Carter, Anne M., Roadblocks in Clinical Research: An Analysis of Common Barriers to the Clinical Research Process. Master of Science (Clinical Research Management), December 2022, 53 pp., 2 tables, 21 figures, bibliography, 14 titles.

Deficiencies in the clinical research process can lead to delays, loss of funding, outdated conclusions, and a lack in participation for both volunteers and scientists or clinicians. This project aimed to identify the specific roadblocks in the clinical research process within the Ophthalmology department at the University of Texas Southwestern Medical Center. The Ophthalmology and Optometry clinical and research faculty were surveyed to identify which aspects of the clinical research process were confusing, needed improvement, or awareness was lacking. Out of the 35 faculty provided with the survey, a total of 11 responded, giving a 31% response rate. Responses showed faculty were not fully aware of the resources available for clinical research or how to conduct clinical research within federal guidelines. They also would like to participate more in clinical research, but they are unaware of current actively recruiting research studies. Finally, all faculty responded they feel that clinical research is important, but most commonly they feel they don't have enough time. Information sessions, monthly newsletters, and faculty meetings are all ways to communicate solutions for these deficiencies in the clinical research process.

ROADBLOCKS IN CLINICAL RESEARCH: AN ANALYSIS OF COMMON BARRIERS TO THE CLINICAL RESEARCH PROCESS

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ROADBLOCKS IN CLINICAL RESEARCH: AN ANALYSIS OF COMMON BARRIERS TO THE CLINICAL RESEARCH PROCESS

CAPSTONE PROJECT REPORT

Presented to the Graduate Council of the

School of Biomedical Sciences

University of North Texas

Health Science Center at Fort Worth

in Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

Anne Carter, BS

December 2022

ACKNOWLEDGEMENTS

I would like to thank my committee members Dr. Raghu Krishnamoorthy and Dr. Dorota Stankowska for their input and guidance in writing and conducting my master's thesis. Their edits and suggestions to the research proposal and thesis practicum were invaluable in developing these papers.

I also would like to thank my capstone site supervisor and committee member Yesenia Leach for her continued support in my career and education. She was also vital in helping to come up with ideas for this project and solutions to problems identified through the survey. Additionally, I would like to thank the CRM program director Dr. Stephen Mathew for his assistance during my time in the Clinical Research Management program and during the capstone semesters.

Finally, I want to thank my husband and family for their continued support, unwavering love, and enthusiastic encouragement. I would not have accomplished my goals without their commitment to me, so I would like to use this space to acknowledge my heartfelt gratitude for them.

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CHAPTER I

INTRODUCTION

The clinical research process is a structured and managed machine designed to facilitate high quality, high recruiting clinical research studies to advance medicine, pharmaceuticals, medical devices, and clinical best practices. Within this structure, clinical research professionals, physicians, researchers, contract research organizations (CROs), Sponsors, Institutional Review Boards (IRBs), the Food and Drug Administration and various government offices, and recruited subject volunteers all must contribute to the exquisite choreography for a successful finale. As a note, successful clinical research doesn't always mean a trial's aim was met or the hypothesis was proven. This conclusion would negate the ethical principles of clinical research. Even if a study drug was shown to be ineffective for a given indication, knowledge was still gained from the process. Successful clinical research ensues from a well-designed clinical research study, submitted through the IRB due process, and includes mechanisms in place to rectify undue delays, inadequate staff training, and unnecessary subject inconvenience. This should also include efficient data capturing, record keeping and maintenance, subject communication, scheduling, payments, adverse event reporting, and accurate equipment inventory. This must all be in place before a subject can ever enter an exam room to volunteer for clinical research.

Therefore, deficiencies in coordinating all noted elements is frequently a source of inefficiency and delay, and there is a noticeable disconnect between knowledge gained from clinical research and active practiced medicine.

In recent years, the average time from a new drug discovery to FDA approval and use in clinical practice totals 14 years (National Institute of Health, 2015). This time frame includes the

necessary steps of preparing approvals, sites, and funding, conducting clinical research, subject enrollment follow up, data analyzation, research conclusions, peer review and publication. Further dissemination of conclusions may be complicated by new evidence learned during this lengthy process, requiring reanalysis of data and necessitating either a change in direction or continuation of the original study. So, while the process does ensure the validity of the data, the timeline to create this actionable data can actually make the initial data obsolete.

When pharmaceuticals are not involved, the process can prove much more advantageous to the rapidly evolving environment of patient care. For example, ICU patient mobility outcomes have only been clinically studies for about 10 years, but protocols for increasing patient mobility are already instituted around the country by the AACN Clinical Scene Investigator (AACN CSI) Academy (Munro, C.L., & Savel, R. H., 2016).

More recently, the rapid acceleration of emergency clinical trials and approvals of the COVID-19 vaccines represent the favorable potential of the future of clinical research. Nevertheless, it should be borne in mind that this was a case of emergency use authorization in the face of an unanticipated pandemic. There is an absolute threshold of how condensed the clinical research process can be, but this was an example of rapid systematic coordination on all clinical research fronts. Funding was provided immediately, approvals were top priority, public information was disseminated, volunteers for enrollment were abundant, and among other reasons, electronic data provided to-the-minute updates for rolling review by overseeing authorities (Renee, Watson, L., 2021). Based on the success of this massive, coordinated effort, as part of their 2021-2025 Strategic plan, the NIH will continue to hold COVID-19 vaccine development as a top priority by their "Accelerating COVID-19 Therapeutic Interventions and Vaccines" public-private partnership. This partnership, among others, represents a promising

direction in the public-health initiatives that clinical research will contribute to (National Institute of Health, 2021).

As clinical research initiatives trickle down from the national level, it is vital that each institution where clinical research takes place maintains their own golden standards for the clinical research process and implements evolving strategies to effectively manage knowledge elucidated from completed research.

This capstone project will survey UT Southwestern Ophthalmology clinical and research faculty to identify common hurdles in clinical research within the clinic, and between PI's and clinical research staff. I seek to evaluate reasons for lack of participation by practicing physicians and ways the clinical research process can be improved within the department. A REDCap survey will be sent out to all practicing faculty with relevant questions to determine their satisfaction with clinical research, awareness, resources, timelines, and outcomes at UT Southwestern. The data from this survey will be evaluated to recognize areas of improvement in the clinical research process and to suggest positive changes to overcome these roadblocks.

CHAPTER II

BACKGROUND AND LITERATURE REVIEW

Subject recruitment and Principal Investigator availability are traditionally the most challenging components for a successful clinical trial. Failure to meet subject recruitment numbers can cause losses within drug development companies of up to 8 million dollars a day due to the discrepancy between projected enrollment and actual enrollment. This discrepancy in delayed enrollment is not accounted for in the original study budget and timeline, therefore requiring the drug development company to continue funding the clinical research study beyond the budgeted allowance, resulting in overspending and loss of revenue (Johnson, O., 2015). These losses can be attributed to a delay of overall study timelines, the cost of maintaining non-expired study materials, delay of the study drug obtaining FDA approval, etc. Lack of participation not only affects loss of revenue for pharmaceutical companies, but can affect study outcomes and viability of study results due to lack of biostatistical power and significance.

Human clinical research studies are vital to the development of new medical drugs and devices, disease treatments, and diagnostics. While the resources and general awareness of clinical research have exponentially increased over the last few decades, the regulations and codes of ethics governing modern clinical research practices require continual review and updating, as shortcomings in past policies led to key failures in ethical clinical research. In the United States, The Tuskegee Syphilis study conducted from 1932 to 1972 in Tuskegee, Alabama withheld medical treatment from Black men suffering from Syphilis to study the effects of disease progression. In this study, sanctioned by the US Public Health Service, it was determined informed consent was unethically withheld from subjects while also denying them available treatment with penicillin (Curran, W., 1973). This ethical failure in part led to the establishment

of Institutional Review Boards (IRBs) who must review clinical research protocols involving human subjects (Reverby, Susan M., 2012).

The Nuremberg Code of 1949 formulated principles to ensure that individuals must provide voluntary informed consent with the right to end participation at any time (The Nuremberg Code, 1949.) This international requirement, among others, developed after the conviction of Nazi war criminals for atrocious and unethical human experimentation. This historical abuse of power could still be a contributing factor to the modern hesitancy to volunteer for clinical research and even trust in medical professionals entirely.

The Belmont Report, published by the FDA in 1979, reaffirmed that clinical research must be ethically conducted with three established principles: respect for persons, beneficence, and justice (The Belmont Report, 1979). These principles remain the cornerstone for the ethical conductance of clinical research by all clinical research professionals. Respect for persons establishes the principle that individuals are autonomous, and those that have reduced decision making capacity are protected. Essentially, individuals can determine for themselves, if given all the facts pertaining to the clinical research study, that they would like to volunteer for participation. Those with reduced decision-making capacity can include adolescents, those with mental or physical illness, mental disability, or prisoners who must be protected from undue influence (The Belmont Report, 1979). In these cases, the protected person's legally authorized representative may make the decision on their behalf, and or special permission and IRB oversight are required to enroll these protected subjects. Beneficence represents the obligation physicians and clinical research professionals must uphold to "do no harm." In the context of clinical research, beneficence must also "maximize possible benefits and minimize possible harms" (The Belmont Report, 1979). The study must not introduce undue risk to the research

participant, and even if a study may not benefit a participant directly, it must potentially provide a benefit to society or future generations. The third principle, Justice, requires that all participating subjects must fairly benefit equally and that any advances from the volunteering population are not available only to certain social or financial classes (The Belmont Report, 1979). Just inclusion of the general population must be represented in research volunteers to avoid disproportionately enrolling disadvantaged or marginalized participants out of convenience. Clinical research must be accessible to all, benefit all, and be conducted with complete honesty and informed consent.

