Monday, October 14, 2013

• Meet with Srishti

Tuesday, October 15, 2013

- Assist with Oasis Follow-Up Visits (April)
- Assist with DermaScience visit (Isabel)

Wednesday, October 16, 2013

- Assist with a 3 study visits for Large Ulcer study at PCC (Srishti)
- IRB still under review

Thursday, October 17, 2013

- Assist DermaScience visit
- Assist with screening and follow-up visits for Oasis at Ben Hogan (April)
- Assist with follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Friday, October 18, 2013

- Work on research project
- Pick up IRB submission materials

Monday, October 21, 2013

- Make copies of survey at Kinkos
- Begin talking to clinic directors

Tuesday, October 22, 2013

• Assist with Oasis Follow-Up Visits (April)

Wednesday, October 23, 2013

• Assist with a 2 study visits for Large Ulcer study at PCC (Srishti)

Thursday, October 24, 2013

- Assist DermaScience visit
- Assist with follow-up visits for Oasis at Ben Hogan (April)

- Assist with follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka) Friday, October 25, 2013
 - Work on research project
 - Begin talking to clinic directors

Monday, October 28, 2013

• Discuss progress with Srishti

Tuesday, October 29, 2013

- Assist with Oasis Follow-Up Visits (April)
- •

Wednesday, October 30, 2013

• Assist with a 2 study visits for Large Ulcer study at PCC (Srishti)

Thursday, October 31, 2013

- Assist DermaScience visit
- Assist with follow-up visits for Oasis at Ben Hogan (April)
- Assist with follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Friday, November 01, 2013

- Work on research
- Learn about AMGA survey and inability to complete my own survey during month of November

Monday, November 04, 2013

- Discuss progress with Srishti
 - Address queries Monitor for Large Ulcer specifies

Tuesday, November 05, 2013

- Assist with Oasis screening and Follow-Up Visits (April)
- •

Wednesday, November 06, 2013

• Assist with a 2 study visits for Large Ulcer study at PCC (Srishti)

Thursday, November 07, 2013

- Assist DermaScience visit
- Assist with a randomization visit, screening and follow-up visits for Oasis at Ben Hogan (April)
- Assist with follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Friday, November 08, 2013

• Work on Research

Monday, November 11, 2013

• Meet with Joanne Mize to discuss AMGA survey

Tuesday, November 12, 2013

• Assist with Oasis Randomization Visits (April)

Wednesday, November 13, 2013

• Assist with a 2 study visits for Large Ulcer study at PCC (Srishti)

Thursday, November 14, 2013

- Assist DermaScience visit
- Assist with a randomization visit, screening visit and follow-up visits for Oasis at Ben Hogan (April)
- Assist with follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Friday, November 15, 2013

• Attend DermaScience training

Monday, November 18, 2013

• Discuss progress with Srishti

Tuesday, November 19, 2013

- Assist with Oasis Follow-Up Visits (April)
- Assist with a screening visit for Small Ulcer study at Ben Hogan (Srishti and Priyanka

Wednesday, November 20, 2013

- Assist with a 2 study visits for Large Ulcer study at PCC (Srishti)
- Assist with recording procedure for Dysport

Thursday, November 21, 2013

- Assist DermaScience visit
- Assist with a randomization visit and follow-up visits for Oasis at Ben Hogan (April)
- Assist with follow-up visits for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Friday, November 22, 2013

• Work on research

Monday, November 25, 2013

Speak with clinic directors again regarding survey help

Tuesday, November 26, 2013

- Assist with a study visit for Large Ulcer study at PCC (Srishti)
- Go to Ben Hogan to assist for a follow-up visit
- Assist with Oasis Follow-Up Visits (April)

Wednesday, November 27, 2013

• Thanksgiving Break

Thursday, November 28, 2013

• Thanksgiving Break

Friday, November 29, 2013

• Thanksgiving Break

Monday, December 02, 2013

• Meet with Clinic Directors regarding the status of AMGA survey

Tuesday, December 03, 2013

- Assist with Oasis Screening and Follow-Up Visits (April)
- Assist in a randomization visit for Small ulcer study (Srishti and Priyanka)

Wednesday, December 04, 2013

- Assist with an End of Study Treatment visit for Large Ulcer study at PCC (Srishti)
 - Process labs
 - o Ship out via Fed-Ex
- Assist in follow-up visit for Large Ulcer
- Worked on a Continuing Review

Thursday, December 05, 2013

- Assist DermaScience visit
- Assist with a screening visit and follow-up visits for Oasis at Ben Hogan (April)

