Adhear Bone Conduction System

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Protocol Title

Comparative study of non-invasive Adhear bone conduction system to traditional bone conduction hearing devices

Objectives*

Aim 1. Determine if non-invasive Adhear is an equally effective treatment solution for unilateral profound sensorineural hearing loss when compared to invasive boneanchored implants.

Hypothesis: We hypothesize that non-invasive Adhear bone conduction technology will provide similar benefit to the more invasive bone anchored implant system for unilateral profound sensorineural hearing loss.

Aim 2. Non-invasive Adhear is an equally effective treatment solution for conductivehearing loss when compared to invasive bone anchored implants.

Hypothesis: We hypothesize that non-invasive Adhear bone conduction technology will provide similar benefit to the more invasive bone anchored implant system for conductive hearing loss.

Aim 3. Non-invasive Adhear is a more effective treatment solution for pediatric hearing loss when compared to bone conduction devices worn on a headband.

Hypothesis: We hypothesize that non-invasive Adhear bone conduction technology will increase objective and subjective benefit when compared to traditional bone anchored implant processors worn on a headband for pediatric conductive hearingloss.

Aim 3a. - To evaluate the validity of the non-invasive ADHEAR bone conduction hearing system in children with bilateral or unilateral conductive hearing loss

Aim 3b. To compare the benefits of the non-invasive ADHEAR bone conduction hearing system in children with bilateral and unilateral conductive hearing loss to traditional non- invasive bone conduction hearing systems worn on a headband.

Background*

Implantable bone conduction technology has been well established as an efficacious and effective treatment solution. Despite this, adoption and acceptance rates for implantable bone conduction devices are low (Andersen et al, 2006; Desmet et al, 2012; Farber et al, 2012; Kompis et al 2001; Siau et al 2015). This has been attributed to aesthetics (Farber et al, 2012); and the need for surgery (Farber et al, 2012; Desmet et al, 2012; Siau, 2015). In fact Siau and colleagues suggestedthat rejection of implantable bone conduction technology is as high as 70% with nearly 30% attributed to subject opposition to surgery (Farber et al, 2012; Siau et al, 2015). In lieu of implantation, bone conduction devices can be anchored to a headband. Non-invasive bone conduction hearing technology is a promising alternative to implantable bone anchored systems. Significant gains in speech perception in quiet and in noise can be achieved with both implantableand headband bone conduction devices. These basic auditory functions are an essential component for effective communication and daily acts of living. Likewise, the inability to performsuch functions results in considerable reduction of quality of life, social exclusion, vocational limitations, and a high disability and handicap index. Issues related to comfort and increased visibility of headband devices, however, have limited the acceptance and use of

such systems. The Adhear (MEDEL, Corp) bone conduction hearing system is a novel hearing device providing non-invasive direct stimulation of the hearing organ via bone conduction without the need for a headband. In the Adjoin system (MEDEL, Corp) the audio processor attaches to a long wear adhesive adapter. The adhesive adapter is worn discreetly behind the ear and allows the processor to stimulate the temporal bone without the use of a visible headband or implant. This provides optimal placement of the processor for maximal stimulation of the hearing organ, as wellas a more natural placement of the microphone for sound collection. This novel approach overcomes the key limitations of current treatment solutions and has the potential to impact individuals with mixed, conductive or unilateral hearing loss in substantial ways.

The ability to provide nonsurgical acoustic stimulation by bone conduction without the discomfort and stigma associated with using a headband will allow for increased adoption and acceptance, while providing the effectiveness of an implantable device. Further, such technology will increase access for both adult and pediatric bone anchored implant candidates. Utilizing Adhear technology provides a less invasive alternative for patients who are unable or unwilling to undergo bone anchored implant surgery and offers an innovative approach to resolving the auditory deficits associated conductive, mixed or unilateral profound hearing loss.In short, the outcomes of the proposed study will provide direct benefit to patients and improveclinical application.

The safety and effectiveness of bone anchored implants (BAI) for the treatment of conductive, mixed, and unilateral profound sensorineural hearing loss (UPSNHL) has been well established. The notable benefits associated with implantable hearing technology have increased the supportfor more invasive forms of treatment. However, a significant number of patients exist who are unable or unwilling to pursue an implantable solution for their hearing loss. Further, in the UPSNHL population, evidence suggests that patients can achieve equal benefits with non-invasivesolutions (Snapp et al, 2016). For conductive and mixed hearing loss, BAIs have been demonstrated to have improved gain and sound quality over traditional hearing aids (Mylanus et al, 1995, Mylanus et al, 1998Hol et al, 2005; McDermott et al, 2002;) and have been an optimal solution for those who have physiological limitations to using traditional hearing aids.