The Declaration of Helsinki of 1996 and 2000 is the most modern set of international guidelines which outline the "Ethical Principles for Medical Research Involving Human Subjects" (World Health Organization, 2001). This report sets the standard for conducting clinical research studies worldwide and reaffirms the duty of physicians in medical research to "protect the life, health, privacy, and dignity of the human subject." While these laws are essential to protecting humans and ensuring ethical research, the sheer legality of conducting clinical research could be overwhelming for PIs. Clinical research professionals play a pivotal role to ensure all regulations are understood and followed. However, there could still be a disconnect with the PI with regards to the comprehension of the full requirements and ethical guidelines to be adhered to in the study.

These past failures in protecting the best interests of all human subjects have potentially contributed to public mistrust in clinical research, which translates to low awareness as well as interest by the public in volunteering for clinical trials. Only about 55% of clinical trials recruit their initial proposed sample size. This, in turn, can contribute to low enrollment numbers and lack of significant evidence to test the research hypothesis (Sully *et. al*., 2013).

Low recruitment numbers due to lack of patient interest can also be compounded by lack of interest among physicians. A significant number of medical doctors are overworked, fatigued, and burned out (Chopra *et. al*., 2004). Burnout can contribute to lack of physician interest in participating in clinical research studies, since research participation is typically in addition to their standard clinical responsibilities. Additionally, Covid-19 has placed even greater stress and burden on physician resources and attention (Amanullah & Shankar, 2020). Sometimes, they simply do not have the time, even if the interest or need is there. It then becomes incumbent upon the clinical research professionals facilitating the study to ensure the PI is following study guidelines, timelines, and inclusion exclusion criteria. Sometimes this can put undue strain on the site staff and consequently removes the PI from essential study procedures, which can produce an out-of-sight, out-of-mind situation.

Essentially, clinical research is a collective team effort, in which all parties must contribute to the best of their abilities and with the upmost standards. Even with this scenario, sometimes patients still aren't recruited, or a study never gets off the ground, but it is up to each individual entity to continue to work toward the common goal.

Significance

At UT Southwestern, I have observed uncertainty among the faculty regarding the organization and scope of the clinical research process, including the timeline of events, contracts, IRB approval, what constitutes as research, data protection and sharing among other things. This misunderstanding can lead to frustration and delays on all sides, which can result in studies never getting off the ground or meeting final endpoints. Additionally, many studies depend on patient referrals from other physicians to meet their enrollment goals, yet this expectation is consistently unmet resulting in a loss of those qualified patients. It is the purpose of this project to identify specific issues experienced by faculty that stymie clinical research, and present possible solutions to identified problems, for improved communication and awareness to conduct high-quality clinical research.

Collecting data to identify possible barriers in the clinical research process will improve the experience for all participating clinical research subjects and can also facilitate higher enrollment in clinical research studies at UT Southwestern Medical Center. This will offer the regional population access to a wider variety of clinical research studies, which may be a direct benefit to the subject and/or will provide a benefit to generations to come.

CHAPTER III

PROBLEM AND HYPOTHESIS

While the current clinical research process frequently does yield successful results, it is my observation that Principal Investigators i.e. Ophthalmologists have minimal awareness and/or interest in participating in clinical research. Some of these impediments which have also been shared by faculty who perform interdepartmental research visits include study timelines, uncertainty of availability, and confusion with study procedures, among other things. These problems can be due to several possible reasons: overwhelming clinical and surgical schedules, lack of awareness of available clinical trials, confusion regarding the clinical research process at UT Southwestern, poor communication from the clinical research team, lack of interest and/or time. Another possibility includes unclear expectations on the lengthy research approval process which can cause confusion and frustration with faculty.

There is a need to improve this process from start to finish. In order to make improvements, I must first determine what can be improved upon. To this end, a secure, anonymous REDCap survey will be sent to all clinical and research Ophthalmology faculty at UT Southwestern Medical Center to collect their opinions regarding the clinical research process.

Hypothesis and Specific Aims

I hypothesize for the purpose of this Capstone project that a survey completed by clinicians will generate actionable solutions to improve the clinical research process at UT Southwestern Medical Center. In surveying the faculty for information that may be unknown to myself and the clinical research team, I can create hypothetical answers that could lead to increased awareness, patient recruitment, and satisfaction for the PI and clinical research department. The primary objective of this study is to identify reasons for lack of participation and or knowledge of clinical research by the clinical and research Ophthalmology faculty. The secondary objective involves determining the importance given by faculty to participation in clinical research, in relation to their opinion of how important clinical research is to society in general. The tertiary objective is to determine possible solutions to the results of the survey data. This project has the potential to generate information on how better to communicate with faculty, how faculty can communicate with their patients regarding clinical research, and the need for the clinical research team to provide realistic information regarding the clinical research process to faculty.

Hypothesis: Evaluation of the current clinical research process and impediments/barriers at UT Southwestern Medical Center will lead to evidence-based solutions to increase PI satisfaction and involvement and overall patient recruitment.

Aim I: Determine the most common barriers to faculty involvement in clinical research and/or frustrations during participation

Aim II: Identify how important participation in clinical research is to faculty members and where the disconnect is to their actual participation.

Aim III: Use survey data to create solutions for improving the clinical research process within the Ophthalmology department at UT Southwestern and improve PI satisfaction and awareness through better communication and access.

CHAPTER IV

RESEARCH DESIGN AND METHODOLOGY

Roadblocks in Clinical Research: An Analysis of Common Barriers to the Clinical Research Process is classified as Exempt Research and is approved by UT Southwestern and North Texas Regional Institutional Review Boards as such. This survey was sent to all practicing clinical and research faculty members of the Ophthalmology department at UT Southwestern. The survey aims to evaluate common issues identified by the clinical research office that dampen the progression of clinical research as well as discern any new problems we are not aware of within the Ophthalmology department at UT Southwestern Medical Center.

The voluntary survey consisted of 20 questions that could be answered on a 1-5 Likert scale, as well as 4 free response boxes for suggestions and/or comments. The electronic REDCap survey was emailed by the Principal Investigator to UT Southwestern Ophthalmology and Optometry clinical and research faculty listserv via Outlook Securemail.

Questions ranged from various topics, including IRB timeline expectations, clinical research contact information, general awareness of available clinical research studies, challenges in patient recruitment, clinician availability/interest etc. For example, “If you wanted to start or join a clinical research study at UT Southwestern, do you know who to contact?” Answer responses consisted of the following: Strongly agree (5), Agree (4), Neither Agree or Disagree (3), Disagree (2), Strongly Disagree (1) and N/A for specific questions.

Baseline information was also collected from the survey taker including number of years in practice, number of years at UT Southwestern, and years of experience conducting research.

The data variables being collected are outlined in IRB approved Form J in the form of a PDF of the exact survey questions being sent out.

Descriptive analysis was utilized to report on data findings and discuss the primary and secondary endpoints of the study. Individual questions are summarized to understand the majority responses depending on their high or low scoring values. Individual questions are also grouped together based on the type of category the question pertains to, and then evaluated with a distribution chart to show the mean and mode of responses. Additionally, if the survey taker provided qualitative feedback in the additional response section the evaluation was extended to include this information. Any outlying data is also summarized to display unique information.

All survey data received will be stored on the REDCap website, on UT Southwestern Secure servers protected by a firewall and only accessed through employee VPN. Only the PI and IRB approved research staff from UT Southwestern will have access to the research information obtained. No PHI was collected, and data was not sent or analyzed in any other location or to any other individual outside UTSW, including any individuals at UNT HSC.

CHAPTER V

RESULTS AND DISCUSSION

In this survey study, a total of 11 REDCap survey submission records were received from the clinical and research Ophthalmology faculty. Their responses overwhelmingly showed they believe clinical research to be important, but starting, conducting, and completing clinical research has its obstacles.

TABLE 1. Respondents baseline demographics

Average years in clinical practice	Average years conducting clinical research	Average Years at UTSW
24.36	15.09	18.11

As shown in table 1, the average length of time in clinical practice from the 11 respondents was shown to be about 24 years. Combined with 15.09 years of experience conducting clinical research and 18.11 average years at UT Southwestern, the faculty respondents of this survey represent an experienced and knowledgeable cohort.

Questions 1-6 were written to encompass the overall clinical research process, including where to start, general timeline, general steps, resources available, and how to conduct clinical research.