Friday, December 06, 2013

• UNT Closed-Inclement Weather

Monday, December 09, 2013

• UNT Closed- Inclement Weather

Tuesday, December 10, 2013

• Worked on Research Proposal

• Assist with Oasis Follow-Up Visits (April)

Wednesday, December 11, 2013

- Assist with a study visit for Large Ulcer study at PCC (Priyanka)
- Assist with recording procedure for Dysport

Thursday, December 12, 2013

- Assist DermaScience visit
- Assist with a randomization visit and follow-up visits for Oasis at Ben Hogan (April)
- Assist with a screening visit for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Friday, December 13, 2013

Work on paper

Monday, December 16, 2013

• Work on Research Proposal

Tuesday, December 17, 2013

• Assist with Oasis and Venous Small Ulcer Subjects

Wednesday, December 18, 2013

- Assist with End of Study Visit for Venous Ulcer Subject
 - o Process lab draw
 - o Ship via Fed-Ex
 - o Fill out source documents

Thursday, December 19, 2013

• Follow-up Visits for Derma-Science and Oasis (With Isabel and April)

CHRISTMAS BREAK

Thursday, January 2, 2014

- Subject follow-up visits for Oasis (With April)
 - o Complete source documents
 - o Learn how to apply the Oasis treatment on a diabetic foot ulcer
- Talk to clinic director at Ben Hogan about survey distribution

Friday, January 3, 2014

• Talked to clinical directors at the PCC about survey distribution

Monday, January 6, 2014

- Begin to pass out survey to the clinical directors for distribution
- Worked on research proposal.
- Worked on internship journal.

Tuesday, January 7, 2014

• Assist with Oasis and Venous Small Ulcer Subjects (With Srishti, Priyanka and April)

Wednesday, January 8, 2014

- Assist in the video recording procedure of Dysport (with Isabel)
- Work on Research Proposal

Thursday, January 09, 2014

- Assist with Oasis and Venous Small Ulcer Subjects (With Srishti, Priyanka and April)
 - Complete source docs
 - Ship specimen via Fedex
- Filed documents for study.
- Worked on research proposal
- Worked on internship journal

Friday, January 10, 2014

- Search for articles relating to generational differences
- Audit source documents for upcoming Monitor visit

Wednesday, January 13, 2014

- Meet with Srishti
 - o Discuss queries from Venous Large Ulcer study

Tuesday, January 14, 2014

- Assist with End of Study Visit for Venous Small Ulcer Subject (Srishti and Priyanka)
 - o Process lab draw
 - o Ship via Fed-Ex
 - o Fill out source documents
- Assist with Oasis Follow-Up Visits (April)

Wednesday, January 15, 2014

- Worked on Research Proposal
- Collect any surveys that have been filled out from the PCC

Thursday, January 16, 2014

• Assist with Oasis Follow-Up Visits (April) and Small Ulcer study subjects (Priyanka and April)

Friday, January 17, 2014

- Worked on Research Proposal
- Collect any surveys that have been filled out from the PCC

Monday, January 20, 2014

• MLK Holiday

Tuesday, January 21, 2014

• Assist with Oasis Follow-Up Visits (April)

Wednesday, January 22, 2014

- Assist with a screening visit for Large Ulcer at PCC (Srishti)
- Discuss progress of project with Srishti

Thursday, January 23, 2014

• Audit source documents to complete any pending queries from last monitor visit

Friday, January 24, 2014

- Worked on Research Proposal
- Collect any surveys that have been filled out from the PCC

Monday, January 27, 2014

- OCT Staff Meeting
 - Current and upcoming Studies
- Meeting with Srishti

Tuesday, January 28, 2014

- Worked on Research Proposal
- Assist with a screening visit for Small Ulcer study at Ben Hogan (Srishti and Priyanka)
- Assist with follow-up visits for Small Ulcer at Ben Hogan (Srishti)
- Assist with Oasis Follow-Up Visits (April)
- Attend WebCast for DermaScience study (Srishti and Isabel)

Wednesday, January 29, 2014

- Assist with a screening visit for Large Ulcer study at PCC (Srishti and Priyanka)
- Assist with a post-study treatment follow-up visit for Large Ulcer study at PCC (Srishti and Priyanka)

Thursday, January 30, 2014

- Worked on Research Proposal
- Assist with a screening visit for Oasis at Ben Hogan (April)

Friday, January 31, 2014

- Collect any surveys that have been filled out from the PCC
- Choose a survey tool (Survey Gizmo)

Monday, February 3, 2014

• Met with Biostatistician to discuss project

Tuesday, February 4, 2014

- Assist with a screening visit for Small Ulcer study at Ben Hogan (Srishti and Priyanka)
- Assist with follow-up visits for Small Ulcer at Ben Hogan (Srishti)
- Assist with Oasis Follow-Up Visits (April)
- Began uploading data onto Survey Gizmo

