University of Lynchburg

Institutional Review Board (IRB) for Human Subjects Research

Minimal Risk Research Protocol Proposal Form

This protocol proposal form is for ***minimal risk research*** (inherently minimal risk or risk that has been sufficiently minimized). **Once the document is complete, please share the file with the IRB director, Dr. Alisha Walker Marciano. If a student is completing the protocol proposal, the faculty/staff mentor must share it with the IRB director. No proposals will be accepted from students.** Undergraduate students are not permitted to serve as Principal Investigator (PI) for a research study and must have a faculty/staff mentor as the study PI; graduate students may serve as Co-Principal Investigator (Co-PI) along with a faculty/staff member. Members of the research team are not permitted to recruit or begin data collection until approval has been provided by the Director of the IRB. Incomplete or improperly completed/submitted protocol proposals will experience a delay in the review process.

Proposal Checklist (PRIOR TO SUBMITTING, PLEASE SELECT EACH BOX TO INDICATE COMPLETION; click on box twice to highlight, then right click to add a check):

- ✓ Proposal filled out completely.
- ✓ Data collection instrument(s) or comparable item(s). Include a copy (not an external link) of all materials at the end of the proposal.
- ✓ Invitation to participate in study (e.g. email, oral script, etc.), if applicable. Please include this at the end of the proposal.
- ✓ At least one of the following (include full consent form (not an external link) at the end of the proposal):
  - ✓ Informed Consent Form (for participants over the age of 18 years old)
  - ☐ Informed Assent Form (for participants under the age of 18 years old) and Informed Parental Consent Form
  - ☐ Description of verbal consent
  - ☐ Explanation of waiver of consent
- ✓ Additional support materials (add as many appendices as necessary at the end of the proposal - no external links to materials, please).
- ☐ Administration Permission Form if research is being conducted at another organization (educational setting, business, etc.) or a signed letter from an organization leader from each data collection site stating data collection is permissible.

  Not applicable for this study. Individuals being interviewed are acknowledging that they are expressing their own views and not those of any associated colleagues, employer, or organization.

Section One: Basic information about the research study and research team

What is the name of the person completing this protocol proposal? XXXXXXXX

Title of the Research Study: Medical Missions for Advancement of Primary Care in Sub-Saharan Africa: Establishing Model Ambulatory Care Centers

Per the Lynchburg IRB Ethical Research Practices Policy, all members of the research team must complete the online NIH ethics training. Please do not submit this protocol without confirmation of this requirement. *(Please note: NIH ethics certificates for ALL research team members listed in this protocol proposal MUST be included at the end of this document).* For questions about this requirement or to request a potential substitution or waiver, please contact the IRB at irb-hs@lynchburg.edu.

Principal Investigator (PI) or Co-Principal Investigators (Co-PIs): XXXXXX (Co-PI), Dr. XXXXXX (Co-PI)

PI Department or Office (list for Co-PIs, if applicable): XXXXXX

PI Email Address (list for Co-PIs, if applicable): XXXXX

Additional research team members and their roles:

Name of researcher and Role of researcher

The only researchers involved are the two Co-PIs, XXXXXX (Co-PI) and XXXXX (Co-PI)

Is this an undergraduate student research project?

No

Is this a graduate student research project?

Yes

Research category/categories selected (by number) for project:

Category 2

Category 12

Explanation of how project fits with research category selected:

My research fits Category 2 because I will be interviewing medical providers and other individuals who have had experience establishing ambulatory care centers in Sub-Saharan Africa. I will not be interviewing patients. I will know the identity of the individuals that I am interviewing, and I will also be the one analyzing the data. However, I will not publish their names or organizational affiliations in my research paper or make their identity publicly known to others, without express permission from them. The information that I will be collecting in my interviews will be about challenges that they faced in setting up ambulatory care centers and the strategies they used to do this successfully. Even if these individuals could be identified by others, this information would not place them at any risk of criminal/civil liability or damage their reputation, financial standing, or employability. I will make adequate provisions to protect their privacy and maintain the confidentiality of the data in my publication.