FIGURE 1. Question 1

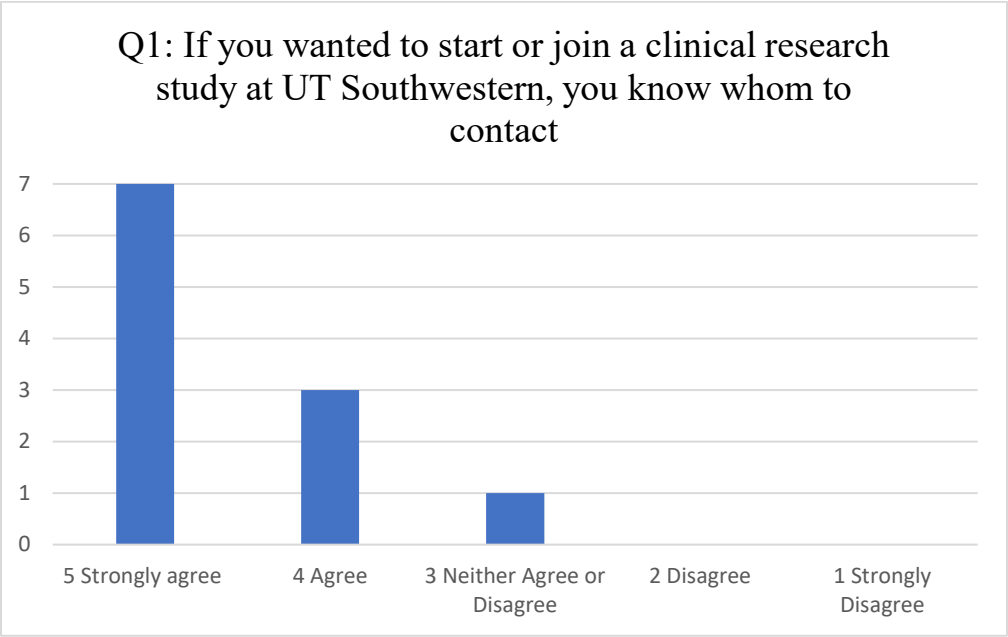


FIGURE 2. Question 2

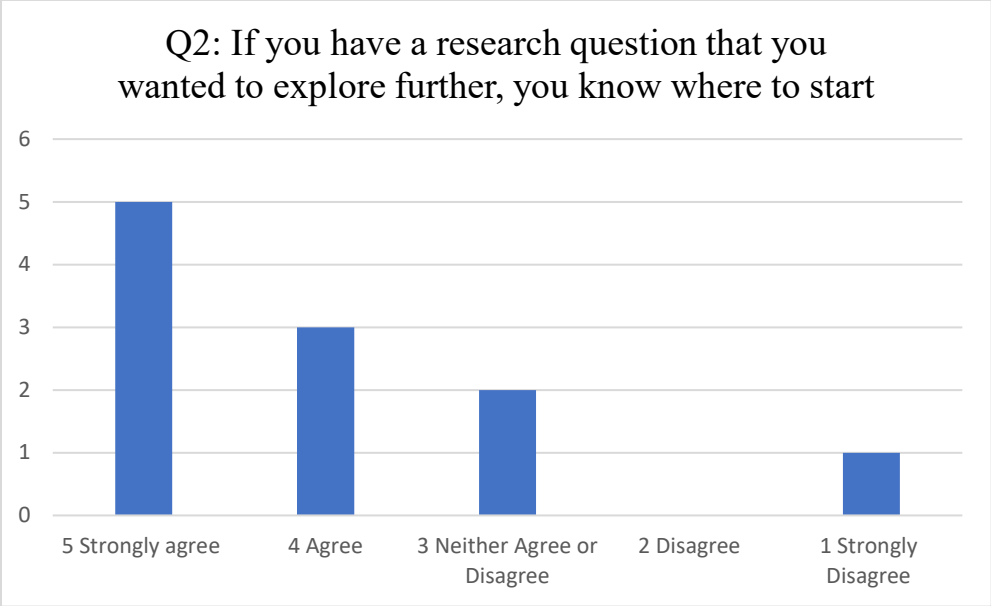


FIGURE 3. Question 3

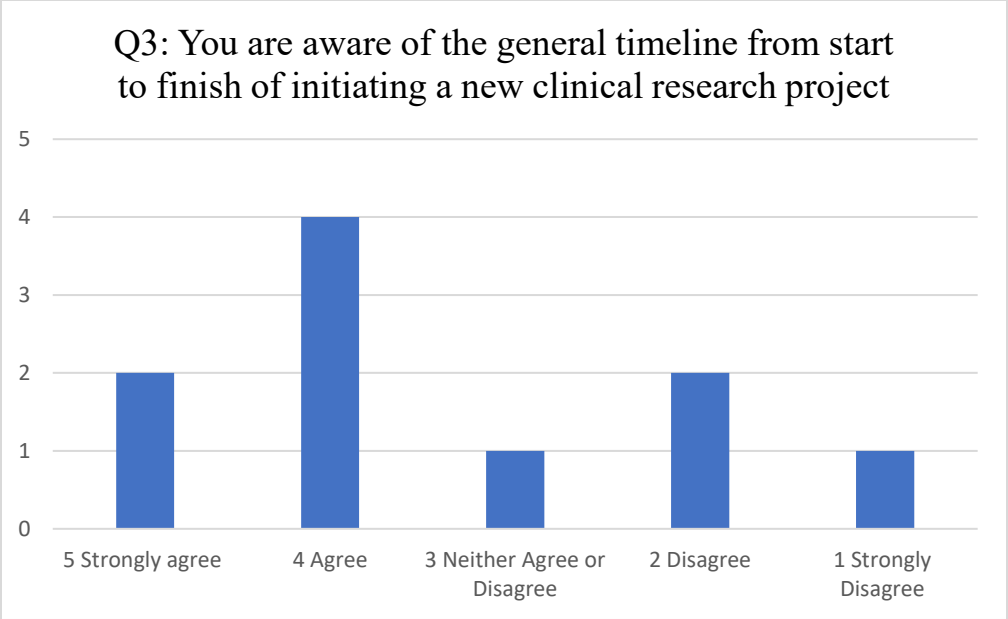


FIGURE 4. Question 4

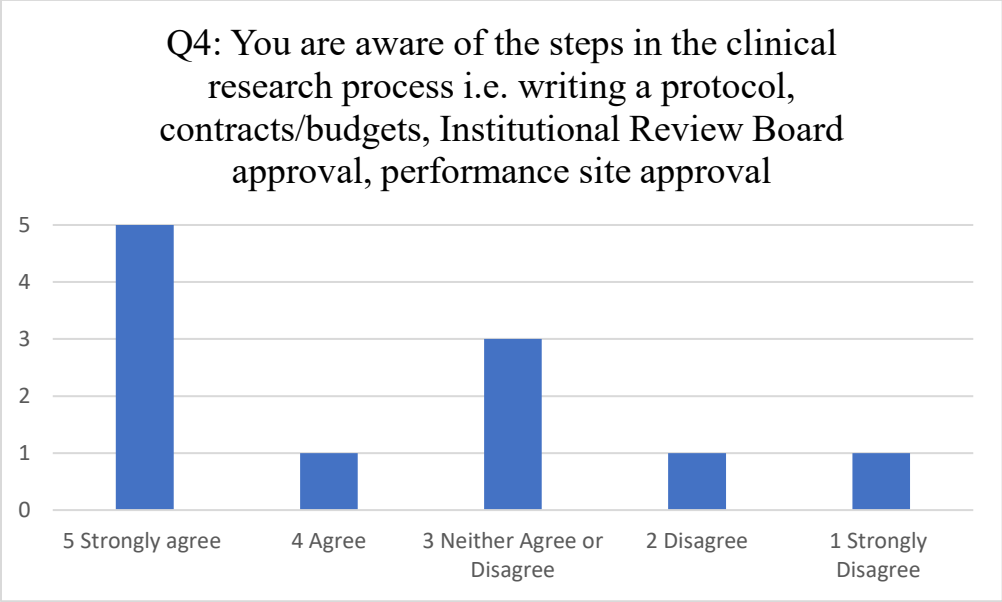


FIGURE 5. Question 5

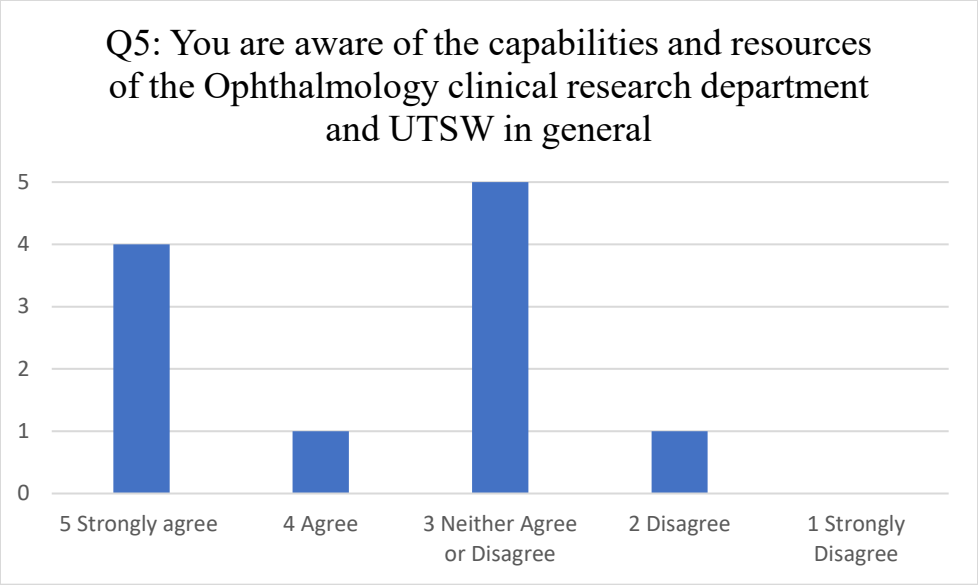
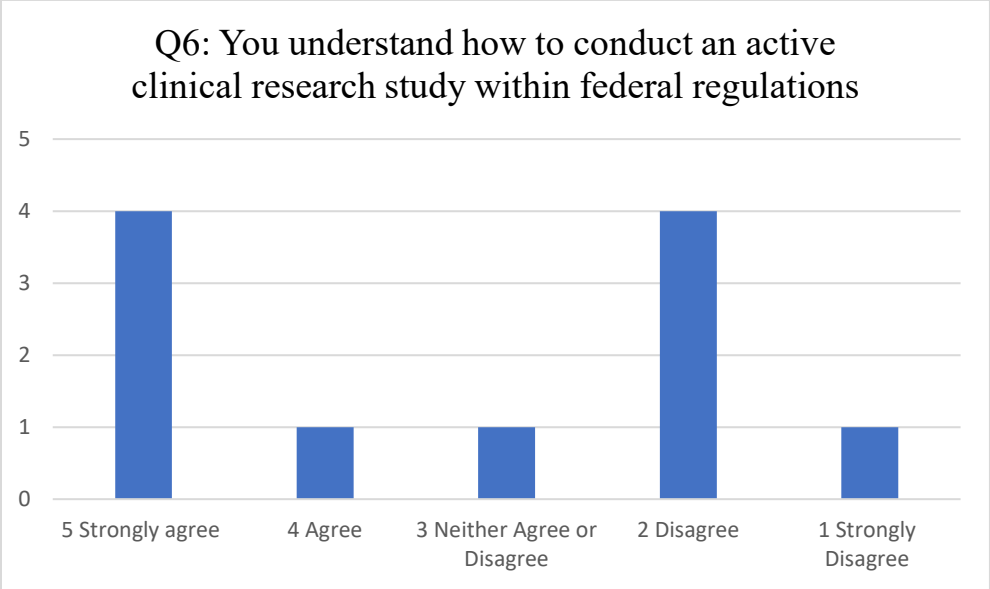


FIGURE 6. Question 6



FIGURES 1-4 display that most researchers do know where to start in the clinical research process, whom to contact, and the general overall timeline with the most common answer being “Strongly Agree” and “Agree”. This information shows that current faculty are able to begin clinical research if they wanted to. Questions 3 and 4 still have multiple answers in the “Neither Agree or Disagree”, “Disagree”, and “Strongly Disagree” categories showing there is still a need for education on the timeline and overall steps for clinical research. The most common responses to FIGURES 5 and 6 are skewed toward “Neither Agree or Disagree”, “Disagree”, and “Strongly Disagree”. These responses show that the faculty are not fully aware of the resources and capabilities of the clinical research department, and they do not know how to conduct an active clinical research study within federal regulations.

To help ameliorate the lack of knowledge displayed from questions 5 and 6, at least annually, a “Clinical Research Process Overview” email could be sent to all faculty members to provide a reference document to current and updated clinical research processes. This

information must be provided to all Ophthalmology faculty, including those who do not participate in clinical research, as well as those who've never participated in a clinical research study. This ensures the information regarding the clinical research process is available should the desire arise for seasoned as well as new clinical research participation. This email will contain any updated changes and "need to know" information on the clinical research process. For example, in the last 6 months UT Southwestern made available biostatistical analysis services for clinical research projects. This type of new information can help inform decisions on how faculty will conduct their clinical research, and spreads awareness regarding the available resources, hence helping them get started when planning a clinical research study.

