



## **University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203  
UB Federalwide Assurance ID#: FWA00008824

## **Complete Research Protocol (HRP-503)**

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## **Template Instructions**

### **Sections that do not apply:**

- In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.
  - If an N/A checkbox is present, select the appropriate justification from the list.
  - If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.
- In addition:
  - For research where the only study procedures are records/chart review: Sections 19, 20, 22, 23, 24, 25, 31, and 32 do not apply.
  - For exempt research: Sections 31 and 32 do not apply.

### **Studies with multiple participant groups:**

- If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:

Response:

Intervention Group:

Control Group:

### **Formatting:**

- Do not remove template instructions or section headings when they do not apply to your study.  
If you are pasting information from other documents using the “Merge Formatting” Paste option will maintain the formatting of the response boxes.

### **Amendments:**

- When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.
- Update the version date or number **on Page 3**.

**PROTOCOL TITLE:**

*Include the full protocol title.*

Response: Impact of Meditation on Bothersome Tinnitus

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

Response:

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Communicative Disorders and Sciences

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**VERSION:**

*Include the version date or number.*

Response: 3

**GRANT APPLICABILITY:**

*Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.*

*NOTE: This question does not apply to studies funded by a sponsor contract.*

*Include a copy of the grant proposal with your submission.*

Response: This study is receiving no funding.

## RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

Location:

Address: University at Buffalo – South Campus, Cary Hall 112A

Department: Communicative Disorders and Sciences

Commented [RJ1]: A response is required.

## 1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research.

Response: The purpose of this mixed methods correlational study is to investigate the effects of meditation on the level of bother in tinnitus patients in the United States. The researchers seek to understand the changes in bother as compared to the amount of time spent meditating. Data is obtained through the Insight Timer mediation application. Outcome measures will include several validated and reliable measures.

1.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response: The reduction level of bother of tinnitus will correlate to the amount of time spent meditating.

## 2.0 Scientific Endpoints

2.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should **not** be a date.

Response: Outcomes will be measured utilizing the Tinnitus Handicap Questionnaire, Tinnitus Functional Index, Hospital Anxiety and Depression Scale, and the University at Buffalo Tinnitus Intake Questionnaire to investigate the reduction in level of bother created by the subject's tinnitus before, during, and after the study period of 8 weeks.

Commented [2]: Are these all the measures, more, less?  
Consider The Mindful Attention Awareness Scale (MAAS) and/or The Five Facet Mindfulness Questionnaire (FFMQ)

Commented [RJ3]: 12 weeks or 8?

Commented [BF4R3]: 8

### 3.0 Background

3.1 *Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.*

Response: Mindfulness is a practice of “careful attention to mental and physical processes.” (“Glossary of Buddhist Terms,” 2018) Mindfulness is a component of various types of spiritual practices including meditation, specifically, from Buddhist tradition. While there are many types of meditative activities, Western medicine has begun to focus on practices most closely related to Vipassana Meditation, also known as, Insight Meditation. Mindfulness can be considered a component of meditation practices, but can also be practiced and incorporated in to an individual’s daily activity.

While meditation has long been a practice in several Eastern religions and spiritual practices, it most notably came to Europe and North America in the early 1960s. By 1976, the Insight Meditation Society, one of the first retreat centers in the United States, was founded by Joseph Goldstein, Sharon Salzburg, and Jack Kornfield (“Celebrating 40 Years (1976-2016),” 2018). From this, developed the medical research around mindfulness of Jon Kabat-Zinn, Founder of the UMass Medical School Mindfulness Based Stress Reduction (MBSR) Program (“History of MBSR,” 2017).

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Mindfulness practice has gained popularity as a first line medical intervention for three main reasons. Mindfulness practice is non-invasive, non-pharmacologic, and has no significant side effects (Cebolla, Demarzo, Martins, Soler, & Garcia-Campayo, 2017). Since it is non-invasive, mindfulness on its own is rarely harmful, however, if used in the place of proven interventions can be dangerous. Those utilizing mindfulness practices and meditation must still be under the care of appropriate medical professionals. As a non-pharmacologic intervention, it can be cost effective and not financially prohibitive or burdensome for patients. While the quality of instruction and subsequent practice should be further investigated, the practice itself has the potential to be available at little cost. Much like exercise, meditation and mindfulness practice can be subject to failure if a patient is not compliant to the regimen. Since there is still much to know about the impacts of the types and qualities of meditation on an individual level, its potential benefits can greatly outweigh any risks.

For the purposes of this study meditation and meditative activities will not be limited only to mindfulness, which can be one aspect of meditation. Meditation can be categorized into three areas. Focused attention (FA) or concentration meditation is a practice in which the practitioner focuses their attention on a singular idea or object (Rinpoche, 1980) as in breath awareness, metta or loving-kindness meditation, or a repeated word or phrase as in transcendental meditation (Rinpoche, 1980). This has typically become a starting point for most novice practitioners. Open-monitoring (OM) includes mindfulness practice, in which the practitioner seeks to become aware of physical and emotional states,

responses, and activities. The third category of meditation is one that combines both Focused Attention and Open-monitoring Meditation. This includes Vipassana practice, or Insight meditation, from which Kabat-Zinn has developed the MBSR model. The first two practices rarely are exclusive of each other, but rather, a practitioner's session may include FA and OM.