My research fits Category 12 because I will be collecting voice recordings of the interviews in order to analyze the interviewee's responses and collect data. I will obtain their express permission to record the conversation before I begin recording, and will then have them state that they have given this permission as part of the recording. These recordings may be

transcribed in order to analyze their responses, but I will make adequate provisions to protect their privacy and maintain the confidentiality of the data.

I believe that the benefits of this study to my interviewees and to the population of Sub-Saharan Africa will outweigh the minimal risks of this study.

Section Two: Background information on the proposed research study

Please respond to all items below. Researchers are encouraged to provide as much detail as they would provide in describing to a faculty member or other academic professional who is not in their discipline/profession. The reviewer may not necessarily be familiar with technical jargon, acronyms, or devices.

1. **Purpose**. Provide a description of the purpose of your study, including the rationale/background for the study. What are the goals and hypotheses of the research? This statement should describe the variables being studied and explain why this topic is important to study.

The overall purpose of this study is to identify common challenges encountered by expatriate medical providers in planting primary care-centered, ambulatory health facilities in Sub-Saharan Africa (SSA) and to identify successful strategies that have been used in this process. "Expatriate" refers to those living outside their native country, such as an American medical provider who moves to Africa to start a medical facility. "Planting" refers to starting a new health facility where previously a comparable one did not exist, in contrast to taking over management of a pre-existing facility. "Ambulatory" refers to a facility that does not have overnight beds for patients, in contrast to inpatient hospital services.

This study will seek to summarize the practical steps and challenges involved in opening a health facility of this type, adapting and expanding it over time in response to local community needs, and ultimately transitioning it to become a self-sufficient, community-supported practice that is less reliant on foreign aid and personnel.

The reason for this study is that currently many SSA nations suffer from high disease morbidity and mortality which could be significantly reduced through increased access to primary health care. There is inadequate access to quality health care in this region of the world. Service delivery is inequitable, often only available to rich or urban populations. Preventative, comprehensive primary care has not received adequate attention or funding in the past, with funding and foreign aid focusing primarily on high profile diseases, such as HIV and Tuberculosis.

Expatriate volunteers from not-for-profit non-governmental organizations (NGOs) are a small but important component of the medical workforce in underserved areas of SSA. Well-trained expatriates can play a key role in modeling and teaching clinical skills to national students and providers and can help to improve health service delivery in areas where there is not an adequate supply of skilled national providers. One large hinderance to accessing medical care for individuals in SSA is the distance to the nearest medical facility. In many SSA countries, there remains a lack of community-centered, primary care-oriented, ambulatory medical centers that are within reasonable distance to the populations in need of these services.

Primary care is vital in providing cost-effective interventions to improve long-term population health, especially with the growing burden of non-communicable diseases in SSA.

However, its practice is not well established in many parts of this region, and there exists a need for model primary care facilities to set an example and help train national medical providers. Expatriates can contribute to health service delivery in this region by planting and staffing new outpatient medical facilities in underserved areas that can partner with, train, and eventually employ nationals to decrease workforce shortage and improve quality of care.

Although there are missions facilities of this type in existence, to the researcher's knowledge, there are currently no studies in the literature outlining the strategies that expatriate providers have used to plant ambulatory primary care centers in Sub-Saharan Africa. It would be beneficial to the medical missions community as well as the underserved populations of Sub-Saharan Africa to generate practical information to equip expatriate providers in planting and operating these facilities. Therefore, this study will function as an initial investigation into the subject to help inform medical missionaries and guide future research initiatives.

Medical providers who have experience in this type of work will be interviewed. The variables being studied are the methods and resources used by these providers to launch, expand, and sustain their international practices. For example, this would include resource acquisition and utilization for the project, such as medical team members, funding, and essential work space resources and supplies. Also, it will include important strategies used to respond to challenges (e.g. adapting to local culture, integrating into the existing national health system). Additionally, it will include the providers' reflection on the plan's strengths and weaknesses and key lessons learned.