This email will also contain a timeline and stepwise overview of the entire clinical research process, including who does what at each stage. For example, the Sponsor reaches out to the PI for interest in their study, the clinical research manager completes Site Qualification Survey, the Sponsor sends the Confidential Disclosure Agreement (CDA), the Clinical Research Manager sends the CDA to UTSW Sponsored Programs Administration, the Research Coordinator schedules Pre-Selection Visit and tours with the Sponsor, waits for site selection from Sponsor, begins study start-up activities (documents, budget, contract), and submits study documents to UT Southwestern and/or Central Institutional Review Boards (IRB). Once the site receives IRB approval, a Site Initiation Visit is completed and the site becomes activated for recruitment.

This process can take months, so it is in the best interest of the PIs to be fully aware of the expected timelines and process, instead of staying outside the loop until recruitment begins. Education is vital to ensure every faculty member is confident in their knowledge of how to conduct a research study and their expectations during a study.

FIGURE 7. Question 7

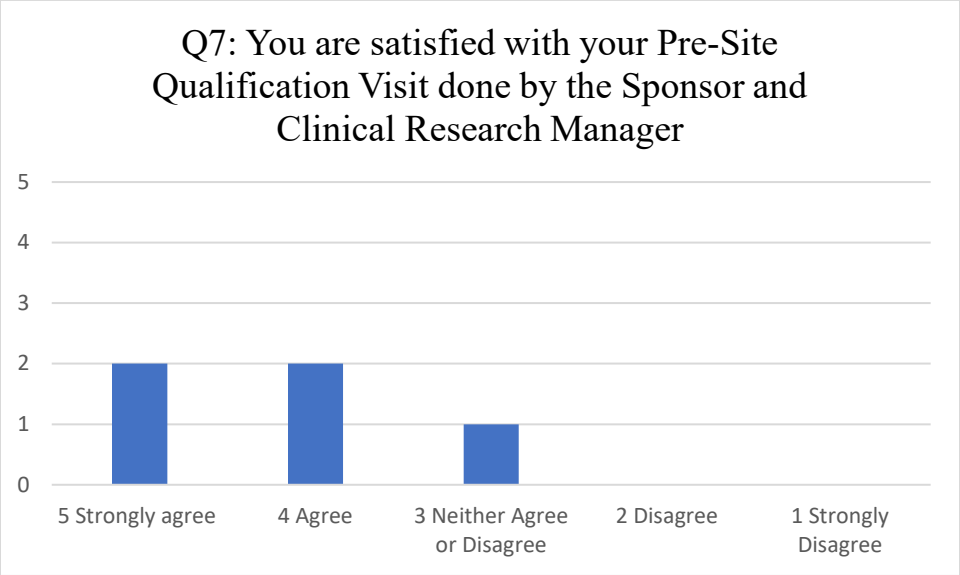


FIGURE 7 represents the specific scenario of those investigators who have conducted a "Pre-Site Qualification Visit" with the Clinical Research Manager. This visit occurs at the beginning of the clinical research process, and is an opportunity for the research study Sponsor to tour and assess the clinical research site (i.e. UTSW Ophthalmology) for adequate resources to carry out the study. It is an opportunity for the Sponsor to question the Principal Investigator and Clinical Research Manger on logistics like freezer space, equipment, and recruitment goals. Question 7 responses were an even distribution of "Strongly Agree", "Agree", and "Neither Agree or Disagree". This balanced response does not necessarily show a need to change this current process.

FIGURE 8. Question 8

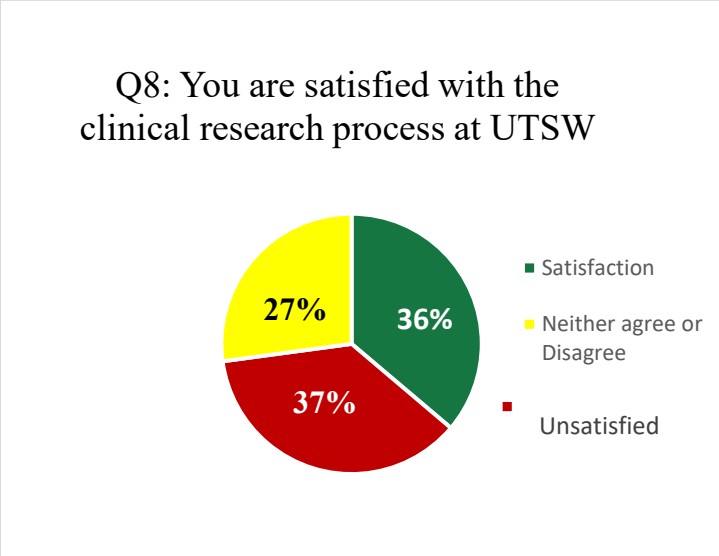


FIGURE 9. Question 8

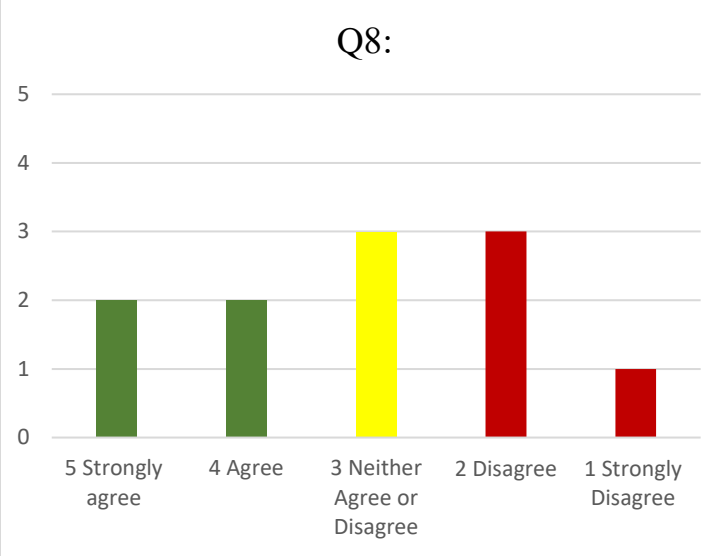


FIGURE 8 and FIGURE 9 representing Question 8 show that the overall satisfaction with the clinical research process is about 36%, "Neither Agree or Disagree" with satisfaction is 27%, and "Disagree" with satisfaction is 37%. This feedback most commonly obtained shows that faculty are either neutral or are not satisfied with the clinical research process. The outliers are important to note, that both ends of the spectrum are represented with "Strongly Agree" and "Agree", and "Strongly Disagree". Even though the most common answers are "Neither Agree or Disagree" and "Disagree", it is meaningful that individual faculty members have extreme opinions on their satisfaction with conducting clinical research at UT Southwestern.