Wednesday, February 5, 2014

• Assist with a screening visit for Large Ulcer study at PCC (Srishti and Priyanka)

Thursday, February 6, 2014

• Worked on research proposal

Friday, February 7, 2014

- Assist in the video recording procedure of Dysport (with Isabel)
- Collect any surveys that have been filled out from the PCC

Monday, February 10, 2014

- Meeting with Srishti
- Assist with a post-study treatment follow-up visit for Large Ulcer study at PCC (Srishti)

Tuesday, February 11, 2014

- Received dates for Defense from Dr. Gwirtz
- Checked with committee on dates

Wednesday, February 12, 2014

- Assist with a post-study treatment follow-up visit for Large Ulcer study at PCC (Srishti)
- Collect any surveys that have been filled out from the PCC

Thursday, February 13, 2014

Attend surgery at Plaza

Friday, February 14, 2014

- Collect any surveys that have been filled out from the PCC
- Upload data onto Survey Gizmo

Monday, February 17, 2014

• Begin to find trends from the data and develop ideas about the discussion section

Tuesday, February 18, 2014

- Confirm date of defense
- Assist with a screening visit for Small Ulcer study at Ben Hogan (Srishti and Priyanka)

Wednesday, February 19, 2014

- Collect any surveys that have been filled out from the PCC
- Upload data onto Survey Gizmo
- Email Abhilash (Biostats) and discuss future plan for analysis

Thursday, February 20, 2014

- Assist with DermaScience screening and follow up visit (With Isabel)
 - Calculate wound size
 - o Process Labs

Friday, February 21, 2014

- Collect any surveys that have been filled out from the PCC
- Work on research proposal

Monday, February 24, 2014

- Meeting with Srishti
- Work on research proposal

Tuesday, February 25, 2014

- Collect any surveys that have been filled out from the Ben Hogan
- Work on research proposal

Wednesday, February 26, 2014

- Meeting with Srishti
- Upload data onto Survey Gizmo

Thursday, February 27, 2014

• Present data collected presently to Dr. Yurvati

Friday, February 28, 2014

- Collect any surveys that have been filled out from the PCC
- Work on proposal

Monday, March 3, 2014

• Get Intent to Defend Form signed by Committee Members

Tuesday, March 4, 2014

- Assist with a screening visit for Small Ulcer study at Ben Hogan (Srishti and Priyanka)
- Assist with follow-up visits for Small Ulcer at Ben Hogan (Srishti)
- Assist with Oasis Follow-Up Visits (April)

Wednesday, March 5, 2014

- Reviewed literature for research proposal
- Made revisions on research proposal

Thursday, March 6, 2014

- Assist with follow-up visits for Small Ulcer at Ben Hogan (Srishti and Priyanka)
- Assist with Oasis Screening Visits (April)
 - o Ship specimens via Fed-Ex

Friday, March 7, 2014

Worked on Research

Monday, March 10, 2014

• Meet with Srishti to begin editing process

Tuesday, March 11, 2014

- Assist with a randomization visit for Small Ulcer study at Ben Hogan (Srishti and Priyanka)
- Assist with follow-up visits for Small Ulcer at Ben Hogan (Srishti and Priyanka)
- Assist with Oasis Follow-Up Visit (April)

Wednesday, March 12, 2014

• Meet with Srishti to go over edits

Thursday, March 13, 2014

- Assist with Oasis Follow-Up Visit (April)
- Attend a Site Selection Visit for Auxilium (April)

Friday, March 14, 2014

Spring Break OCT

Monday, March 17, 2014

- Discuss project with Srishti
 - Finalize Specific Aims

Tuesday, March 18, 2014

- Assist with a screening visit for Small Ulcer study at Ben Hogan (Srishti and Priyanka)
- Assist with follow-up visits for Small Ulcer at Ben Hogan (Srishti and Priyanka)

Wednesday, March 19, 2014

- Go over edits and continue working on practicum report
- Finalize data collection and entry
- Look up how to analyze data via SPSS

Thursday, March 20, 2014

- Work on proposal edits
- Check out "Practical Statistics" from the library to try to understand SPSS
- Discuss research status with Dr. Simecka

Friday, March 21, 2014

- Work on proposal edits and finalize copy
- Read "Practical Statistics"

Monday, March 24, 2014

- Work on research paper
 - o Analyze data
 - Write results
 - Make edits

Tuesday, March 25th, 2014

- Finalze results/discussion section
- Edit tables

Wednesday, March 26th, 2014

• Finish research paper

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