Previous study of meditation has demonstrated activations and changes in specific regions of the brain. Findings from Manna et al., indicate

that expert meditators control cognitive engagement in conscious processing of sensory-related, thought and emotion contents, by massive self-regulation of fronto-parietal and insular areas in the left hemisphere, in a meditation state-dependent fashion. We also found that anterior cingulate and dorsolateral prefrontal cortices play antagonist roles in the executive control of the attention setting in meditation tasks. ... Finally, our study suggests that a functional reorganization of brain activity patterns for focused attention and cognitive monitoring takes place with mental practice, and that meditation-related neuroplasticity is crucially associated to a functional reorganization of activity patterns in prefrontal cortex and in the insula. (2010)

Others have confirmed through the use of fMRI that meditative methods of MBSR, Mindfulness Cognitive Behavioral Therapy (MCBT), and dispositional mindfulness – the present moment awareness in daily life – change functional and structural components of the prefrontal cortex, cingulate cortex, insula, hippocampus, and amygdala after an eight-week program. These findings indicate emotional and behavioral changes being related to those functional and structural changes (Gotink, Meijboom, Vernooy, Smits, & Hunink, 2016). These changes were found to be similar to those noted in experienced meditators.

Others found changes in functional connectivity in the medial prefrontal cortex, right thalamus/parahippocampal gyrus, and bilateral anterior insula/putamen during meditation. These findings were associated with top-down cognitive, emotion, and attention control in the practice of mental silence in Sahaja Yoga meditation (Hernandez, Barros-Loscertales, Xiao, Gonzalez-Mora, & Rubia, 2018).

A meta-analysis by Merkes of fifteen studies on the effects of MBSR has demonstrated improved functional outcomes for chronic conditions including “fibromyalgia, chronic pain, rheumatoid arthritis, type 2 diabetes, chronic fatigue syndrome, multiple chemical sensitivity, and cardiovascular diagnoses.” This analysis also reported no negative outcomes between baseline and follow-up assessments (Merkes, 2010).

While it can be difficult to differentiate and locate the source of a patient's tinnitus, it is thought to originate in any combination of three areas – namely peripherally from the auditory system, centrally, or from somatosensory input. Tinnitus is commonly associated with specific regions of the brain, particularly, the Dorsal Cochlear Nucleus, Central Auditory Pathway, and Auditory Cortex (Han, Lee, Kim, Lim, & Shin, 2009). Most recently, using residual inhibition,

Sedley et al. found tinnitus activity in the thalamus, and contrary to expectations, almost all of the auditory cortex and large portions of the temporal, parietal, sensorimotor, and limbic cortex (2015).

Given tinnitus is believed to cause neuroplastic changes in several areas of the brain (Han et al., 2009) and that meditation and mindfulness activities are shown to make restorative changes in those same areas while improving emotional responses, this study investigates the association between the amount of time spent and type of meditation and relief from tinnitus through reduction of bother.

McKenna et al., have found significant reduction of bother in patients with chronic tinnitus through the use of Mindfulness-Based Cognitive Therapy (MBCT), a standardized approach to tinnitus management following an eight-week MBCT program led by clinical psychologists. They rightly point out that much of the current research in non-standardized approaches, like the one proposed in this study, has been limited by small sample sizes (2018). This study looks to add to the body of research for non-standardized interventions and lead to the possibility of increased access to care for patients.

### *3.2 Include complete citations or references.*

Response:

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doi:10.1007/s12529-012-9241-6 Study

#### 4.0 **Study Design**

4.1 *Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).*

Response: This study is a non-randomized interventional study in which subjects with bothersome tinnitus will meditate to investigate how meditation effects the level of bother of their tinnitus.

**Commented [RJ5]:** This information is more appropriate to integrate into section 10.1. Section 4.1 should simply be a brief description of the study design.

## 5.0 Local Number of Subjects

5.1 *Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.*

Response: Target enrollment will be 30 subjects, however, the design of the study will allow for more or less.

5.2 *If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).*

Response: It is not expected that there will be a significant number of failures during screening.

5.3 *Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*

Response: Subjects will be recruited from the University at Buffalo's Tinnitus Support Group, which has 400 members, and the Speech-Language and Hearing Clinic. Additionally, information will be sent to area ENT doctors and audiology clinics, ideally adding another 100 potential participants. Online participants will be targeted through public announcements shared with various universities and clinics. With a target of 30 participants, 6% of the potential pool will fulfill that goal.

**Commented [RJ7]:** This section is meant to describe the feasibility of the study. This appears to be a description of recruitment methods.

**Commented [BF6]:** Too vague?

**Commented [BF8]:** Revise to reflect the group size not the potential enrollment

## 6.0 Inclusion and Exclusion Criteria

6.1 *Describe the criteria that define who will be **included** in your final study sample.*

*NOTE: This may be done in bullet point fashion.*

Response:

- Adults, age 18 and above, self-reporting bothersome tinnitus lasting longer than three months.
- Have been evaluated by an audiologist or otologist.
- Those willing and able to utilize their own smart device or computer meeting the following requirements.