Until now, those who were unwilling or unable to undergo bone anchored implantation were limited to bone conduction devices on a headband, a solution that has been plagued with poor acceptance due to unfavorable aesthetics and discomfort with long- term use. In this study, subjective and objective hearing outcomes utilizing a novel hearing device branded as the Adhear providing non-invasive bone conduction stimulation (MEDEL, Corp) will be compared with outcomes using traditional BAI technology.

Inclusion and Exclusion Criteria*

All subjects will be prospectively enrolled for study.

Aims 1 and 2 will include adult English speaking patients who are experienced users of BAIs for the

indication of either single sided deafness or conductive hearing loss. Experienced will be defined as greater than 6 months of device use and no intermittentfunction of the device within 2 weeks of enrollment. Aims 1 and 2 will require retrospective chart review to identify potential study subjects for recruitment. Subjectswho spontaneously present to the clinic may also be enrolled should the meet inclusioncriteria. Subjects will be limited to those who have normal hearing by bone conduction defined as a pure tone average of 25 dBHL or better at 500, 1000, 2000, & 3000 Hz in atleast one ear.

Aim 3 will include English speaking children 5 to 17 years of age and their primary guardian who present to the clinic for treatment by BAI on a headband device for the indications of single sided deafness or conductive hearing loss. Because subjects for aim 3have not previously been users of a BAIs, subjects for aim 3 will be recruited during spontaneous presentation to the clinic. Subjects will also be recruited for aim 3 from various sites using flyers and email. Subjects will be limited to those who have no prior use of a BAI or bone conduction hearing device, normal hearing by bone conduction defined as a pure tone average of 25 dBHL or better at 500, 1000, 2000, & 3000 Hz in at least one ear. For those children where this cannot be definitively established, children will be included who display clinical signs of normal bone conduction hearing beyond a reasonable doubt and may include such evidence as (but not limited to): auditory brainstem response, speech awareness thresholds, visual reinforcement audiometry, conditioning play audiometry, CT scans, etc.)

Aims 3 a & b are an extension of Aim 3 and will include pediatric bilateral or unilateral conductive hearing loss patients who are between the ages of 2 and 17 years of age and are currently managed by the UMEI with a bone conduction device attached to a softband will be enrolled for study.

Exclusion Criteria:
The study is limited to English speakers, as speech perception measures are only available in English so non-native English speakers do not undergo the standard clinical protocol.

For aim 3, parents of English speaking subjects who do not speak English will not be specifically excluded. Due to the high incidence of English speaking children in Spanish speaking homes, for primary guardians who speak Spanish, Spanish materials will be provided. Children who have previous experience with a BAI or bone conduction hearingdevice will not be included for study.

Subjects will be screened for any allergies related to adhesives as the experimental devicerequires use of an adhesive adapter. Those reporting allergies to adhesives or highly reactive skin will be excluded from study as a precautionary measure.

Procedures Involved*

The medical records of patients who received a bone conduction hearing device follow-up between January 1, 2010 through September 23, 2021 will be retrospectively reviewed. We anticipate review of approximately 500 medical records. Demographic data for review include gender, age, primary spoken language, and etiology. Standard clinical hearing outcome data will be reviewed for both groups and will include audiometric thresholds, word recognition ability, and speech perception measures. This information will be used to determine study candidates. Those who meet the inclusion criterion willbe contacted for study participation. Once we have received a minimum of 10 but no greater than 30 participants for each study group, retrospective review will be completed and no new charts will be accessed. Participants will then only be studied prospectively. Demographic and audiometric data will be maintained under a unique identifier code linked to the consented study

participant for reference to study outcome data.

Study Populations

- Minimum of 10 established adult unilateral profound sensorineural hearing loss recipients of bone anchored implants
- Minimum of 10 established adult conductive hearing loss recipients of bone anchored implants
- Minimum of 10 new pediatric headband bone conductive device candidates.
- Minimum of 10 guardians of the pediatric population involved
- Minimum of 15 established pediatric unilateral conductive hearing loss patients currently fit with a bone conduction device on a softband.
- Minimum of 10 established bilateral conductive hearing loss patients currently fit with a bone conduction device on a softband.