As this study seeks to answer the question of what challenges an expatriate medical missionary would face in planting a new clinic in Sub-Saharan Africa, it will not investigate clinics that were started or staffed primarily by national medical providers (those residing in their country of origin), as it is expected the challenges encountered by these two groups would have significant differences.

2. **Participants**. Briefly describe the study population (e.g., college students, adults, etc.) and specify the <u>maximum</u> number of participants in your study. Include inclusion and/or exclusion criteria (e.g., age restrictions, health restrictions, etc). Describe any circumstances under which a participant's participation may be ended by the researcher.

The study population is adult health professionals who have been involved with the planning, opening and/or operation of an ambulatory care center that is still operational in 2018 in a Sub-Saharan African country that is different than their native country. The maximum number of participants in this study will be 30. The participants will need to be 18 years or older, English-speaking, and be/have been a licensed health professional (e.g., MD, DO, PA, NP, nurse, midwife). Exclusion criteria will include providers who were only involved in national plants (those within their native country), non-English speaking individuals, and individuals under 18 years of age. A participant's participation may be terminated by the researcher if it is determined that the participant is knowingly providing false information, fails to respond to the research questions within the time frame allowed for collection of data, or if it is determined that the risks to the participant outweigh the benefits of participation.

3. **Recruitment**. Recruitment is the responsibility of the PI and research team. Explain how you will recruit participants (who will be recruited, how will they be recruited, how they sign up, etc.). If procedures include recruitment via email, specify who will send the recruitment email and to whom it will be sent. <u>Include a copy of the recruitment email at the end of this proposal.</u>

As there is no comprehensive database to identify participants with relevant experience, the researcher will use a focused internet search and personal-networking approach to identify possible research participants. Internet search engine queries (e.g. Google) will be used to find relevant websites with information about organizations or individuals that are involved with planting ambulatory medical centers in Sub-Saharan Africa. The researcher will review the websites of these organizations to determine applicability, as well as to identify other related organizations that may be applicable. The relevant medical missions organizations that are identified online will be contacted via email with information about the study and a request for contact information for any individuals they know who could be potential candidates for the research. This initial email will be sent by the researcher, XXXXXXX, to the contact address specified on the organization's website. If the organization responds positively with contact information for individuals they know who may be interested in participating, XXXXX will then send a recruitment email to these specified individuals using contact email addresses provided by the organization. The recruitment email will be similar to the email initially sent to the organization in that it will give information about the study and ask if the candidate would be interested in participating. If the candidate replies by saying that they would be interested in participating, they will then be sent the informed consent form to review and sign, which will give them more comprehensive information about the nature and purpose of the study. XXXXX will also give them opportunity to have any questions about the study answered via email prior to consenting.

This online approach to identifying research participants will be supplemented by word-of-mouth referrals from individuals or organizations that XXXXX has contact with. For example, organizations that XXXXX has identified through his online searches may suggest other individuals or organizations that he can contact. Additionally, medical professionals or others that XXXXX comes in contact with through professional or social engagements may refer him to organizations or individuals they know who would be relevant for the study. These referrals will further help to expand the number of candidates identified via the internet searches. The contact process will still be similar to that described above using a recruitment email sent by XXXXX to the potential participant. For example, XXXXX may meet an American physician who has worked internationally, and the physician may suggest several organizations or individuals that may be of help in this study. XXXXX will further research those organizations online and contact the organizations or individuals via email with the methods described above.

The reasoning behind this design is that there is no complete database that can be used to identify all of the relevant research participants. Therefore, in order to decrease sample bias, XXXXX will attempt to identify as many organizations as possible using the methods above and will include individuals from multiple organizations involved in multiple countries within Sub-Saharan Africa. Additionally, it will be explicitly stated in the informed consent form that participants will be expressing their own views and not those of any associated organization or colleagues. Even though organizational websites are used as a means to identify individual participants, this study examines the views of individuals in and of themselves and not the views of any larger organization.