**Commented [RJ9]:** Over 18?

**Commented [RJ10]:** You may want to only include individuals with a smart phone or internet access.

- For Mac: Requires iOS 10.0 or later. Compatible with iPhone, iPad, and iPod touch.
- For Android: varies by device.
- Data and/or Wi-Fi access

6.2 *Describe the criteria that define who will be **excluded** from your final study sample.*

*NOTE: This may be done in bullet point fashion.*

Response:

- Individuals with meditation training or consistent meditation practice (practice that totals more than 20 minutes daily) within the past six months.
- Those indicated by the Hospital Anxiety and Depression Scale to have “abnormal” indications for anxiety or depression.
- Those with any conditions that would restrict them from being able to either sit, walk, or lie down for at least 30 minutes at a time.

6.3 *Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.*

*NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.*

Response:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

6.4 *Indicate whether you will include non-English speaking individuals in your study. **Provide justification if you will exclude non-English speaking individuals.***

*In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience.*

*In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies*

*in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.*

Response: Subjects will be limited to English speaking individuals given that the study is not funded and the numerous questionnaires would not be able to be translated to ensure their reliability.

## 7.0 Vulnerable Populations

*If the research involves special populations that are considered vulnerable, describe the safeguards included to protect their rights and welfare.*

*NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.*

7.1 *For research that involves **pregnant women**, safeguards include:*

*NOTE CHECKLIST: Pregnant Women (HRP-412)*

Response: There is no increased risk to pregnant women by participating in this study.

**N/A:** This research does not involve pregnant women.

**Commented [RJ11]:** Your eligibility criteria and screening description does not address the possible enrollment of pregnant women. Are you screening for pregnant women? If so, how? If there is no increased risk to including pregnant women because of the nature of this study, please state so here.

7.2 *For research that involves **neonates of uncertain viability or non-viable neonates**, safeguards include:*

*NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)*

Response:

**N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

7.3 *For research that involves **prisoners**, safeguards include:*

*NOTE CHECKLIST: Prisoners (HRP-415)*

Response:

**N/A:** This research does not involve prisoners.

7.4 *For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*

*NOTE CHECKLIST: Children (HRP-416)*

Response:

**N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

7.5 *For research that involves cognitively impaired adults, safeguards include:*  
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

**N/A:** This research does not involve cognitively impaired adults.

7.6 *Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.*

Response: **N/A**

Commented [RJ12]: Why are you screening for these groups?

Commented [BF13R12]: They may respond differently to the intervention. Maybe this is not part of the screening process but rather the analysis in their demographic information.

## 8.0 Eligibility Screening

8.1 *Describe screening procedures for determining subjects' eligibility.*  
Screening refers to determining if prospective participants meet inclusion and exclusion criteria.

*Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).*

Response:

Screening will be performed using the attached form (Tinnitus Meditation Screener.)

Commented [14]: <https://drive.google.com/file/d/10rAjXaLHMuUt-7ZKWKb2SmAY9NkQKDkc/view?usp=sharing>

Interested participants will be mailed this form, return it to our clinic in person or by mail, and be notified of their enrollment at least two weeks prior to the beginning of the study.

Commented [BF15]: Possible to put on REDCap?

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Online participants will be screened using an online version of the same form through REDCap.

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**N/A:** There is no screening as part of this protocol.

## 9.0 Recruitment Methods

**N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

9.1 *Describe when, where, and how potential subjects will be recruited.*

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g.

*searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).*

Response: Recruitment will begin following IRB approval and will end one week prior to the commencement of the study.

The following methods will be used for recruitment:

Area audiologists and otolaryngologists agreeing to participate in referring participants and UB Speech-Language and Hearing Clinic Faculty will be given information on this study to share with patients. The following clinics and groups will be contacted with recruitment materials:

- Diversified Hearing Services
- Buffalo Hearing & Speech
- Hearing Evaluation Services
- Lake Shore Audiology
- Dr. Ernesto Diaz-Ordaz, MD

Commented [RJ16]: Are you targeting specific practices?

Commented [BF17R16]: I could likely produce a list of who I'll send this out to if that would help.

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Interested patients will be given the Eligibility Screening Form to complete and send to or drop off at the UB Speech-Language and Hearing Clinic or utilize the link in the recruitment materials to an online version through REDCap.

The UB Speech-Language and Hearing Clinic and Center for Hearing and Deafness host the Western New York Tinnitus Support Group, informational meetings for tinnitus patients and their families. These patients have volunteered their information to be contacted regarding meetings and research taking place at UB. Using the volunteered information from the Western New York Tinnitus Support group an informational letter (attached) will be sent by mail and email. This information is not derived from electronic medical records.

Commented [BF18]: <https://buffalo.box.com/s/e4cwo9fvi6f4d02hnnlzd2p4rkbk6zc>

Commented [RJ19]: Is this a database kept for future research purposes? If so, I recommend including an IRB reference number of the study that was previously approved. Either way, more detail is needed here.

Commented [BF20R19]: This was a group that was started years ago and I've recently started running. It's a long standing list of folks who come to informational sessions throughout the year and to whom we send mailers to. They're often former patients, but they are made aware that there may be opportunities to participate in research. So it may be used for recruitment again in the future. Does that answer your question?