TABLE 2. Question 8 Free Response

Response 1:	Hard to contact clinical research team and the IRB process is extremely lengthy
Response 2:	More clarity about how to get started, the steps in the process and the general timeline would be helpful
Response 3:	Clinical research office is not engaged; faculty members have to push for progress and check every step; poor communication

TABLE 2 displays 3 responses to the free response box related to Question 8, which received 4 responses. One response is omitted for inapplicability and answers are summarized. These additional responses that are indicative of satisfaction with the process reinforce the need for updated information emails, and increased communication and transparency.

Questions 9-13 represent physician interest in starting or participating in clinical research and how their participation relates to patient recruitment and interest.

FIGURE 10. Question 9

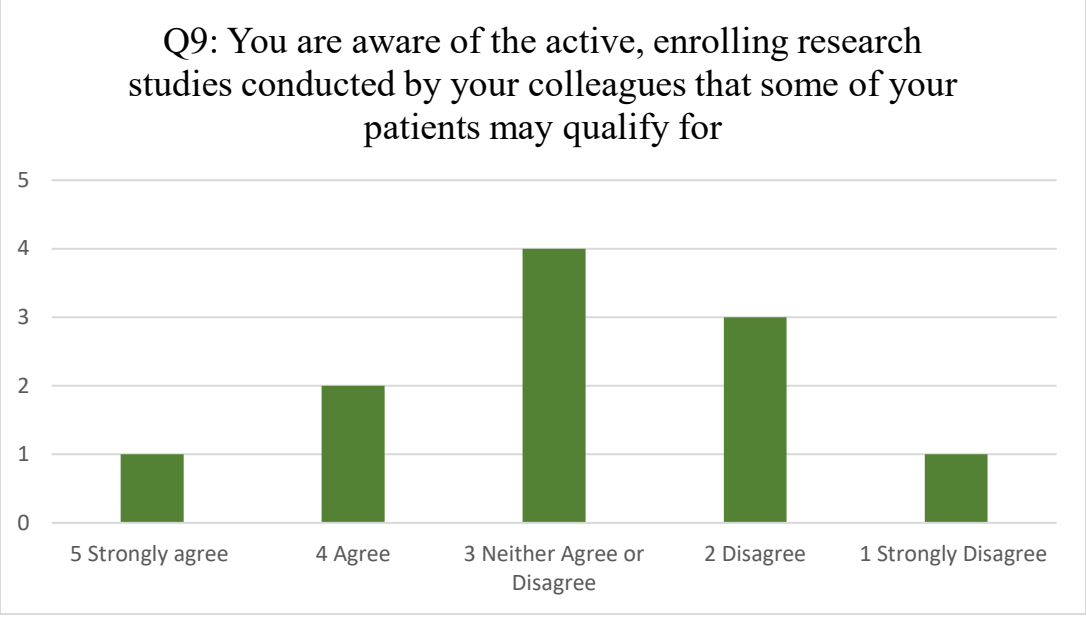


FIGURE 11. Question 10

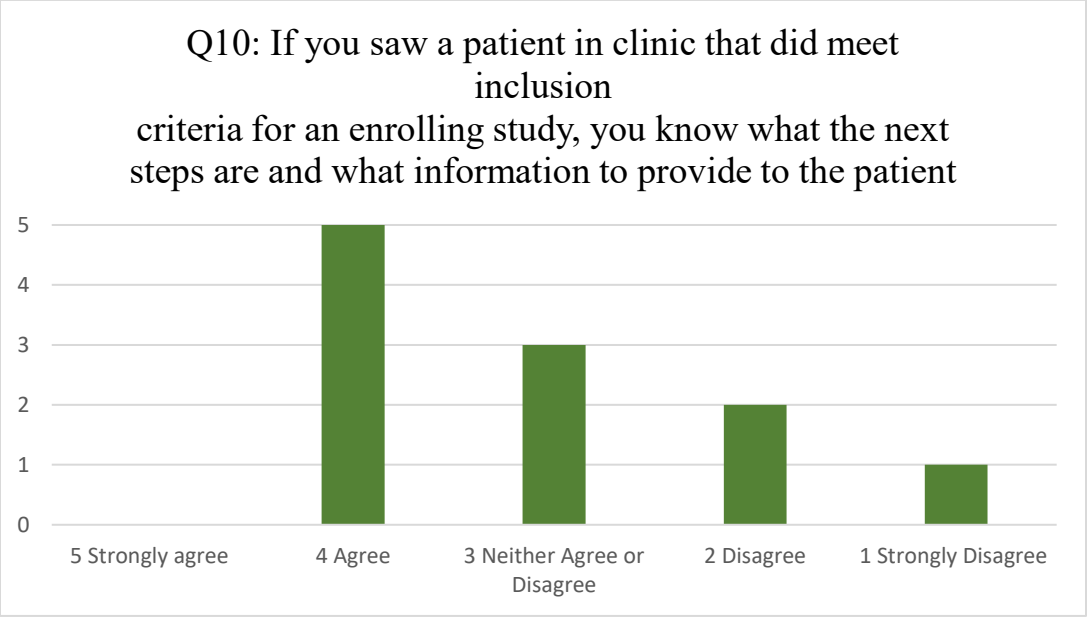


FIGURE 12. Question 11

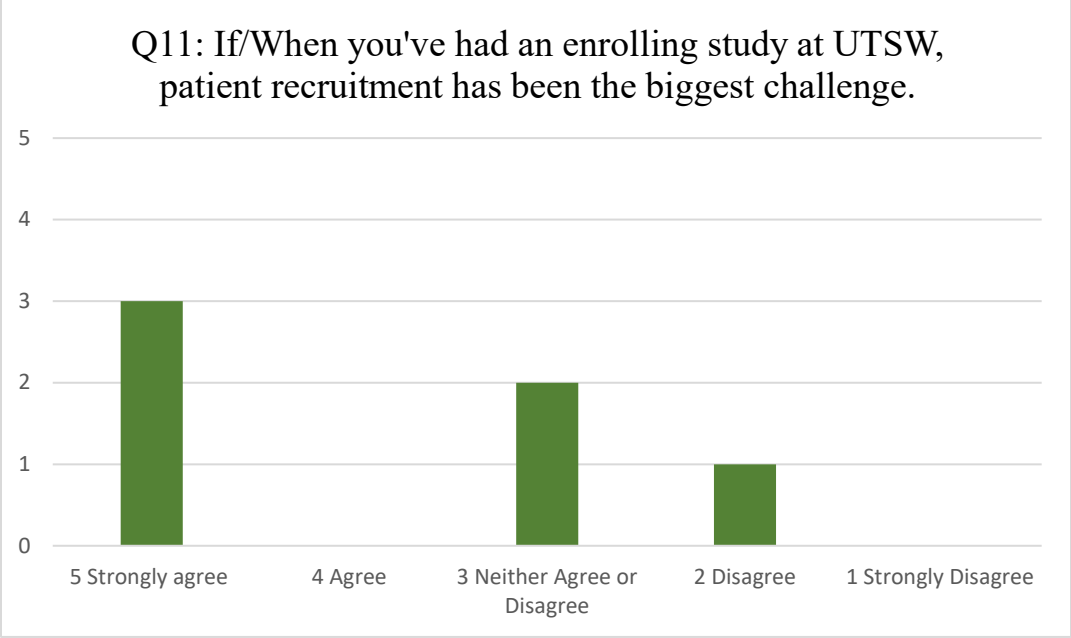


FIGURE 13. Question 12

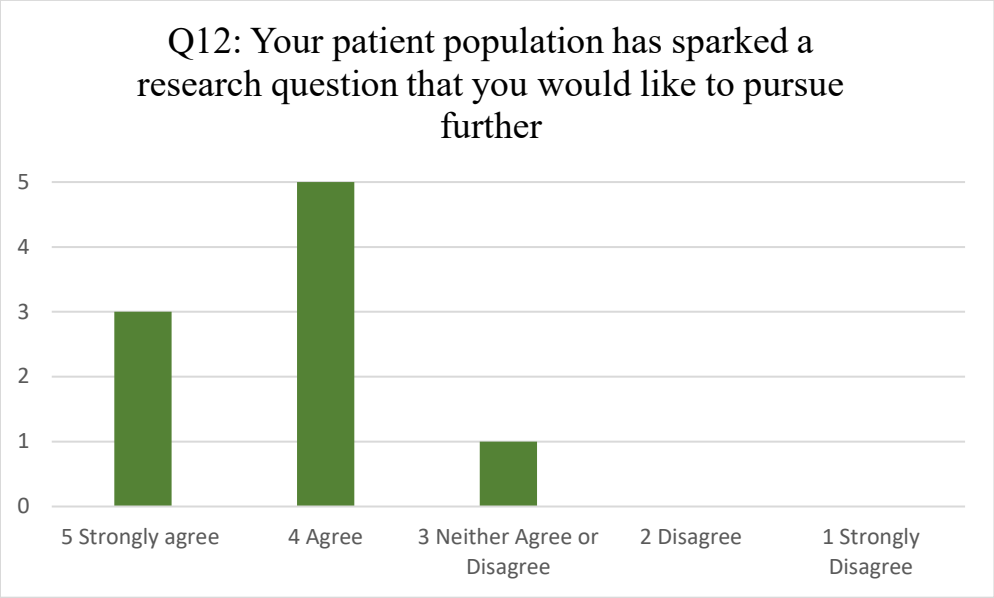
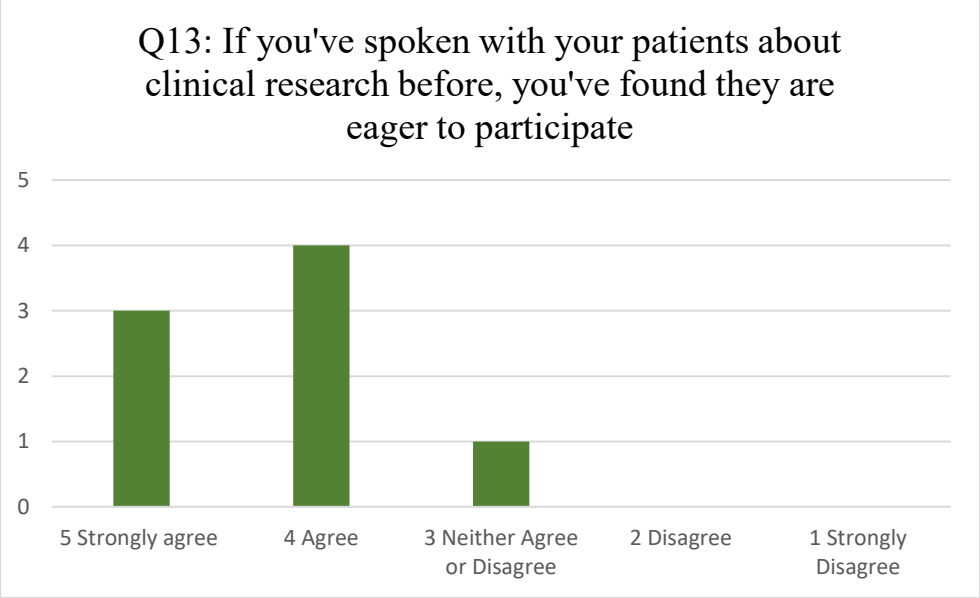


FIGURE 14. Question 13



FIGURES 13 and 14 show that very commonly, the physician's patient population has sparked a research question they theoretically would like to pursue, and their patients are eager to participate (most common "Agree" and "Strongly Agree"), but most often the provider is neutral or unaware of other actively recruiting studies and next steps (FIGURES 10 and 11).

FIGURE 12 displays with the most common answer of "Strongly Agree", that patient recruitment is the biggest challenge with their study. Otherwise "Neither Agree or Disagree" or "Disagree" possibly represent other struggles. These responses to questions 9-13 show that providers may want to pursue a research question themselves, and their patients are even interested, but if the majority of faculty are not aware of other ongoing clinical research studies, it is expected that those studies could not get adequate recruitment numbers due to lack of referrals. It is vital that all faculty are generally aware of all ongoing clinical research studies to assist recruitment in all studies.