4. **Procedure**. Describe the research methodology and study design (step-by-step details of what will happen to participants in this study), including expected duration (time in a single session, number of sessions, etc.) of participation. Be specific about your procedures for data collection

(including whether online or in-person) and describe the data collection materials. Include a copy of all materials (not an external link) at the end of this proposal.

First, participants must agree via email to participate in the study and sign the informed consent form, which will also give permission for the interviews to be recorded. They will then participate in a one-on-one phone or online video interview with the researcher. The interviews will not be conducted in person.

For each interviewee, participation in the study is expected to take a total of approximately two to seven hours over the course of a maximum of five to eight months. There will be a minimum of one interview session lasting approximately one to two hours. If needed, there may be additional interview sessions of similar length, up to a total of approximately two to three interview sessions. At maximum, this would total six hours of interview time, but it is expected that most participants will only have one interview lasting no more than two hours. In addition to interview time, participants may also need to spend up to approximately one hour responding to written electronic communication (e.g. email) in order to coordinate interview times and respond to additional questions. All reasonable measures will be taken to minimize the time required of participants in this study and to be flexible to their availability.

With the interviewee's written and verbal consent, audio from the interview will be recorded for later transcription and analysis. The interview will be based upon a general question outline which will be made available for the interviewee to review prior to the interview. This outline is attached at the end of the document. As this will not be an exhaustive interview due to time constrictions and not all questions will be equally relevant to each interviewee depending on their experience, freedom will be given to the researcher to adapt the interview to allow interviewees to focus on select questions most pertinent to their experience or to respond to other relevant questions not specifically listed in the general interview outline. The interview will use mainly open-ended questions and will be individualized based on the interviewee's responses. The interviewer will begin by asking an open-ended question and will listen as the interviewee responds. The interviewer will then respond with clarifying questions or move on to the next major open-ended question. The interview will conclude when the researcher determines that the interviewee has adequately answered the relevant questions or the time availability of the interviewee necessitates ending the interview. If the initial interview needs to end prematurely due to time constraints, then the researcher will arrange a follow up interview to finish the process.

5. **Compensation/Remuneration.** Describe whether participants will receive any compensation or remuneration (e.g., $$, gift certificates) or token gifts (e.g. candy, stickers), and how they will obtain the compensation. [Note: If participants are paid, the Business Office will require personal information for participants for tax purposes. Details regarding compensation and release of personal information must be included in the consent form.]

Participants will not receive any compensation, remuneration, or token gifts as part of this study.

6. **Vulnerable populations**. Describe whether your study will involve vulnerable populations such as individuals under the age of 18, prisoners, or cognitively, economically, or educationally disadvantaged participants; and describe safeguards planned to protect the welfare of this population.

This study will not involve vulnerable populations as described above.

7. **Minors**. If participants will be minors (under the age of 18) describe the process of obtaining parental/guardian consent and child assent. Include a copy of parental consent form and assent form (not an external link) at the end of the proposal.

This study will not involve any minors under the age of 18.

8. **Consent**. Explain the process (how, when, where) of how consent will be obtained and specify what will be included in the consent form (or verbal consent, when applicable). Explain how you will ensure participants will not feel coerced to participate. If requesting a waiver of documentation of consent, provide a reason for why obtaining signed consent is not appropriate. Include a copy of the consent form (not an external link) at the end of the proposal.