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Flyers will be used in these offices as a means for recruitment as well. (Attached as Tinnitus Recruitment Flyer and Tinnitus Recruitment Flyer TEAR-OFFS)

A digital version of the information contained in the aforementioned recruitment letter will be posted on ClinicalTrials.gov, the Buffalo Research Registry, and ResearchMatch.org.

In addition to the Recruitment Letter information, Research Match will include the following:

If you are interested in this study and having the research team contact you directly, please select the "Yes, I'm interested" link below. By clicking the "Yes, I'm interested" link, your contact information will be released to the research team. If you select the "No, thanks." link or do not respond to this study message, your contact information will not be released to the research team.

QUICK LINK OPTION: YES      QUICK LINK OPTION: NO

Thank you for your interest in ResearchMatch.

Digital Display Boards at UB: We will be posting a digital flyer on digital display boards located at the UB Jacobs Medical School, Clinical and Translational Research Center and UBMD upon approval from building administration. (Attached as TINNITUS Digital Display Board Post)

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9.2 *Describe how you will protect the privacy interests of prospective subjects during the recruitment process.*

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response: All screening forms will be sent to the UB Speech-Language and Hearing Clinic and secured in a locked area. From here forms will be relocated to a secure office in University at Buffalo – South Campus, Cary Hall 112A.

Potential subjects participating online will submit information via REDCap where it will be stored. Data may be extracted by UB's CTSI office for analysis following completion of collection and stored securely by that office.

Following recruitment and enrollment, all prospective subjects will be notified if they are enrolled. Anyone not enrolled will be notified of such and their screening forms disposed of in secure trash.

Commented [BF21]: Again, See redcap

9.3 *Identify any materials that will be used to recruit subjects.*

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

☐ For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response: Participants will not be called directly to participate in this study, however, phone contact information will be provided in recruitment materials. If interested participants do call the research team the following script will be used to give information:

Researcher (R): Hello, this is [researcher's name] from the Department of Communicative Disorders and Sciences. I understand you may be interested in participating in a study involving tinnitus and meditation practice.

[if affirmed]

Commented [22]: Write AuD recruitment and patient/tinn. Group letters

Commented [RJ23]: You will need a phone script to detail what is said to the subject when the researchers call to invite the participant to enroll in this study.

The letter mentioned above should also be indicated here.

Commented [BF24R23]: I wasn't planning on recruiting by calling, but exclusively by letters and email. Though, if I need a script if they call me to express their interest, would I need a script for that or simply follow my screener document and fill it out with/for them?

R: Great. I'd like to tell you a bit more about the study and if you are still interested I can email an online form that you can complete to see if you are eligible to participate.

R: This study will ask that you attend a brief meeting on [INSERT DATE AND TIME] or view a video of the session, whichever you would like. In that session, you will learn how to meditate and use the app that we will use to track your meditation. After the information session, I'll ask you to meditate a half hour per day, five days per week, for eight weeks or at the very least, one hour per week. You will be asked to fill out surveys online and submit your data from the app. While the app is free, you will need to use Wi-Fi or data on your smart device or tablet that can run the application. You would be responsible for any charges for data or Wi-Fi.

Do you have any questions about the study or how this might work?

Are you interested in participating in the study?

- [if yes] I would like to take down your email and send you our eligibility screening form. Can I have that?
- [email will be sent using secure, UB email; prospective participant will be sent the appropriate link to the REDCap Screener]
- [if no] Thank you for your time and consideration.

R: I will send a link to that email that will bring you to the screening form. After you fill that out, someone will contact you if you have been selected the study within two weeks. This will not automatically enroll you. You will sign a consent form before the study begins with more details about the study. If you have questions, please contact me at this number (716) 222-2735 or email bpf4@buffalo.edu.

Recruitment materials and letters are attached.

## 10.0 Procedures Involved

*10.1 Provide a description of all research procedures or activities being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

*NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.*

Response:

Interested participants will contact the researcher by phone or email and be emailed the screening form and return it to our clinic in person, by mail, or through the REDCap system. They will be notified of their enrollment at least two weeks prior to the beginning of the study.

Following screening, eligible participants will be contacted by mail or email with information regarding the one-time meeting at UB. For subjects participating exclusively online, this session will be video recorded and posted to be viewed prior to the start of the intervention.

At this meeting they will learn about the study, acknowledge their ability to utilize either a smart device or computer to report their meditation times, participate in an educational session, and sign consent forms. Online consent will be obtained through REDCap by a form. Following consent, subjects will be asked to complete the first round of surveys and questionnaires which will include:

- Tinnitus Handicap Questionnaire
- Tinnitus Handicap Inventory
- Tinnitus Functional Index
- Hospital Anxiety and Depression Scale
- Mindful Attention Awareness Scale
- University at Buffalo Tinnitus Intake Questionnaire

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Subjects will begin their meditation practice at home using suggested guided meditations. Subjects will be asked to create an account on the meditation website InsightTimer. This website has an accompanying smart device application that allows users to access guided meditations and timed sessions. With an account, users' session data is logged. Subjects will be encouraged to use guided meditations of their choice or timed meditation using the InsightTimer. They will be asked to practice a half hour, five days per week for eight weeks. Subjects must complete at least one hour per week to remain in the study. Every week during the study, subjects will be asked to submit their data from the application into REDCap. Subjects will have the PI's email and a phone number for technical assistance.