To help increase clinical research awareness, I suggest a monthly presentation of actively recruiting studies during their regularly scheduled monthly meeting to keep all faculty aware of current enrolling studies. During this meeting, I would also reiterate the overall clinical research process and clinical research contact information, so they know whom to contact and what to do next. Additionally, once they become aware of current enrolling studies, place the study information in each faculty member's clinic information box, so each provider can then give information regarding the study (even if it's not their study) to their patient who may qualify for the relevant research study. The patient can then contact the research coordinator for additional study information if they are interested. This suggestion of increasing awareness and making recruitment resources available could increase patient referrals and overall recruitment numbers.

Questions 14-16 are specifically targeted towards those Ophthalmologists who have performed interdepartmental visits i.e. Ophthalmology screenings for UT Southwestern oncology, endocrinology, and internal medicine clinical research offices.

FIGURE 15. Question 14

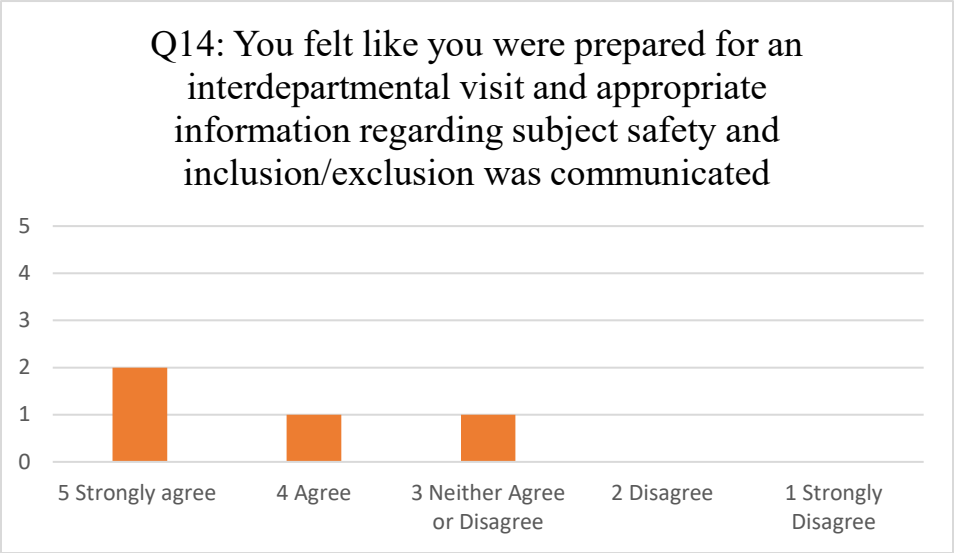
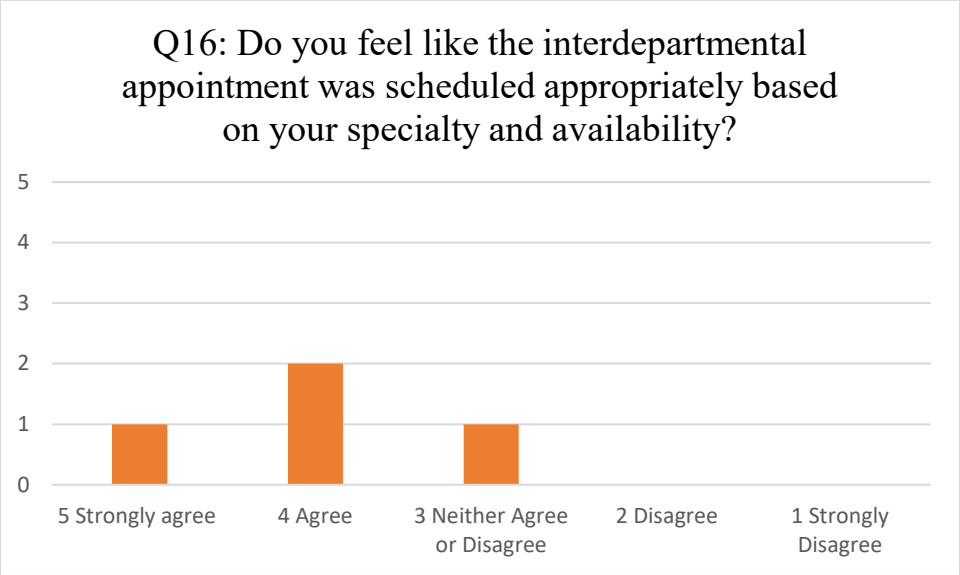


FIGURE 16. Question 15

FIGURE 17. Question 16



These questions are unique to certain providers so the answers are limited, but overall favorable. The providers who perform interdepartmental visits are also usually regularly involved in clinical research, so these questions provide valuable insight to the success of the interdepartmental process. It is within reason to also assume that those providers who are regularly involved in interdepartmental visits are also familiar with the overall clinical research process. Therefore, providing a favorable answer for the processes with interdepartmental visits could translate to the overall clinical research process. This theory supports the idea that additional communication and education for all faculty, especially those not already involved, could help increase overall faculty interest and participation due to increased exposure.

Questions 17- 20 were used to gauge the researcher's interest in clinical research compared to their opinion on the importance of clinical research. Also related to this group is assessing their awareness of the national and international laws involving clinical research. This question helps show how exposed they are to the national/international requirements.