A written informed consent form will be sent via email from the researcher to the participant to review and sign prior to the interview. The participant will be given information about whom to contact with questions about the study. The written consent form will include the title and purpose of the study, the participation and time requirements, potential risks and benefits, and information about compensation, confidentiality, and whom to contact with questions. Additionally, it will inform the patient that their participation is voluntary, and they can withdraw at any time without a penalty. The candidate will be free to decline to participate at any time, and these measures will ensure that there will be no coercion to participate. The written informed consent will also inform the participant that audio from the interviews will be recorded and transcribed, and that if they wish to retract any statements or speak off the record, they may do so. Also, the agreement section of the informed consent will affirm that the opinions expressed by the participant are their own and do not reflect the view of any organization that they are employed by or associated with. Prior to recording audio from the interview, the researcher will then verbally ask the interviewee if they give permission for the audio recording, and once they give permission will begin the recording. The researcher will then have the candidate state on tape that they are giving their permission for the recording.

9. **Data Safety**. Describe the data storage and protection plan (federal guidelines state that data be kept for at least three years). Explain specifically where data will be stored (hard copies and/or electronic) and how it will be protected. Describe how the researchers will maintain the confidentiality of participants' responses.

The data will be stored electronically in an encrypted, password protected folder on the primary researcher's (XXXXX) password-protected personal computer, with a backup password-protected copy on an external hard drive. The data will be stored for at least 3 years. Both PIs will have access to the data during that 3 year period. Each participant's interview transcript will be stored in a separate file in this encrypted folder. Participants' confidentiality will be protected by labeling the participants' response transcript with a code of letters and numbers (e.g. A01)instead of their name. A password-protected spreadsheet with the codes responding to individual participants' names will be stored in the encrypted folder, with a backup password-protected copy on an external hard drive. Only the Co-PIs will have access to this spreadsheet key and know the names of the participants and which responses correspond to each participant. The manuscript that is created from the research data will not include the participants' names or the names of their associated/employing organizations, nor will it contain information about the participants' specific age (other than that they are 18 years or older), ethnicity, or other easily identifiable data. For geographic information, it may state what country the participant is from, but not the state or city. Additionally, for information regarding the Sub-Saharan medical center associated with the participant, the country and general region will be given, along with some

descriptive factors about the local context. However, the name of the clinic and the name of the town that the clinic is in will not be given.

10. **Risks and Benefits**. Describe any foreseeable risks and/or discomforts to the participants and explain how these risks will be minimized (e.g. referral to professional, removal from study, etc.). Describe potential direct and indirect benefits of the study (how participants, society, science, etc. will potentially benefit from the findings). These risks and benefits should also be described in the consent form.

The potential risks associated with this study include identification of the participants with their responses, identification of the participants with their associated or employing organization(s), and identification of the communities in which the participants' associated health facilities are located. Although the likelihood is low, there is the possibility that these identifications could cause harm if others took offense to the participants' responses. Additionally, the participant may be uncomfortable with questions asked in the interview, but the participant will not be required to respond to questions if they are not comfortable. In order to minimize these risks, measures will be taken to maintain the confidentiality of the participants, their associated organization(s), and associated health facilities, as described above under data safety. Additionally, if it is determined that the identification of the participant, organization, or health facility with the participant's responses could cause a risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation, the participant will be removed from the study.

The potential benefits associated with this study are increased support for medical services in Sub-Saharan Africa, increased practical knowledge for medical providers seeking to plant ambulatory care facilities internationally, an increase in the number and efficacy of these projects, establishment of model primary care centers, increased access to quality health care for underserved communities in these regions, and the initiation of additional research to expand knowledge in this area. Participants and underserved Sub-Saharan African communities will be benefited by this study as it raises awareness and support for humanitarian medical work in these areas. Medical professionals will be better equipped with practical knowledge to help plant ambulatory care centers internationally, which will increase access to quality care for patients in underserved communities where these health centers are planted. By learning more about the challenges that providers involved in creating these facilities face, better training, resources, and strategies can be utilized to facilitate more effective projects of this type in the future. Additionally, individuals or organizations seeking to plant international medical facilities may learn valuable lessons from this study that will help them to be effective and avoid financial loss and project failure. It is the assessment of the researcher that the potential benefits of this study far outweigh any risks.