Subjects' meditation practice will last for eight weeks with measures being utilized after week three and week eight. The following measures will be sent to participants by email and submitted through REDCap.

- Tinnitus Handicap Questionnaire
- Tinnitus Handicap Inventory
- Tinnitus Functional Index
- Hospital Anxiety and Depression Scale
- Mindful Attention Awareness Scale

← **Commented [RJ25]:** What technology is needed?

**Commented [RJ26]:** What application? Please describe the requirement here in further detail.

**Commented [BF27R26]:** I hope this is clearer now.

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**Commented [RJ28]:** You describe above participation for 3 weeks. Are there additional research procedures or activities that are required up to 8 weeks?

**Commented [BF29R28]:** My language was unclear. The intervention lasts 8 weeks with measures after weeks 3 and 8.

## 10.2 Describe what data will be collected.

*NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.*

Response:

- [Each week, participants will enter the amount of time spent meditating on a form through REDCap.](#)
- [Before week 1:](#)
  - [Tinnitus Handicap Questionnaire](#)
  - [Tinnitus Handicap Inventory](#)
  - [Tinnitus Functional Index](#)
  - [Hospital Anxiety and Depression Scale](#)
  - [Mindful Attention Awareness Scale](#)
  - [University at Buffalo Tinnitus Intake Questionnaire](#)
- [After week 3:](#)
  - [Tinnitus Handicap Questionnaire](#)
  - [Tinnitus Handicap Inventory](#)
  - [Tinnitus Functional Index](#)
  - [Hospital Anxiety and Depression Scale](#)
  - [Mindful Attention Awareness Scale](#)
- [After week 8:](#)
  - [Tinnitus Handicap Questionnaire](#)
  - [Tinnitus Handicap Inventory](#)
  - [Tinnitus Functional Index](#)
  - [Hospital Anxiety and Depression Scale](#)
  - [Mindful Attention Awareness Scale](#)

 10.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

*Include copies of these documents with your submission.*

Response:

- [Tinnitus Handicap Questionnaire](#)
- [Tinnitus Handicap Inventory](#)
- [Tinnitus Functional Index](#)

- Hospital Anxiety and Depression Scale
- Mindful Attention Awareness Scale
- University at Buffalo Tinnitus Intake Questionnaire

**Commented [BF30]:** [https://drive.google.com/open?id=104a3hbqsAAkvfesLVLFQCv168M2\\_RYQa](https://drive.google.com/open?id=104a3hbqsAAkvfesLVLFQCv168M2_RYQa)

10.4 *Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).*

Response: No additional records will be requested or gathered from subjects.

10.5 *Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response: Individual subject results will not be shared with any other parties.

10.6 *Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: Study results will be used towards the completion of the principal investigator's Doctorate of Audiology degree, presented to the community, and published.

## 11.0 Study Timelines

11.1 *Describe the anticipated duration needed to enroll all study subjects.*

Response: Recruitment, screening and enrollment will take no more than two months.

**Commented [31]:** ATTACH Gant chart

**Commented [32R31]:** [https://docs.google.com/spreadsheets/d/14xirM\\_wiNqISiwlwV6XbiPVP1pR3fExYkp2nOtwEQ/edit?usp=sharing](https://docs.google.com/spreadsheets/d/14xirM_wiNqISiwlwV6XbiPVP1pR3fExYkp2nOtwEQ/edit?usp=sharing)

11.2 *Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.*

Response: Subjects will participate in the study for a total of eight weeks. After providing consent, subjects will participate in an informational session at the UB Speech Language and Hearing Clinic lasting an hour and a half. Online participants will view a video recording of this informational session before the start of the intervention.

**Commented [RJ33]:** 8 or 10 weeks?

**Commented [BF34R33]:**

This study investigates meditation practice over the course of eight weeks. The goal is averaging 30 minutes, five days each week and a requirement of at least one hour per week. Subjects can practice their meditation anywhere, on their own.

**Commented [RJ35]:** At the end of week 2 or at enrollment? This is not indicated in section 10.1.

**Commented [RJ36]:** What is the requirement? Is it 30 minutes a day for 8 weeks?

In addition to the initial information session, subjects will be asked to complete surveys that are emailed to them after the third and eighth weeks of the study and submitted through REDCap. These surveys should take less than 30 minutes to complete each time they are administered. Additionally, subjects will enter their weekly meditation times in REDCap.

11.3 *Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).*

Response: The duration to complete this study will be 10 months.

## 12.0 Setting

12.1 *Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.*

*NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."*

Response: The one in-person meeting of this study will be held at the UB Speech-Language and Hearing Clinic in a room equipped with a computer and projector.