Study Design

Aims 1&2

- Experienced adult bone anchored implant recipients with either unilateral profound sensorineural hearing loss or conductive hearing loss will be enrolled for study. Subjectswill be given the Adhear hearing system on trial for 2 weeks ± 90 days. Prior to dispensing of the experimental system, function of the subject's implant system will beverified. Custom pre-post subjective measures will be administered. Subjects will undergo behavioral measures of benefit in the 1) implant aided condition and 2) the Adhear Aided condition
- Conditions will be randomized by subject and will consist of the following:
    - Speech perception in noise ability using the BKBSIN (Etymotic, Elk Grove, IL) adaptive tests for speech front, noise front (0º/0º azimuth), speech poorer ear, noise better ear (90º/270º azimuth), speech better ear, noise poorer ear (90º/270º azimuth)
    - Soundfield aided narrow band signal thresholds – better ear plugged
    - Soundfield aided speech reception thresholds – better ear plugged
- At 2 weeks ± 90 days, subjects will undergo behavioral measures of benefit in the Adhear aided condition. Tests will be repeated using the subjects own processor on asoft headband to evaluate transcutaneous stimulation.
- Conditions will be randomized by subject and will consist of the following:
    - Speech perception in noise ability using the BKBSIN (Etymotic, Elk Grove, IL) adaptive tests for speech front, noise front (0º/0º azimuth), speech poorer ear, noise better ear (90º/270º azimuth), speech better ear, noise poorer ear (90º/270º azimuth)
    - Soundfield aided narrow band signal thresholds – better ear plugged
    - Soundfield aided speech reception thresholds – better ear plugged

Aim 3

- Pediatric conductive hearing loss patients who are between the ages of 5 and 15 years of age and present to the UMEI hearing rehabilitation by bone conduction technology along with their primary guardian will be enrolled for study. Subjects will be evaluated intwo phases:
    - Phase 1 – random assignment to trial with either a traditional bone conduction

device on a headband or an Adhear hearing system for 3 weeks ± 90 days. Pediatric and parent subjective questionnaires will be administered prior to andat the end of phase 1.
  - Phase 2- trial with system alternate to that which was assigned for phase 1. Pediatric and parent subjective questionnaires will be administered prior to andat the end of phase 2.

Objective and behavioral outcome measures.
  - Data logging of device use
  - Soundfield aided narrowband signal thresholds – better ear plugged
  - Soundfield aided speech reception thresholds – better ear plugged
  - Word recognition ability using PBK words and speech shaped noise at +5dB SNRfor soft at 35, 45, and 55 dB for speech front, noise front (0º/0º azimuth)

- Aim 3a

Pediatric unilateral conductive hearing loss patients who are between the ages of 2 and17 years of age and are currently managed by the UMEI with a bone conduction device attached to a softband will be enrolled for study. Subjects will be given the ADHEAR bone conduction system on trial for 2 weeks ± 90 days. Subjects will be evaluated over 2 experimental visits.
  - VISIT 1: Assessment of subject's bone conduction device on the headband and initiation of ADHEAR trial
    - Prior to dispensing of the experimental system, function of the subjects current bone conduction device will be verified.
    - Subjective measures will be administered to determine benefit and satisfaction with the subject's own device on the headband.
    - Subjects will undergo behavioral measures of benefit with own bone conduction device on a headband
    - Subjects will be provided ADHEAR bone conduction hearing system
  - VISIT 2:
    - Subjective measures will be administered to determine benefit and satisfaction with the ADHEAR bone conduction hearing system
    - Subjects will undergo behavioral measures of benefit with ADHEAR bone conduction hearing system
    - ADHEAR system will be returned to the research site upon completion of the trial

<u>Objective and behavioral outcome measures unilateral conductive hearing loss subjects:</u>
  - Data logging of device use (parent and subject report)
  - Soundfield aided narrowband signal thresholds – better ear plugged
  - Soundfield aided Ling thresholds – better ear plugged using the DSLio - Ling 6(HL) test (v2.0) which provides calibrated, pre-recorded Ling 6 sounds (m, u, a,i, sh, s) for use in measuring unaided or aided thresholds.
  - Soundfield aided speech reception thresholds using Calibrated and pre-recorded Auditec Spondee lists– better ear plugged
  - Word recognition ability using the Auditec Inc PBK-50 words. The majority of subjects enrolled are expected to be between the ages of 3 and 7 and the PBK word list offers the most age appropriate assessment of word recognition ability for this age group, while also allowing for accurate assessment of audibility in older children under aided condition. In those children who are not able to repeat words reliably, a detection

task will be conducted. Tests will be conducted in the soundfield with the better ear plugged for soft (35 dB) and average (50 dB) speech inputs at speech front, noise front (0º/0º azimuth)