FIGURE 18. Question 17

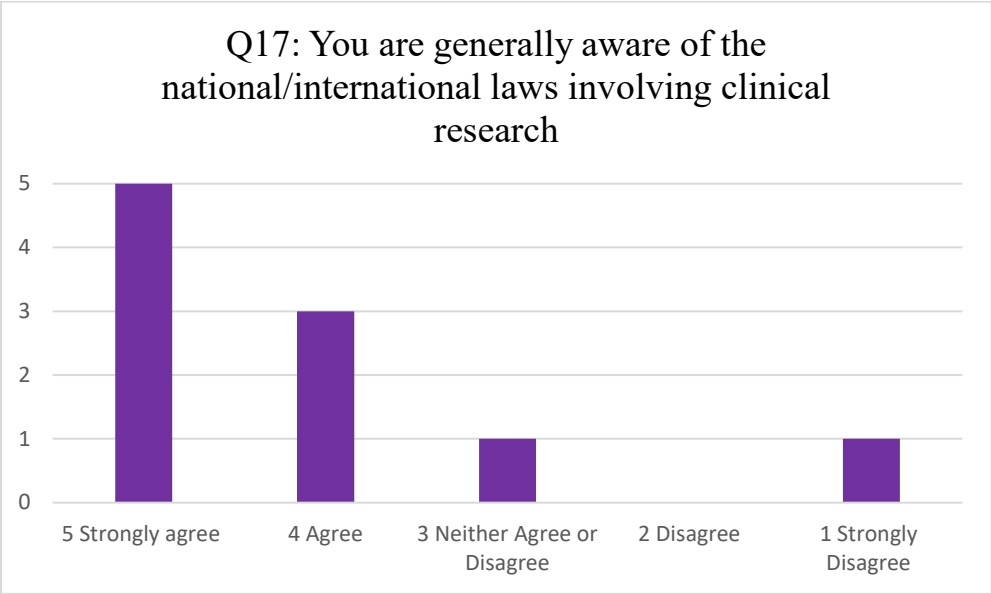


FIGURE 19. Question 18

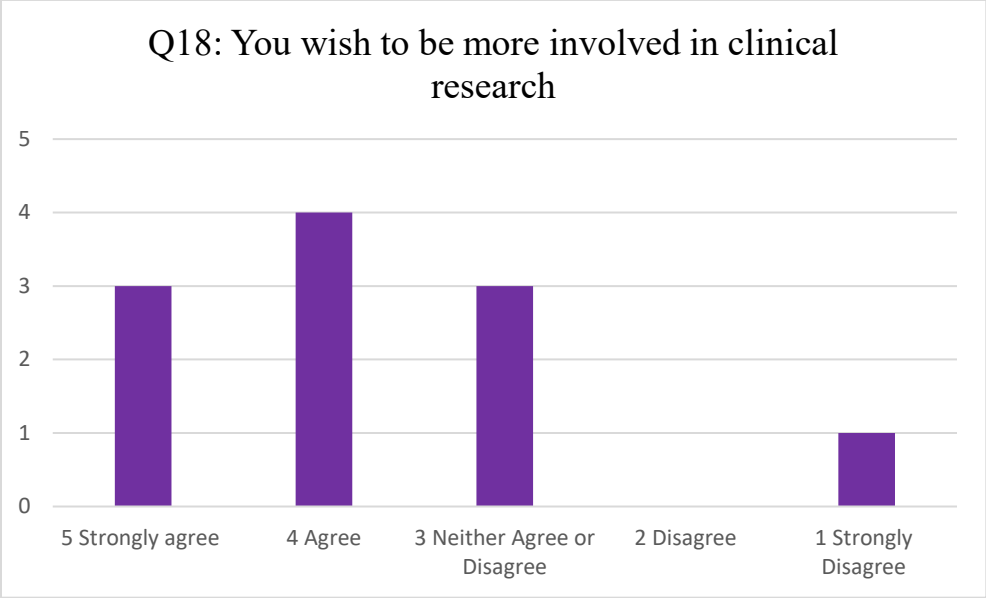


FIGURE 20. Question 19

FIGURE 21. Question 20

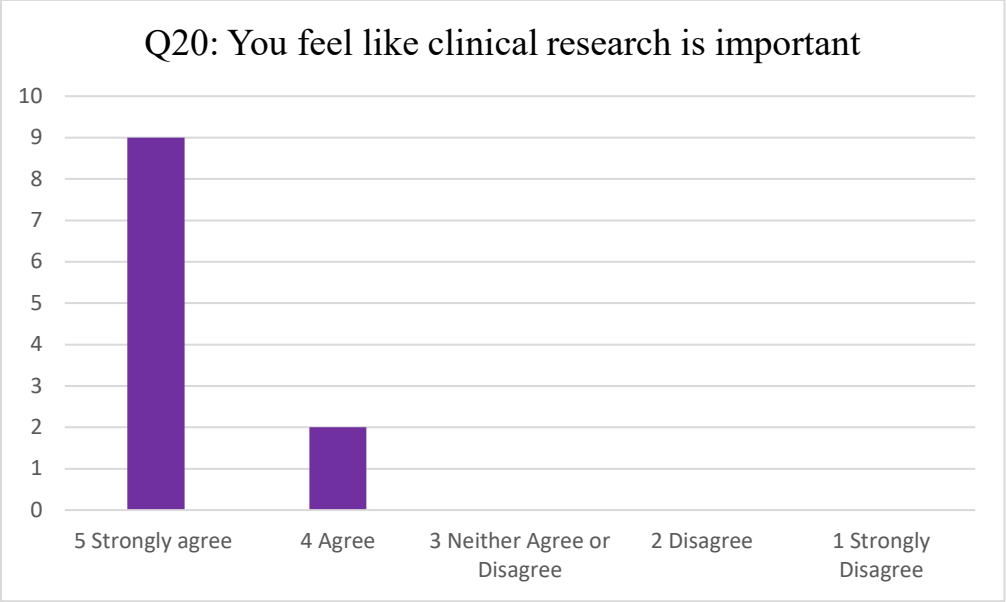


FIGURE 21 shows that all survey respondents answered that they feel like clinical research is important, with the most common response “Strongly Agree”. The majority are also interested and wish to be more involved in clinical research as shown by FIGURE 19, with “Agree” the most common answer, followed by “Strongly Agreed” and “Neither Agree or Disagree”. So while clinical research is important and more faculty wish to be involved, most commonly “Neither Agree or Disagree”, “Strongly Agree”, and “Agree” faculty feel like they don't have enough time. Responses also show that researchers are generally aware of the national and international laws involving clinical research. So, even if clinicians have sufficient interest and knowledge about clinical research, they don’t have the time to pursue it. This verifies that most faculty are favorable toward clinical research as an idea but are unsure or frustrated with the reality of time and energy that participating in clinical research entails.

A potential solution to managing these expectations is adequate investment in education and communication with a monthly newsletter sent to all clinical and research faculty. This

newsletter would contain information on updates, logistical reminders, clinical research information, any process changes, and encouragement to participate in clinical research. Having this information readily accessible and frequently presented may help establish expectations for faculty who have no prior experience in clinical research, and keep information updated to those who have to encourage participation and awareness in clinical research for everyone.

The annual email sent to faculty outlining the clinical research process and University resources will also be helpful to reinforce the point that clinical research is a collaborative process, and the clinical research team will be available to help every step of the way.

A few outliers should be noted, 1 respondent "Strongly Disagreed" with Question 17 that they are generally aware of national and international laws governing clinical research. This shows that clinical research education in the form of an annual or even monthly email would still be valuable to ensure all faculty could conduct a clinical research study if they so choose.

CHAPTER VI

SUMMARY AND CONCLUSIONS

The results from this survey elucidated 3 main barriers to faculty involvement in clinical research, the first of which that most researchers lack knowledge and education on the overall steps of the clinical research process, resources available for clinical research, and how to continue a clinical research project over time.

I propose that an educational email be sent out at least annually to inform all clinical and research faculty about the clinical research process, including the overall process timeline and expected time and effort commitments for Principal Investigators.

The next theme from survey responses focuses on identifying roadblocks in recruitment. Most providers have a research question in mind they would like to pursue based on their patient population, and if a topic of research is brought up to their patients, they are eager to participate, but generally the providers are not aware of current recruiting studies or how to get their patients involved. If a provider isn't aware of other current, actively recruiting studies, it is difficult to expect their potential studies to garner much recruitment due to lack of overall awareness. This creates a vicious cycle of multiple, low recruiting studies that cannot answer the initial research question due to low statistical power.

To create an environment with high-quality, high-enrolling studies, I suggest a monthly in-person meeting between the clinical research department and Ophthalmology faculty. Frequently presenting actively enrolling studies and contact information of those involved will ensure the most up to date study enrollment criteria remains fresh on their minds and is easily referenced within their clinic. Making this information short, in a listed format, current, and

easily available will help providers when they see a patient in clinic that may qualify for an Ophthalmology study.

The final theme to understand is the disconnect between the desire to participate in clinical research and its importance to society, and the reality of actually participating. It is our goal to make clinical research more accessible to faculty and patients to help further each research question being studied. With the majority of faculty reporting neutral, or they agree to the idea that they don't have enough time to participate in clinical research, it is incumbent upon the clinical research team to ensure every study is a collaboration and that communication is open and frequent.

As previously stated, a monthly newsletter should be sent to all clinical and research faculty with logistical updates, process changes, and staff contact information, and encouragement to participate. Having this information readily accessible and frequent may help establish expectations for faculty who have no prior experience in clinical research, and keep information updated to those who have, to encourage participation in clinical research for everyone. This monthly newsletter should also include a summary of the information presented during the in-person monthly meeting, ensuring information is easily referenced for attendees and those who were not present.