12.2 *For research conducted outside of UB and its affiliates, describe:*

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

*NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.*

Response:

**N/A:** This study is not conducted outside of UB or its affiliates.

## 13.0 Community-Based Participatory Research

13.1 *Describe involvement of the community in the design and conduct of the research.*

*NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.*

Response:

**N/A:** This study does not utilize CBPR.

*13.2 Describe the composition and involvement of a community advisory board.*

Response:

**N/A:** This study does not have a community advisory board.

## 14.0 Resources and Qualifications

*14.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

*NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.*

Response: The following roles are in place for the duration of this study. All study personnel are educated, trained, and licensed as required for their delegated role in this study. All study personnel have also received the required university training.  
Principle Investigator:

- Graduate Student in Audiology
- Training and clinical experience in tinnitus management
- Participates in the Western New York Tinnitus Support Group

Study Advisor:

- Licensed Doctor of Audiology
- American Speech and Hearing Association Certified in Clinical Competence in Audiology (CCC-A)
- Training and clinical experience in tinnitus management.

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**Commented [RJ37]:** This is a good start. You can always generalize qualifications (see example below).

"All study personnel are educated, trained, and licensed as required for their delegated role in this study. All study personnel have also received the required university training.

PI is an educated, trained, board certified, and licensed research professor and interventional cardiologist working at the CTRC. Sub-PIs are educated, trained, and licensed cardiac surgeons. Sub-Is are educated, trained and licensed interventional cardiologists, neurologists and echocardiographers.

Study staff will be trained in study procedures by the PI as needed."

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**Describe other resources available to conduct the research.**

14.2 *Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.*

*NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.*

**Response:** The PI will dedicate 6-12 hours weekly to this study. The PI and study advisor that are assigned to this study will be able to devote sufficient time to the procedures in adherence with the protocol.

**Commented [38]:** Again, not sure on the exact language to describe the specifics of who does what.

14.3 *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.*

*NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.*

**Response:** Potential subjects scoring “abnormal” on the Hospital Anxiety and Depression Scale will be referred to area mental health services.

**Commented [RJ39]:** You can state 3 hours a week or .5 FTEs. Whatever you and your research team can devote to conducting this study (example below).

“The PI, study coordinator, or other study staff that are assigned to this study and will be able to devote sufficient time to the procedures in adherence with the protocol.”

**Commented [BF40R39]:**

14.4 *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

**Response:** The PI will be conducting all aspects of the study. The study advisor will correspond weekly to ensure continued adherence to the protocol and procedures.

**Commented [RJ41]:** Example: “All study personnel are required to receive study specific on-site training by the study PI. The PI will discuss the protocol, the procedures, and specific duties with all study personnel before the study starts. Any training that is necessary will be done prior to start of any study procedures.”

**Commented [BF42R41]:** Since it really is just my advisor and me, it seems a little tricky to word. Is this ok?

## 15.0 Other Approvals

15.1 *Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).*

**Response:** Access for a location for the in-person meeting at the beginning of this study will be obtained through the study advisor.

**N/A:** This study does not require any other approvals.

**Commented [RJ43]:** Do you need approval from the area offices for recruitment?

**Commented [BF44R43]:** I'm supposing they would simply opt in or not.

## 16.0 Provisions to Protect the Privacy Interests of Subjects

16.1 *Describe how you will protect subjects' privacy interests during the course of this research.*

*NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.*

*Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."*

**Response:** Patients will be placed in a private location for obtaining informed consent and the administration of patient care. Participants will be informed of the group instructional meeting and requested to maintain the privacy of others during the consent process. All steps will be taken to ensure that patient's privacy will be protected.

**16.2 Indicate how the research team is permitted to access any sources of information about the subjects.**

*NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question **does apply** to records reviews.*

**Response:** Consent of the subject. Any physical documents pertaining to the study (i.e.: screening forms, consent forms, and surveys) will be held in a secure location at the University at Buffalo – South Campus, Cary Hall 112A. Electronic information gathered by within REDCap of this information will be maintained and shared securely within REDCap.

No electronic medical records systems will be accessed or used throughout the study.

Contact information that is drawn from the Western New York Tinnitus Support group is maintained in a secured UB Box account. This information is available to the Speech-Language and Hearing Clinic, since they assist in maintaining this list.

**Commented [RJ45]:** Please delete. This describes confidentiality, not privacy. Privacy refers to an individual's right to control access to him or herself (example below).

"Patients will be placed in a private location for obtaining informed consent and the administration of patient care. Participants will not be placed in a common area and exposed to others. This is to prevent anyone else from overhearing any conversations regarding their personal information or study information. All steps will be taken to ensure that patient's privacy will be protected."

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## **17.0 Data Management and Analysis**

**Commented [RJ46]:** Please respond to this section.

**17.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.**

**Response:** Data will be collected and secured using the REDCap System. Analysis may include the use of paired t-tests and/or ANOVA with assistance from UB's office of Clinical and Translational Science Institute.

**17.2 If applicable, provide a power analysis.**

*NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit*

*whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.*

Response: N/A

*17.3 Describe any procedures that will be used for quality control of collected data.*

Response: N/A

## **18.0 Confidentiality**

### **A. Confidentiality of Study Data**

*Describe the local procedures for maintenance of confidentiality of **study data** and any records that will be reviewed for data collection.*

*18.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response: Electronic records will be managed in the REDCap system. Physical documents will be secured in University at Buffalo – South Campus, Cary Hall 112A. Data may be extracted by UB's CTSI office for analysis following completion of collection and stored securely by that office.