- Aim 3b
  Pediatric bilateral conductive hearing loss patients who are between the ages of 2 and 17 years of age and are currently managed by the UMEI with a bone conduction device attached to a softband will be enrolled for study. Subjects will be given the ADHEAR bone conduction system on trial for 4 weeks ± 7 days. Subjects will be evaluated over 3-4 experimental visits.
    - VISIT 1: Assessment of subject's bone conduction device on softband and initiation of ADHEAR trial
      - Prior to dispensing of the experimental system, function of the subject's current bone conduction device will be verified.
      - Subjective measures will be administered to determine benefit and satisfaction with the subject's own device on the softband.
      - Subjects will undergo behavioral measures of benefit with own bone conduction device on a softband. It is anticipated that the majority of bilateral conductive hearing loss subjects will be unilaterally fitted. Subjects will be tested in their everyday listening condition
      - Subjects will be provided ADHEAR bone conduction hearing system unilaterally
      - In those who are bilaterally fit with a bone conduction device, testing will be conducted unilaterally. To maintain the child's everyday listening condition, participants will be fit with 2 ADHEARs (i.e. bilateral). T
    - VISIT 2 (2 weeks ± 90 days):
      - Subjective measures will be administered to determine benefit and satisfaction with the ADHEAR bone conduction hearing system
      - Subjects will undergo behavioral measures of benefit with ADHEAR bone conduction hearing system unilaterally
      - Subjects will be provided ADHEAR bone conduction hearing system bilaterally
      - In those who are bilaterally fit at time of enrollment, testing will be conducted bilaterally with the ADHEARs, and trial will discontinue.
    - VISIT 3 (4 weeks ± 90 days):
      - Subjective measures will be administered to determine benefit andsatisfaction with the ADHEAR bone conduction hearing system
      - Subjects will undergo behavioral measures of benefit with ADHEARbone conduction hearing system bilaterally
      - Time and subject permitting subjects will be tested in bilateral softband condition, otherwise this will be completed in an additional visit (4)

  <u>Objective and behavioral outcome measures bilateral conductive hearing loss subjects:</u>
    - Data logging of device use (parent and subject report)
    - Soundfield aided narrowband signal thresholds bilaterally aided
    - Soundfield aided Ling thresholds using the DSLio - Ling 6(HL) test (v2.0) which provides calibrated, pre-recorded Ling 6 sounds (m, u, a, i, sh, s) for use in measuring unaided or aided thresholds.
    - Soundfield aided speech reception thresholds
    - Word recognition ability using the Auditec Inc PBK-50 words under bilaterally aided conditions. Tests will be conducted in the soundfield with the better earplugged for

soft (35 dB) and average (50 dB) speech inputs at speech front, noise front (0º/0º azimuth)

Subjective outcome measures
In light of COVID-19 restrictions, the subjective questionnaires will be collected over the phone given that the subjects and/or guardian cannot come into the clinic. A verbal addendum will be read to the participant(s) over the phone to confirm they agree with the new changes. The questionnaires will be administered after participant gives verbal consent.

Subjective questionnaires (included in this submission) will be administered prior to andat the end of each phase to the subject. A parent proxy of the subjects questionnaire will also be administered to the subjects guardian to gauge parent/guardian perception of benefit with bone conduction technology. These subjective questionnaires will be given pre- and post-evaluation to both the subject and his/her guardian in order to determine the impact of bone conduction technology on subject and guardian perceptions of benefit. The pediatric questionnaire uses images to help ensure the child understands the response choices. Additionally both the child and the guardian will fill out the questionnaire with a study team member present so that they may ask for clarification if/when necessary. For the pediatric questionnaire 2 practice questions are included to ensure the child understands the question and response format and is capable of completing the questionnaire reliably. Note that the questionnaire given prior to assignment of a device will inlcude only questions 1 - 15 for the guardian version and only questions 1 - 18 for the pediatric version since the remaining questions are device-specific. The unabridged full version of the questionnaire will beadministered at both the end of phase 1 and phase 2.