11. **Ethics Certificates.** Please insert an NIH ethics certificate for ALL research team members here. If any research team member does not have an NIH ethics certificate below, the protocol proposal will be returned to the PI and will need to be resubmitted once all certificates have been added.

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that
successfully completed the NIH Web-based training course
"Protecting Human Research Participants".

Date of completion: 01/28/2018.

Certification Number:

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that successfully completed the NIH Web-based training course "Protecting Human Research Participants."

Date of Completion: 10/01/2017

Certification Number:

NIH National Institutes of Health
Office of Extramural Research

Please insert all additional documentation below (include text/images, not external links to documents because reviewers have had difficulty accessing information via external links which delays the review process). If the documentation requested does not apply to your study, please type "not applicable" in the space provided.

Insert Recruitment Email/Oral Script (include text, not links to documents):

Following is the recruitment email that will be sent out by the primary researcher, XXXXXX, to relevant organizations to identify interview candidates. This email will be personalized for each organization, but the basic structure will remain the same. Once individuals are identified by the

organizations, a personalized but similar email will be sent to the individuals to inquire if they would be interested in participating in the study.

Hello,

I am a XXXXXX from the U.S. interested in international medical work in the future, with the hopes of being involved in planting international medical clinics.

I am conducting a doctoral research project wherein I am interviewing individuals from organizations that have helped establish ambulatory care/community health centers in Sub-Saharan Africa to identify successful strategies that these individuals utilized. My end goal is to publish the data I collect in order to better equip medical providers to be involved in international work and to increase access to health care for the underserved populations in Sub-Saharan Africa.

I have learned about your organization's international work through my research, and would like to ask if anyone from your organization or partner organizations that has had experience planting medical clinics in Sub-Saharan Africa would be interested in talking with me about their experience?

I greatly appreciate your time in considering this and any help you can provide. Please reach out to me with any questions at XXXXXXX

Respectfully,

XXXXXXXX

Insert Data Collection Materials (include text, not links to documents):

Planning and Launch

- What goals did you have or not have for the clinic?

- How did you prepare, and what did your long-term vision for execution look like or not look like?
- Did you plan for the role of the local community in the support and operation of your clinic to change or not change over time (why or how)?
- Did you plan or not plan to collaborate with nationals in teaching, training, or other functions of the clinic (why or how)?
- How did you decide where to and where not to plant your clinic?
- What did you know or not know about the target community and the national health system, and how did you find this out?
- How did you decide what services to offer and not to offer, what were they, and how did you plan to offer them?
- How did you decide who would and would not be on your team, and how did you recruit and prepare them?
- How did you determine the basic resources and funds you needed or did not need to start the clinic, what were they, and how did you attain them?
- What were the greatest difficulties in starting your clinic?
    - How did you respond to these difficulties?
    - What did not work and what worked well (why)?

Ongoing Operation and Reflection

- What changed and what did not change about the goals, services, resources, and support of your clinic from its beginning until now (why)?
- When living and working within the surrounding culture and community, what went well and what did not go well (why)?

- What kind of impact or value did your clinic have in its community (why or for whom)?
- What were the greatest difficulties in the ongoing operation of your clinic?
    - How did you respond to these difficulties?
    - What did not work and what worked well (why)?
- How do you view this project as having succeeded or failed (why)?
- If someone interested in a similar project approached you for advice, what would you tell them to do and not to do (why)?

Insert Consent Document(s) (include text, not links to documents):

Informed Consent Agreement

Please read this consent agreement (or listen carefully if it is being read to you) before you decide to participate in the research study. Please keep a copy for your records.

Project Title: Medical Missions for Advancement of Primary Care in Sub-Saharan Africa: Establishing Model Ambulatory Care Centers

Purpose: The purpose of this research study is to collect information about practical strategies that have been used to create new ambulatory care medical centers in Sub-Saharan Africa, understand the common challenges in this process, and create general recommendations for future efforts in this area.