Based on the data extrapolated from the survey responses, this study was able to support the hypothesis by creating evidence-based solutions to identified barriers and impediments to the clinical research process at UT Southwestern Ophthalmology. I hope that implementation of these solutions will lead to increased PI satisfaction, participation and communication, increased patient recruitment, and increased clinical research success.

Limitations

Limitations to this study may arise because of the single-site nature of data collection. Since we are only surveying practicing Ophthalmologists and Optometrists at UT Southwestern Medical Center, this project can only represent the unique limitations and possible bias of practices here. However, potential solutions may be valid in many similar academic institutions due to the structure of clinical research practices compared to other research organizations.

Additional limitations arise due to the number of clinicians and researchers who responded to the survey. While 11 responses allowed me to get a general idea of the opinions within the department, it is about a 40% response rate of the Ophthalmology faculty population. Therefore, the collected data may be skewed by outlying responses more than a high yield survey may elicit.

Future Directions

This survey study captured a snapshot of opinions regarding the clinical research process within the Ophthalmology department of UT Southwestern Medical Center. While the opinions are relevant to this point in time, the solutions could potentially positively impact research operations in the future. It is the hope that this survey identified specific areas for improvement and the proposed solutions to these areas are implemented effectively to increase PI satisfaction, patient awareness, and PI involvement.

This study could be repeated annually to help the clinical research department continue to gauge areas for improvement in an ever-evolving clinical practice and research landscape.

CHAPTER VII

BIBLIOGRAPHY

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CHAPTER VIII

CAPSTONE PROJECT EXPERIENCE

Project Site

My capstone project was conducted in the Ophthalmology department at University of Texas Southwestern Medical Center where I am employed as a Clinical Research Coordinator. The clinical and research faculty specialize in all aspects of Ophthalmology, including glaucoma, retina, cornea, dry eye, and oncology.

Journal Summary

I conducted this capstone project as a new IRB approved study to collect information regarding clinical research management of the Ophthalmology department. As this was a new study, I created all of the relevant documents including the research proposal, protocol, REDCap survey, IRB approved forms, and this practicum report and accompanying PowerPoint presentation.

APPENDIX A

IRB APPROVALS

UT Southwestern Medical Center — eIRB System

DATE:	Friday, August 12, 2022
TO:	Walter Petroll, Anne Carter,
CC:	
FROM:	HRPP Designated Reviewer
PROTOCOL NUMBER:	STU-2022-0722
TITLE:	Roadblocks in Clinical Research: An Analysis of Common Barriers to the Clinical Research Process
FUNDING:	Internal - Departmental

Agency	Grant Number
There are no items to display	

REVIEW:	New Exempt Study Review – ***Activated***
REVIEW TYPE:	Exempt
Documents:	FormB-Personnel.docx, FormJ-DataCollection-RedCapSurvey.pdf, FormE.I-InfoSheet.doc, Flow diagram.docx, FormA-ResearchProtocol.docx, FormC-Population.doc

Dear Principal Investigator,

Your new study was reviewed and ACCEPTED by the IRB on Friday, August 12, 2022.

Your submission was reviewed and determined to meet Exempt criteria under 45 CFR 46.104(d). The Designated Reviewer made regulatory determinations for this study which may be found in eIRB in the Determinations tab.

As of Friday, August 12, 2022, the study met all the required approvals and may begin at the performance sites below with a status of "Approved." **For those performance sites listed as "Pending," you may not begin research activities until approval has been issued.**

Approval Component	Component Name	Status
Performance Site	UTSW	Approved
Performance Site	Children's	Not Applicable
Performance Site	Parkland	Not Applicable
Performance Site	THR	Not Applicable
Coverage Analysis	Coverage Analysis	Not Required
Contract	Clinical Trial Agreement	CTA Not Required

If the study is sponsored, sponsor activation may be required before study activities may begin.

This exempt determination does not expire.

If changes are made to this research which may affect this determination, submit those changes to HRPP for review.

University of Texas Southwestern Medical Center
Institutional Review Board

5323 Harry Hines Boulevard
Dallas, Texas 75390-8843
phone: 214-648-3060
fax: 214-648-2171

3500 Camp Bowie Blvd
Fort Worth, TX 76107
NorthTexRegIRB@unthsc.edu
(817) 735-0409

DATE:	August 19, 2022
TO:	Stephen Mathew
FROM:	North Texas Regional Institutional Review Board
PROJECT TITLE:	[1951826-1] Roadblocks in Clinical Research: An Analysis of Common Barriers to the Clinical Research Process
REFERENCE #:	2022-093
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF EXEMPT STATUS
DECISION DATE:	August 19, 2022
REVIEW CATEGORY:	Exemption category # 2(i)

Thank you for your submission of New Project materials for this research project. The North Texas Regional Institutional Review Board has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations:

- [45 CFR 46.104 (d)] per the following category: (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

You are responsible for complying with any institutional policies and requirements regarding projects involving human subjects and for ensuring that the research is conducted as specified in the approved protocol. In addition, you are required to use ONLY the reviewed and approved documents, materials and/or procedures designated for this protocol that have been acknowledged and stamped by the North Texas Regional Institutional Review Board.

You must report to the North Texas Regional Institutional Review Board 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.

The following documents are approved with this submission:

- Capstone Research Proposal _AC

APPENDIX B

CAPSTONE PROJECT JOURNAL

06/06/2022- 06/17/2022

I met with my site manager, Yesenia Leach, to discuss and brainstorm specific ideas for the Capstone Research Proposal. I started working on a general layout of ideas for the first draft of my research proposal and came up with ideas for each section.

Next, I started drafting the proposal. This included researching primary sources for references and performing general research for the proposal topics. While writing the research proposal, I spent extensive time determining what information should be included and the general layout of how the research project will be conducted.

06/20/2022- 07/01/2022

Conducted a meeting with my Graduate Advisory Committee to discuss my capstone project and research proposal. Dr. Krishnamoorthy and Dr. Stankowska provided feedback on how I will develop questions for the faculty survey and how best to format the numerical responses. After this meeting, I made the suggested edits and finalized my first draft. This included researching common Likert Scale examples to ensure my survey was formatted correctly.

The first draft of the Capstone Research Proposal was submitted to my advisory committee.

07/04/2022- 07/15/2022

I corresponded with the advisory committee on questions and input they provided regarding my research proposal. I researched the timeline of submission on the North Texas Regional IRB website to ensure my project is feasible for the Capstone timeline.

I also spent time determining which forms are needed for submission to UTSW's IRB in order to determine this Quality Improvement project as "non-research".

07/18/2022- 07/29/2022

The advisory committee provided feedback for my research proposal, and I also met with UT Southwestern biostatistical services for assistance on data analysis. Based on these comments I modified my research proposal accordingly. After these final edits I submitted my Capstone Research Proposal to the advisory committee for review.

The determination was made that this project requires IRB exempt review and does not qualify as a Quality Improvement project. I spent the week corresponding with UTSW faculty members to find a PI, and also created all documents for submission to the UTSW IRB.

08/01/2022- 08/12/2022

I used this week to understand and familiarize myself with the REDCap system and how to build a survey with their software. I met with members of the IRB to ensure the REDCap survey was formatted correctly and showed no coercion to the survey taker. In these meetings, I also discussed the documents for submission to the IRB and ensured, along with the IRB

reviewer, that all required elements were in place. After these meetings, I submitted this study to the IRB.

After submission, the IRB had minor questions on wording of the survey introduction. I modified the wording and submitted the survey back to them.

08/15/2022-08/26/2022

This week I received Exempt approval from the UT Southwestern IRB, so all approved documents were then sent to Dr. Mathew for submission to North Texas Regional IRB. A few days following, Dr. Mathew created the study in NRT IRB and submitted the UTSW approved documents. North Texas Regional IRB then approved and activated this study.

After study approval and activation from UTSW and NTR IRBs, the PI for this project emailed a like to the survey and accompanying information to clinical and research faculty at UT Southwestern. As responses started to come in, I began analyzing the answers for common trends.

I began formatting the Capstone Thesis Report document per UNT HSC guidelines. This week, I also began researching and drafting the summary and introduction sections of the Capstone thesis report.

08/29/2022- 09/09/2022

I continued conducting research for relevant articles for the literature review section and used this time to edit and add to that section.

Data began to come in from the survey submitted to faculty, so I began to save and analyze the responses returned. I input this data into Excel and began creating graphs with the preliminary data. I worked on formatting the graphs and ensuring all subsequently entered data could be added seamlessly to the existing graphs.

I also began writing the results and discussion sections with ideas from the initial survey responses.

09/12/2022- 09/23/2022

This week I finalized the data from all submitted surveys and input all information to the tables and figures in Excel. I worked on the formatting of adding all figures and graphs to the practicum word document and adding their corresponding location in the table of contents.

I finished the results, summary, and conclusion sections in the thesis practicum document.

09/26/2022- 10/07/2022

The first draft of my thesis was sent to the advisory committee for review. Dr. Krishnamoorthy provided suggestions which I accepted, and I revised the document as needed.

I submitted the “Intent to Defend” to GSBS and scheduled my Practicum defense Zoom meeting.

10/10/2022-10/21/2022

I wrote the abstract section for my thesis document and finalized all sections for the final draft. I submitted the final draft to my Advisory Committee.

I also created the PowerPoint presentation for the Zoom defense meeting, including formatting the graphs and main points of my presentation.