Data and Specimen Banking*

All the previously described data will be stored on the PI's computer and used for analyses purposes in room 526 of the clinical research building at the University of Miami Medical Center located at 1120 NW 14th street, 5th Floor, Miami FL, 33136. It will be password protected, and unique identifiers used forsubject protection. Data will not be distributed, except in the form of peer- reviewed publication or oral presentation maintain the confidentiality of the subjects.

Data Management*

Data to collected includes: Gender, age, language, etiology and type of hearing loss, treatment ear, audiometric data including thresholds and speech outcomes, prior hearingtreatment, date of activation or device use, aided thresholds, aided speech in noise performance, hours of device use, and subjective outcomes (see questionnaires included).

All the previously described data will be stored on the PI's computer and used for analysespurposes in room 526 of the clinical research building at the University of Miami MedicalCenter located at 1120 NW 14th street, 5th Floor, Miami FL, 33136. It will be password protected, and unique identifiers will be used for subject protection. Descriptive statistics will be used to report demographic (e.g. age and

gender) data. Quantitative data will be presented as mean, standard deviation (SD) and range (minimum and maximum); qualitative data will be presented as frequencies and percentages. Inferential statistics will be applied to detect differences in speech in noise performance as a function of transcranial attenuation. For this purpose, parametric Student's t-tests or nonparametricWilcoxon signed rank tests will be performed, depending on the data distribution. Statistical significance will be set to $p<0.05$. The subjective questionnaires will be summarized by visit using descriptive summaries. For numeric measures the change frombaseline will be calculated and inferential tests applied. For categorical measures, a shift from baseline will be presented demonstrating the subjects as being better, the same, or worse.

Risks to Subjects*

The risks to the subjects will be minimal. At most, a breach of confidentiality composes the majority of the risk. We will take extensive measures to protect confidentiality and toensure data security.

The proposed device, Adhear (MEDEL Corp.) is now FDA approved. (see attached correspondence). Further the application for use is compatible with the currently marketed headband bone anchored device (see 510k #K002913 https://510k.directory/clearances/K002913) and the processor is compatible with currentapproved processors (see 510k's K090720 https://510k.directory/clearances/K090720 , K132278 https://510k.directory/clearances/K132278 , K110996 https://510k.directory/clearances/K110996 , K161123 https://510k.directory/clearances/K161123 , K100360 https://510k.directory/clearances/K100360) and presents no new concerns about safetyand effectiveness. The novel component to Adhear is the long-wear adhesive which provides an aesthetically appealing alternative to the use of a headband with virtually nodiscomfort. Use of the headband applies a constant pressure to the bone and skin which can lead to indentation of the skin and discomfort (van der Pouw et al., 1999). Long-wearmedical grade adhesives have wide range application and have been shown to be safe forover-the-counter use for such applications as would care dressing, skin-bonded monitoring devices, drug or therapeutic delivery systems, transdermal patches, etc.
Because of their widespread commercial use, we do not anticipate any increased risk overthat which is reasonably expected in the general population for use of such adhesives. Wewill take extra precautions to reduce any risk by excluding subjects who report a known skin sensitivity or allergen to adhesives. Further, we will enforce strict adherence to manufacturer specifications for use of the long-wear adhesive.

Potential Benefits to Subjects*

The present study has the potential to benefit the included subject directly as well as future patients undergoing treatment for conductive hearing loss or single sided deafness. Children and their guardians who enroll in aim 3 of this study may directly benefit from the anticipated increased adoption and acceptance of this technology over current BAI systems. In the long term, sucha solution may provide a long-term non-surgical solution for both children andadults. Therefore, patients may benefit from the investigation and findings contained within. The data generated from this investigation will help audiologists and otolaryngologists determine the benefits and limitations to non-invasive alternatives to traditional BAIs.

Vulnerable Populations*

The study will include children.

Setting

The study will take place in the Department of Otolaryngology for patients seenin the Department of Otolaryngology for BAI services.

Resources Available

The PI and Co-investigators are well qualified to perform the described study protocol. We have an established clinic with a long history of evaluation and management of individuals who use BAIs. Further, the PI has an established research profile resulting in peer-reviewed publication on the described topic.The Department of Otolaryngology has 2 study coordinators to assist in management of study procedures.