Commented [RJ47]: Please respond to this section.

*18.2 A. How long will the data be stored?*

Response: Data will be stored until June 1, 2020.

*18.3 A. Who will have access to the data?*

Response: The Principal Investigator, Study Advisor, and analysts assigned by UB's CTSI office will have access to this data.

*18.4 A. Who is responsible for receipt or transmission of the data?*

Response: The data will be received by utilizing the REDCap system.

*18.5 A. How will the data be transported?*

Response: Electronic data will be collected through REDCap.

## B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of study specimens.*

**N/A:** No specimens will be collected or analyzed in this research.  
(Skip to Section 19.0)

*18.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.*

Response:

*18.7 B. How long will the specimens be stored?*

Response:

*18.8 B. Who will have access to the specimens?*

Response:

*18.9 B. Who is responsible for receipt or transmission of the specimens?*

Response:

*18.10 B. How will the specimens be transported?*

Response:

## 19.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

**N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

*NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.*

*19.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.*

Response: [N/A: This is a minimal risk study that does not pose any anticipated harm to participants.](#)

19.2 *Describe what data are reviewed, including safety data, untoward events, and efficacy data.*

Response: [N/A](#)

19.3 *Describe any safety endpoints.*

Response: [N/A](#)

19.4 *Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*

Response: [N/A](#)

19.5 *Describe the frequency of safety data collection.*

Response: [N/A](#)

19.6 *Describe who will review the safety data.*

Response: [N/A](#)

19.7 *Describe the frequency or periodicity of review of cumulative safety data.*

Response: [N/A](#)

19.8 *Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.*

Response: [N/A](#)

19.9 *Describe any conditions that trigger an immediate suspension of the research.*

Response: [N/A](#)

## 20.0      Withdrawal of Subjects

**N/A:** This study is not enrolling subjects. This section does not apply.

Commented [RJ48]: Please respond to this section.

20.1 *Describe anticipated circumstances under which subjects may be withdrawn from the research without their consent.*

Response: Subjects may be withdrawn for the following reasons:

- Failure to submit mediation data in a timely manner.
- Failure to complete surveys and questionnaires in a timely manner.
- Failure to comply to participating in the intervention. Subjects practicing meditation less than one hour per week may be withdrawn from the study.

20.2 *Describe any procedures for orderly termination.*

*NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.*

Response: Participants will be informed of their removal from the study and asked to complete questionnaires (Tinnitus Handicap Questionnaire, Tinnitus Handicap Inventory, Tinnitus Functional Index, Hospital Anxiety and Depression Scale, Mindful Attention Awareness Scale) via the REDCap system. This intervention poses low risk from discontinuing abruptly.

20.3 *Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.*

Response: Data already collected from subjects who withdraw will be analyzed up to the point of their last completed questionnaires.

## 21.0 Risks to Subjects

21.1 *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.*

*NOTE: Breach of confidentiality is always a risk for identifiable subject data.*

Commented [RJ49]: Please respond to this section.

Response: Subjects will be asked to be seated and still for long periods of time. Some subjects may experience minor physical discomfort. There may also be an increased risk for circulation to be reduced due to subjects being in one position for an extended period of time.

21.2 *Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.*

Response: To reduce discomfort and poor circulation that can occur in seated meditation, subjects will also be instructed to participate in lying or walking meditation.

21.3 *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*

Response: N/A

21.4 *If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.*

Response: N/A

21.5 *If applicable, describe risks to others who are not subjects.*

Response: N/A

## 22.0 Potential Benefits to Subjects

22.1 *Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.*

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: Benefits may include reduction in the level of bother of the subject's tinnitus. Because this study is a first of its kind, probability, magnitude, and duration cannot be reliably predicted, however, there have been several studies of mindfulness interventions demonstrating long-term positive outcomes and reduction of symptoms for patients with anxiety, depression, and chronic pain. Additionally, mindfulness practice was associated with "improvement in quality of life and/or sense of well-being" in a meta-analysis (Merkes, 2010).

Commented [RJ50]: Please respond to this section. If no direct benefit, indicate that.

## 23.0 Compensation for Research-Related Injury

**N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

23.1 *If the research procedures carry a risk of research related injury, describe the available compensation to subjects in the event that such injury should occur.*

Response:

23.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with different language regarding research related injury, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

## 24.0 Economic Burden to Subjects

24.1 Describe any costs that subjects may be responsible for because of participation in the research.

*NOTE: Some examples include transportation or parking.*

Response: Subjects are responsible for postage for screening forms and transportation to the campus on the day of the in-person instruction.

Commented [RJ51]: Are subjects required to pay for the postage of mailing the questionnaires back to the research team?

Subjects are responsible for data and Wi-Fi charges to their personal devices through the duration of the study.

**N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

## 25.0 Compensation for Participation

25.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response:

**N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

**N/A:** There is no compensation for participation. This section does not apply.

## 26.0 Consent Process

26.1 Indicate whether you will be obtaining consent.

*NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 27.0.*

**Yes** (If yes, Provide responses to each question in this Section)  
 **No** (If no, Skip to Section 27.0)

26.2 *Describe where the consent process will take place. Include steps to maximize subjects' privacy.*

Response: All subjects will be directed to consent materials online through REDCap.