Participation: As a participant in this study, you will be asked to respond to questions via written electronic communication (e.g. email) and/or live voice or video interview(s) regarding your knowledge and experience with starting ambulatory care centers. You will need internet or phone access in order to communicate with an interviewer residing in the United States but will not otherwise be required to travel from your current location in order to participate. Audio from the interviews will be recorded and transcribed to allow for accurate analysis of your responses. You will acknowledge that the views expressed are your own and do not represent the views of your colleagues or any of your associated or employing organizations.

Time Required: Your participation is expected to take a total of approximately two to seven hours over the course of a maximum of five to eight months. There will be a minimum of one interview session lasting approximately one to two hours. If needed, there may be additional interview sessions of similar length, up to a total of approximately two to three interview sessions. At maximum, this would total six hours of interview time, but it is expected that most participants will only have one interview lasting no more than two hours. In addition to interview time, you may also need to spend approximately one hour responding to written electronic

communication (e.g. email) in order to coordinate interview times and respond to additional questions. These estimated times are generous, and as a valued participant, all reasonable measures will be taken to minimize the time required of you in this study and to be flexible to your availability.

Voluntary Participation: Please understand that participation is completely voluntary. You have the right to refuse to participate and/or answer any question(s) for any reason, without penalty. You also have the right to withdraw from the research study at any time without penalty. If you want to withdraw from the study please tell the researcher or a member of the research team who is present during your participation.

Potential Risks: The potential risks associated with this study include identification of you with your responses, identification of your associated or employing organization(s), and identification of the community in which your associated health facility is located. However, if it is determined that there is a risk of criminal or civil liability or damage to your financial standing, employability, or reputation, you will be removed from the study in order to minimize your risks. Additionally if you are uncomfortable with any of the interview questions, you will not be required to respond.

Potential Benefits: The potential benefits associated with this study are increased support for medical mission work in Sub-Saharan Africa, increased practical knowledge for medical providers seeking to plant ambulatory care facilities internationally, an increase in the number and success of these projects, increased access to quality health care for underserved communities in these regions, and the initiation of additional research to expand knowledge in this area.

Compensation: You will not receive compensation for participation in this study.

Confidentiality: Your individual privacy will be maintained throughout this study. In order to preserve the confidentiality of your responses, your name, easily identifiable personal data, associated organization(s), medical facility name(s), and audio recordings will only be available to the researcher and will not be released to the public without your express permission. The data obtained in this study will be stored digitally in a secure manner, and you will be notified if there is any breach of security that could endanger your confidentiality.

Whom to Contact with Questions: If you have any questions or would like additional information about this research, please contact XXXXXX at XXXXXX. You can also contact my faculty research sponsor, XXXXXX, at XXXXX, who is the Principal Investigator (PI) for this project and is supervising my work on the study.

The University of Lynchburg Institutional Review Board (IRB) for Human Subjects Research has approved this project. This IRB currently does not stamp approval on the informed consent/assent documents; however, an approval number is assigned to approved studies – the approval number for this study is _____. You may contact the IRB Director, Dr. Alisha Walker Marciano, through the Office of the Provost at the University of Lynchburg at 434.544.8266 or irb-hs@lynchburg.edu with any questions or concerns related to this research study.

Agreement: I understand the above information and have had all of my questions about participation in this research study answered. I affirm that the opinions expressed in my responses as a participant in this study are my own and do not necessarily represent the views of my colleagues or the organization(s) of which I am employed or associated. I also give permission for the researcher to record and transcribe audio from my interview session(s) in order to facilitate with data analysis. If I wish to retract any of my recorded statements or speak off-the-record, I must notify XXXXXX at XXXXXX in a timely manner. By signing below I voluntarily agree to participate in the research study described above and verify that I am 18 years of age or older.

Signature of Participant _____
Date _____

Printed Name of Participant _____

Signature of Researcher _____
Date _____

Printed Name of Researcher _____