Prior Approvals

N/A

Recruitment Methods

For Aims 1&2 the medical records of patients who received a bone conduction hearing device follow-up between January 1, 2010 through September 23, 2021 will be retrospectively reviewed. We anticipate review of approximately 500 medical records. Demographic data for review include gender, age, primary spoken language, etiology. Standard clinical hearing outcome data will be reviewed for both groups and will include audiometric thresholds, word recognition ability, speech perception measures. This information will be used to determine study candidates. Those who meet the inclusion criterion will be contacted for study participation. Potential subjects will be contacted by phone and/or email to participate (see attachment). Once we have received a minimum of 10 but no greater than 30 participants for each study group, retrospective review will be completed and no new charts will be accessed. Participants will then only be studied prospectively. Demographic and audiometric data will be maintained under a unique identifier code linked to the consented study participant for reference to study outcome data.

For Aim 3, pediatric patients who spontaneously present to the clinic for BAI evaluation with their guardian and meet inclusion criteria will be informed of the study. If the patient and the guardian express interest the study purpose, procedures, benefits, limitations, duration, voluntary nature, costs, and risks willbe explained in detail. Children over the age of seven will assent participation. We will provide information about the study in a language understandable to the participant, answer all questions in terms understandable to the child, use written and verbal explanations, and obtain voluntary agreement to participate.The assent document will be written in language at an appropriate level of readability.
Subjects for Aim 3 will also be recruited by flyer or email advertisement. Flyers will be posted at the following locations:

University of Miami at the Clinical Research Building, UHealth Plantation, UHealth Boca, UHealth Palm Beach, UHealth Lennar and Miami Children’s Hospital Division of Audiology.

Potential subjects will also be identified through the UMiamiHealthResearch.org platform. On the UMiamiHealthResearch.org platform, potential subjects will be able to contact the study team if they are interested in participating in the study. A study team member will then follow-up with the potential subject via telephone or email to determine interest and eligibility for the study (see "Script for Screening Phone Call").

There is no financial compensation for participation in this study.

Local Number of Subjects

60

Confidentiality

To ensure confidentiality of the information shared with the investigative team, all information pertaining to a subject will be given a coded number. All data will be stored under this code number and not the subject's name. Records which link subjects' identification with their code number will be kept in a locked file on a password protected computer that only the PI has access to and stored separately from the subject data. All computer files that include study data will be stored on a computer with password security and only IRB approved individuals will have access to these codes. The investigator and her co-investigators will consider these records confidential to the extent permitted by law. Identifiable records and results will not be included in any publication, and collected data will not be used in any other studies without a subject's expressed permission.

Provisions to Protect the Privacy Interests of Subjects

N/A

Consent Process

Due to COVID 19, we also will be consenting remotely. When consenting remotely, we will follow the recommendations provided by both Universityof Miami and the FDA. Potential subjects will be called and/or emailed for recruitment and if agreed to participate, a zoom meeting and/or RedCap econsenting application will be used for the consenting process; a witness will be present in the zoom call. All steps will be documented in the formatattached.

It is possible that while our study is limited to English speaking patients, theparents of some patients included for aim 3 may be non-english speakers. Because only a maximum of 15 subjects will be enrolled for aim 3 it is anticipated that only a small number of subjects (<5) may be enrolled whose guardians will not understand English. Based on population data for Miami-Dade, we expect this to be limited to Spanish speakers. For those participants all required documents will be translated into Spanish. Furthera native Spanish speaker and certified medical translator will be present forconsent and all test sessions.

When determining whether a child is capable of assenting, the ages, maturity, and psychological state of the child will be taken into account. ThePI will consider the child's experience and level of understanding, ensure the child is cooperative and agreeable to participation, and ensure the child's

rights are maintained. As with adult consents, assent will be conducted in a manner and location that ensures participant privacy, Givingadequate information about the study in a language understandable to the participant, Providing adequate opportunity for the participant to consider all options, Responding to the participant's questions, Ensuring the participant has understood the information provided, Obtaining the participant's voluntary agreement to participate, and Continuing to provide information as the participant or research requires.

Process to Document Consent in Writing

N/A

Authorization for Use and Disclosure of Protected Health Information (HIPAA)

Type of Request:
Waiver of Authorization (to waive the requirement for signature and date) approved due to current COVID-19 pandemic.

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity. ☒ ***I confirm***

Confirm that the Protected Health Inform (PHI) you acquire from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

☒ ***I confirm***