Commented [RJ52]: Please respond to this section.

26.3 *Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.*

*NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.*

Response: Subjects will be sent consent links through REDCap immediately after eligibility is confirmed. Subjects will have at least one week before the informational meeting to review this consent and ask questions as needed by phone or email.

26.4 *Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.*

Response: N/A

26.5 *Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:*

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Commented [BF53]: Will be done via REDCap

#### ***Non-English Speaking Subjects***

**N/A:** This study will not enroll Non-English speaking subjects.  
(*Skip to Section 26.8*)

26.6 *Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.*

*NOTE: The response to this Section should correspond with your response to Section 6.4 of this protocol.*

Response:

26.7 *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

*NOTE: Guidance is provided on “SOP: Informed Consent Process for Research (HRP-090).”*

Response:

#### ***Cognitively Impaired Adults***

**N/A:** This study will not enroll cognitively impaired adults.  
(*Skip to Section 26.9*)

26.8 *Describe the process to determine whether an individual is capable of consent.*

Response:

#### ***Adults Unable to Consent***

**N/A:** This study will not enroll adults unable to consent.  
(*Skip to Section 26.13*)

*When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) and, where possible, assent of the individual should also be solicited (Sections 26.11 and 26.12).*

26.9 *Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” for research in New York State.*

*NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.*

Response:

We have reviewed and will be following “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”

**26.10 For research conducted outside of New York State, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”**

Response:

**26.11 Describe the process for assent of the adults:**

- Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.

Response:

- If assent will not be obtained from some or all subjects, provide an explanation of why not.

Response:

**26.12 Describe whether assent of the adult subjects will be documented and the process to document assent.**

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the “Template Consent Document (HRP-502)” Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

**Subjects who are not yet Adults (Infants, Children, and Teenagers)**

N/A: This study will not enroll subjects who are not yet adults.  
(Skip to Section 27.0)

**26.13 Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years). For research conducted in NYS, review “SOP:**

*Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

*NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.*

Response:

**26.14** *For research conducted outside of New York State, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

**26.15** *Describe whether parental permission will be obtained from:*

Response:

- One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
- Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- Parent permission will not be obtained. A waiver of parent permission is being requested.

*NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."*

**26.16** *Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

**26.17** *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

*26.18 When assent of children is obtained, describe how it will be documented.*

Response:

## 27.0 Waiver or Alteration of Consent Process

*Consent will not be obtained, required information will not be disclosed, or the research involves deception.*

**N/A:** A waiver or alteration of consent is not being requested.

*27.1 If the research involves a waiver or alteration of the consent process, please review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.*

*NOTE: For records review studies, the first set of criteria on the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” applies.*

Response:

*27.2 If the research involves a waiver of the consent process for planned emergency research, please review the “CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)” to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:*

Response:

## 28.0 Process to Document Consent

**N/A:** A Waiver of Consent is being requested.  
*(Skip to Section 29.0)*

*28.1 Indicate whether you will be following “SOP: Written Documentation of Consent (HRP-091).” If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.*

*NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as ‘verbal consent.’ Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information.*

 *If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).*

Commented [54]: Do I not need consent considering the risk is so low?

Commented [RJ55R54]: You need to consent.

Commented [BF56R54]:

Response: All subjects will be consented through a form on REDCap. Subjects will be sent consent links through REDCap immediately after eligibility is confirmed. Subjects will have at least one week before the informational meeting to review this consent and ask questions by phone or email as needed.

We will be following "SOP: Written Documentation of Consent" (HRP-091).

## 29.0 Multi-Site Research (Multisite/Multicenter Only)

  **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

29.1 *If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

29.2 *Describe the method for communicating to engaged participating sites:*

- *Problems*
- *Interim results*
- *Study closure*

Response:

29.3 *Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.*

Response:

29.4 *If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.*

Response:

## 30.0 Banking Data or Specimens for Future Use

**N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

30.1 *If data or specimens will be banked (stored) for future use, that is, use or research outside of the scope of the present protocol, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

*NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).*

Response:

30.2 *List the data to be stored or associated with each specimen.*

Response:

30.3 *Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*

Response:

## 31.0 Drugs or Devices

**N/A:** This study does not involve drugs or devices. This section does not apply.

31.1 *If the research involves drugs or devices, list and describe all drugs and devices used in the research, the purpose of their use, and their regulatory approval status.*

Response:

31.2 *Describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.*

Response:

***If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:***

31.3 *Identify the holder of the IND/IDE/Abbreviated IDE.*

Response:

31.4 *Explain procedures followed to comply with FDA sponsor requirements for the following:*

FDA Regulation	Applicable to:		
	IND Studies	IDE studies	Abbreviated IDE studies
21 CFR 11	X	X	
21 CFR 54	X	X	
21 CFR 210	X		
21 CFR 211	X		
21 CFR 312	X		
21 CFR 812		X	X
21 CFR 820		X	

Response:

## 32.0 Humanitarian Use Devices

**N/A:** This study does not involve humanitarian use devices. This does not apply.

32.1 *For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.*

Response:

*32.2 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.*

Response: