[redacted]

TITLE PAGE

Information Type: Clinical Protocol

Title:	Smartphone Enabled Hearing Study

Development Phase:	Clinical Validation
Protocol Number:	099-37012
Version:	[redacted]
Effective Date:	May 24, 2023

Version	Date	Significant Revisions
[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

		[redacted]

		[redacted]

INVESTIGATOR'S CIP SIGNATURE PAGE

Protocol Title: **Hearing Data Collection Study**

I confirm that I have read and understood this Clinical Investigation Plan (CIP) and attached appendices and will conduct this study in compliance with the CIP, all statements regarding confidentiality, local regulations, International Council for Harmonization Good Clinical Practice E6 (ICH-GCP), and United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (21 CFR Parts 50 [Protection of Human Subjects], 54 [Financial Disclosure by Clinical Investigators], 56 [Informed consent and Institutional Review Board (IRB) requirements], 45 CFR Part 46 [Protection of Human Subjects]), ISO 14155 [Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice].

With my signature, I agree to:
(i) Conduct the investigation in accordance with the agreement, the clinical investigational plan, applicable provisions of and other Food and Drug Administration (FDA) regulations, and conditions of approval imposed by the reviewing IRB or FDA;
(ii) Supervise all testing of the device involving human subjects; and
(iii) Ensure that the requirements for obtaining informed consent are met.

Reviewed and Approved by:

_____
Printed Name of Investigator

_____
Signature of Investigator

_____
Date

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[redacted]

STUDY, SPONSOR, AND SITE INFORMATION PAGE

Title	Smartphone Enabled Hearing Study
Sponsor	Apple Inc. [redacted]
Sponsor Medical Monitor	[redacted]
Principal Investigator	[redacted] IQVIA RDS Inc [redacted]
Protocol Number	099-37012
Version	[redacted]
Protocol Date	May 22, 2023

List of Abbreviations

Abbreviation	Definition
4PTA	Pure Tone Audiometry (equivalent air conduction audiometry) average of four hearing level frequencies (0.5, 1, 2, and 4 kHz)
ACHIEVE	Aging and Cognitive Health Evaluation in Elders
AE	Adverse Event
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
COVID-19	Coronavirus Disease 2019
DII	Directly Identifiable Information
GCP	Good Clinical Practices
HL	Hearing Level
I/E	Inclusion/Exclusion
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ID	Identifier
IOI-HA	International Outcome Inventory for Hearing Aids
IRB	Institutional Review Board
MAD	Mean Absolute Deviation
PI	Principal Investigator
PF	Professional-Fitted
PTA	Pure Tone Audiometry (equivalent to air conduction audiometry)
QC	Quality Control
SAE	Serious Adverse Event
SBHT	Software-Based Hearing Test
SF	Self-Fitted
SIN	Speech-In-Noise Audiometry
SR	Significant Risk

[redacted]

1. Protocol Synopsis

1.1. Title of Study

Smartphone Enabled Hearing Study

1.2. Study Sponsor

Apple Inc.

1.3. Study Period

Approximately up to 1 year after IRB approval.

1.4. Study Design

A prospective, multi-center, non-significant risk study.

1.5. Study Objectives

1.5.1. Primary Objectives

Assess subjective non-inferiority in user-perceived benefit between a Self-Fitted (SF) (tuned) hearing assist settings group and a Professionally-Fitted (PF) (tuned) hearing assist settings group in participants with perceived or measured mild-to-moderate hearing loss.

1.5.2. Exploratory Objectives

Assess objective improvement in hearing between a SF (tuned) hearing assist settings group and a PF (tuned) hearing assist settings group in participants with perceived or measured mild-to-moderate hearing loss.

1.6. Study Size

Preceding the start of the clinical validation study, approximately [redacted] participants will be enrolled into a sub-study cohort. These participants will follow the same study procedures outlined in this protocol. After the completion of the sub-study, the clinical validation study will commence. This sub-study is primarily intended to provide assurance that all of the data collection, evaluation, and data transfer tools are performing as intended prior to the start of the clinical validation study. As such, these participants are a separate cohort and will not be included in any of the endpoint analyses for the pivotal study.

[redacted]

Clinical Validation Study: Approximately 112 participants will be enrolled

Sub-Study: Approximately [redacted] participants will be enrolled

1.7. Study Environment

Special consideration will be made to mitigate risk of exposure and transmission of COVID-19 (coronavirus disease 2019) to the Study Staff and participants.

This study includes at-least four in-person (one screening and three in-clinic) scheduled visits. Study time between visits can be conducted from participants' homes.

1.8. Target Population and Stratification

Adult participants ages 18 years and over may enroll in this study upon satisfying the Inclusion/Exclusion criteria outlined in sections 4.2 and 4.3. Binning minimums are based on the number of participants enrolled, not the number of usable datasets.

The minimum recruitment targets for the study population are outlined in section 4.2.

1.9. Inclusion Criteria

Please see section 4.3.

1.10. Exclusion Criteria

Please see section 4.4.

1.11. COVID-19 Specific Criteria

Please see section 4.5

1.12. Study Overview

This study is designed to assess subjective improvement in hearing perceived by participants with mild- to moderate- hearing loss between an SF (tuned) hearing assist settings group and industry standard NAL-NL2 PF (tuned) hearing assist settings group [2]. An additional objective is to assess objective improvement in hearing between groups.

1.13. Study Design

Prior to enrollment, all participants will have an examination of the ears by an audiologist using PTA reference testing to assess for any contraindications to proceeding. PTA will include the NAL-NL2 PF algorithm assessment [2]. Participants with >60 dB HL at 0.25-3kHz and >65 dB HL at 4kHz in either ear will not be invited to continue in the Clinical Validation Study. Following the enrollment process, participants will be randomized to the SF group or the PF group.

On *Clinic Visit 1*, enrolled participants will be provided with wireless headphones and a smartphone for use throughout the study. Those in the SF group will have software assisted self-tuning of their wireless headphones and may further fine-tune to preference. Those in the PF group will have settings selected by an audiologist who may further fine-tune as guided by participant interaction. Participants will leave clinic for *Home Interval 1* and return after 3-8 days of wearing the headphones in their routine environment to guide fine-tuning settings by self or audiologist on *Clinic Visit 2*. This second clinic visit will additionally include Real Ear measures with headphones *in situ*, and unaided baseline SIN testing. Participants will leave for *Home Interval 2* for 14-22 days of continued headphone use in their routine environment and will be advised to adjust settings with their software based on preference. Upon returning for final visit on *Clinic Visit 3*, participants will complete the IOI-HA survey, have final Real Ear measures with headphones *in situ*, and complete aided SIN testing with their tuned headphones *in situ*. Finally, participants will return all devices and offboard from the study.

1.14. Protocol Duration

Participation is approximately 18-31 days upon enrollment.

1.15. Study Duration

Approximately 5 months

1.16. End-of-Study Definition

Unless a participant withdraws, is withdrawn, or is lost to follow-up during participation, the end of study is defined as the completion of all study visits associated with their enrollment group. This is a total of at least four in-person (one screening and three in-clinic) visits.

1.17 Study Procedure Stopping Criteria

There are no prespecified stopping criteria, as there are no treatment interventions in this study. A participant may withdraw from the study at any time. The Sponsor will be notified of withdrawal. Data obtained up until withdrawal may be used. A participant may be asked to or the study team may terminate participation if they cannot comply with the procedures outlined in the Protocol.

1.18 Criteria for Study Termination

The Sponsor and the investigators reserve the right to terminate the study or participation in the study, respectively, at any time. Both parties will arrange discontinuation procedures. In terminating the study, the Sponsor and the investigators will assure that adequate consideration is given to the protection of the subjects' interests.

The Sponsor reserves the right to discontinue the study at any time for medical or administrative reasons. When feasible, a 30-day written notification will be given.
The entire study will be stopped if:

- Evidence has emerged that, in the opinion of the Sponsor or the investigator(s), makes the continuation of the study unnecessary or unethical.
- The stated objectives of the study are achieved.
- The development of the study device is discontinued.
- Determined appropriate per Sponsor's discretion.

Regardless of the reason for termination, all data available for subjects at the time of discontinuation of follow up must be recorded on the eCRF. All reasons for discontinuation of treatment study participation must be documented.

2. Introduction

2.1. Background

Hearing loss is the third most common chronic health condition, affecting nearly a quarter of Americans [4,5]. Age-related hearing loss is the most common cause and progresses over years from *mild* (26-40 dB hearing level [HL]) to, in increasing disability categories by 20 dB steps, *profound* (81 dB HL or greater)

[1,4,5]. The majority of those affected have mild hearing loss, though individuals with normal range hearing, and those with unilateral hearing losses with normal hearing in their better ear, may also experience hearing problems [1,5]. Hearing loss is associated with significant comorbidities, including loneliness and social isolation [6]. Untreated hearing loss is associated with greater incident morbidity than no hearing loss across a range of health conditions, including dementia, depression, falls, and cardiovascular disease [7,8].

These comorbidities may occur many years before intervention for hearing loss, including in the mild -to -moderate hearing loss range where disability may be perceived as subtle [9]. This delay in intervention may be related in part to an access issue, as current standard is referral to an audiology clinic for testing and subsequent fitting for a hearing aid, which may occur over many months at significant cost in most regions of the United States [9]. This is related in-part to limited availability of audiologists and high volume of referrals. This supply and demand ratio is expected to negatively compound with the recent CDC (Centers for Disease Control and Prevention) recommendation for annual hearing screen for all adults with diabetes (11.3% of the US population) [10,11].

2.2. Rationale

Most who would benefit from aided hearing do not seek intervention, in part due to challenges with hearing aids after discovery. Hearing aid adoption rate is poor at approximately 33%, with a reported range of 10 or more years after initial diagnosis to time of first hearing aid fitting [9,12]. Reasons for this delay in care may include cost, stigma, and ease of use [9]. Delays in hearing aid may contribute to the comorbidities associated with the condition. The Aging and Cognitive Health Evaluation in Elders (ACHIEVE) trial was designed to assess for cognitive benefit in hearing loss intervention in an elderly population; findings are expected in 2023. In the pilot cohort, mental activity engagement increased in the hearing intervention group and decreased in the successful aging education intervention group that did not focus on improving hearing [13].

There is need for earlier and more efficient screening and intervention options with lower user barrier for adults with hearing problems. Here we propose a study to support decreased burden for hearing aid by smartphone enabled software settings for widely available wireless headphones.

2.3. Study Objectives

2.3.1. Primary Objective

Primary Objective	**Procedure Measures**
Assess subjective non-inferiority in user -perceived benefit between a Self-Fitted (tuned) hearing assist settings group and a Professionally-Fitted (tuned) hearing assist settings group in participants with perceived or measured mild to moderate hearing loss.	***Clinic Visit 1*** Following enrollment, participants will be randomly assigned into 2 independent groups (SF or PF). The software enabled hearing aid algorithm will be used in SF group, and the audiologist best practice algorithm will direct baseline hearing aid settings in PF group.

	Home Interval 1 During daily activities, participants will observe strengths and weaknesses of their hearing aid settings to guide/inform subsequent fine-tuning in clinic. Participants have the option to make setting adjustments during this interval for listening needs and/or to avoid discomfort. ***Clinic Visit 2*** Real Ear measures will follow fine-tuning in both groups. Specifically, a probe microphone will be placed in the ear canal by an expert with headphones *in situ* to assess the precise level of amplification at every frequency and at different input levels. These measurements assess the frequency-level dependent gain that a given ear receives relative to the acoustic targets defined for a chosen fitting formula (i.e., NAL-NL2 [National Acoustic Laboratories for prescribing nonlinear gain]). Participants in both groups will have baseline unaided Speech-In-Noise (SIN) objective assessment to gauge independent ability in these primary aspects of hearing. ***Home Interval 2*** Participants will return to their baseline environmental exposures for at least 14 days with ability to adjust settings within parameters to optimize their settings. ***Clinic Visit 3*** When participants return for the final clinic day, they will complete the IOI-HA survey, have final Real Ear measures with headphones *in situ* to assess changes after field adjustments, and participate in aided SIN testing.

2.3.2. Exploratory Objectives

Exploratory Objectives	**Procedure Measures**
Assess objective improvement in hearing between a SF (tuned) hearing assist settings	See Primary Objective (Section 2.3.1) for detailed Participant variables. The outcome measures

group and a PF (tuned) hearing assist settings group in participants with perceived or measured mild- to moderate- hearing loss.	associated with the exploratory objectives are Real Ear measures and SIN.

3. Study Design

3.1. Overview

This is a prospective intervention-based study that will involve data collection from individuals with measured or perceived mild-to-moderate hearing loss. This study is deemed to meet the qualifications of a research study with non-significant risk.

The study includes in-clinic data collection, and data collected in a participant's- home environment or when completing daily activities.

After a screening visit, the study will involve at least three clinic visits to obtain a smartphone and wireless headphones, in-clinic assessment and measures, survey data, and two home intervals for optimization of hearing assist settings.

3.1.1. The Sub-Study Cohort

Preceding the start of the clinical validation study, a smaller group of participants will be enrolled into a sub-study [redacted]. These participants will follow similar study procedures outlined in this protocol. After the completion of the sub-study, the clinical validation study will commence at a later date. This sub-study is intended to provide assurance that all of the data collection, evaluation, and data transfer tools are performing as intended prior to the start of the clinical validation study or reveal unanticipated aspects of the study. As such, these participants are a separate cohort and will not be included in any of the endpoint analyses for the pivotal study.

3.2. Study Procedures

Participants will have a screening visit and up to three scheduled clinic visits interspersed by two home intervals. The participants enrolled into the sub-study cohort will follow similar study procedures:

- ***Screening Visit (~2 hours):*** informed consent, potential Pure Tone Audiometry (air conduction audiometry), medical history, and brief physical exam of the ears conducted by site clinician; time from Screening Visit to Clinic Visit 1 will be no longer than 3 weeks
- ***Clinic Visit 1 (~1.5 hour):*** examination of the ears by an audiologist who may remove ear wax if deemed required and consented to by participants, bone conduction audiometry, tympanometry, Pure Tone Audiometry (air conduction audiometry), enrollment, and baseline hearing assist software settings
- ***Home Interval 1 (3-8 days; begins on same day as Clinic Visit 1)*:** observations of baseline hearing assist software settings during participant's daily activities, Participants have the option to make setting adjustments during this interval for listening needs and/or to avoid discomfort, regular charging of study devices, and encouraged daily use of devices. Participants who have no evidence of at least daily use for several days will be contacted by study staff to assess for troubleshooting needs. Minimum expected wear time is at least 30 minutes per day for at least 3 days during this interval.
- ***Clinic Visit 2* (*~1.5 hours):*** examination of the ears by an audiologist who may remove ear wax if deemed required and consented to by participants, hearing assist software setting fine-tuning, Real Ear measures, and SIN objective hearing test
- ***Home Interval 2 (14-22 days; begins on same day as Clinic Visit 2):*** fine-tuning of hearing aid settings during participant's daily activities, regular charging of study devices, and encouraged daily use of devices. Participants who have no evidence of at least daily use for several days will be contacted by study staff to assess for troubleshooting needs. Minimum expected wear time is at least 30 minutes per day for at least 14 days during this interval.
- ***Clinic Visit 3 (~1-2 hours):*** examination of the ears by an audiologist who may remove ear wax if deemed required and consented to by participants, IOI-HA survey, Real Ear measures, SIN objective hearing test, and end of study items
- Participants may be asked to complete additional study procedures due to unforeseen circumstances such as replacing study equipment due to loss, theft, or damage.

4. Study Population

4.1. Geographic Location and Study Site

Study visits to be completed at in-clinic sites located in the United States.

4.2. Target Number and Distribution of Participants

Adult participants ages 18 years and over may enter into this study upon satisfying the Inclusion/Exclusion criteria in Sections 4.3 and 4.4.

[redacted]

Clinical Validation Study

Approximately 112 participants will be enrolled in the clinical validation study to achieve minimum 90 useable data sets. The following details outline the demographic minimum recruitment targets for the clinical validation study population:

- At least 37 enrolled participants with female sex assigned at birth
- At least 45 enrolled participants should be <60 years of age

The minimum recruitment targets for categories of hearing loss are based upon the four pure-tone average (4PTA), which is the average of hearing levels measured at of 0.5, 1, 2, and 4 kHz, as measured in the ear with least hearing loss. The minimum recruitment targets for categories of hearing loss are as follows:

- Approximately 12 enrolled participants with No Impairment (4PTA: 15-25 dB HL) and perceived hearing loss where degree of hearing impairment is determined by the ear with least hearing loss.
- Approximately 37 enrolled participants with Mild hearing loss (4PTA: 26-40 dB HL) where degree of hearing impairment is determined by the ear with least hearing loss.
- Approximately 37 enrolled participants with Moderate hearing loss (4PTA: 41-60 dB HL) where degree of hearing impairment is determined by the ear with least hearing loss.

Sub-Study:
Approximately [redacted] participants will be enrolled in the Sub-Study and in the bins below:

- Approximately 10 enrolled participants with female sex assigned at birth
- Approximately 12 enrolled participants should be <60 years of age
- Approximately 3 enrolled participants with No Impairment (4PTA: 15-19 dB HL) and perceived hearing loss where degree of hearing impairment is determined by the ear with least hearing loss.
- Approximately 10 enrolled participants with Mild hearing loss (4PTA: 20-34 dB HL) where degree of hearing impairment is determined by the ear with least hearing loss.
- Approximately 10 enrolled participants with Moderate hearing loss (4PTA: 35-49 dB HL) where degree of hearing impairment is determined by the ear with least hearing loss.

4.3. Participant Inclusion Criteria

Study participants must satisfy the following criteria to be enrolled in the study:

- Age ≥ 18 years
- Proficient in written and spoken English, defined by self-report
- Mild- to moderate- hearing loss as measured by pure tone audiometry (PTA) reference test, or self-report of perceived hearing loss and 15-25 dB HL (by 4PTA)
- Participants have access to stable internet connection

4.4. Participant Exclusion Criteria

Study participants who meet any of the following criteria will be excluded from participating in the study:

- Ear anatomy non-conducive to comfortable wear of headphone
- Active ear disease
- Cerumen impaction that cannot be removed
- Sudden loss of hearing (in the preceding 90 days), defined by self-report
- Self-report of loud environmental sound exposure (e.g., concert; construction site; fireworks) without hearing protection within 72 hours of reference PTA assessed at Clinic Visit 1
- Tinnitus that impacts one's daily life, defined by self-report
- Use of cochlear implants
- Self-reported issues with small or confined spaces such as a single-person enclosed booth, and/or claustrophobia
- Health technology, fitness, media outlet employees (or spouse of employees), or employees of CRO/sites contracted to execute this study
- User noted preference to not wear headphone consistently, or charge headphone and smartphone consistently, during field-use
- Hearing loss >60 dB HL at 0.25-3kHz and >65 dB HL at 4kHz in either ear; assessed during PTA
- Hearing loss that requires electroacoustic settings which are not acoustically stable in the participant's ear per audiologist judgement
- Current regular use of hearing aids
- Active treatment, or treatment in the past 6 months, with either a chemotherapeutic drug for cancer, or radiation therapy to the head or neck region
- Active treatment, or treatment in the past 6 months, with parenteral aminoglycoside antibiotics
- In the Investigator's opinion, unable to adhere to study procedures

4.5. COVID-19 Specific Criteria

Apple takes the health and well-being of its study teams and study subjects very seriously. As a result, Apple has worked to take precautionary measures against the spread of COVID-19. Participants agree to comply with the applicable safety protocols.

Despite the precautionary measures taken to reduce the risk of transmission, it is not possible to guarantee that COVID-19 will not be spread during the Study through the equipment provided to participants or at the Study site (as applicable).

4.6. Recruitment Timeline and Recruitment Method

Recruitment for the study will begin prior to the first scheduled screening visit to allow adequate time to support screening throughput.

Potential participants will be provided a general description of the study, basic study eligibility criteria, and the Study Staff's contact information. Interested participants will contact the Study Staff directly to begin the study screening process and determine eligibility.

4.7. Participant Enrollment

Before any study specific procedures are performed, informed consent will be obtained from each potential study participant:

Each participant who is screened for the research study will be assigned a unique participant identifier.

Randomization:

- Following the enrollment process, participants will be randomized into either SF or PF groups, so that approximately half of the useable datasets will derive from each group.

4.8. Participant Discontinuation

A participant may voluntarily withdraw from the study for any reason, at any time. A participant may be discontinued from the study in any of the following circumstances:

- Any adverse event (AE) that renders the participant ineligible or in the opinion of the principal investigator (PI), makes it not in the best interest of the participant to continue participation.
- After enrollment, if a participant does not meet the inclusion/exclusion criteria of the study (either newly developed or not previously recognized).
- Protocol violation that renders data to be unusable or of questionable accuracy, in accordance with the Data Management and Quality Plan.
- Lost-to-follow up; unable to contact participant.
- Termination of the study by the PI or Sponsor.
- Withdrawal of consent: a research participant may withdraw from participation for any reason at any time.
- Loss of two study-provided devices (smartphone and/or wireless headphone(s) or case).
- PI discretion.

A participant who develops active ear disease (e.g., otitis media; otitis externa; acute tinnitus), even if unilateral, may be withdrawn per PI discretion from participation.

If a participant reports loud environmental sound exposure (e.g., concert; construction site; fireworks) during participation, this should be recorded as it may contextualize setting changes by the participant.

The PI or designee(s) will advise the discontinuation of any participant. Participants who discontinue or are discontinued should be compensated for the study visits they have completed, according to the compensation information in the Informed Consent Form (ICF).

In the event of a participant withdrawal, coded participant data that was previously recorded may be retained and used in accordance with the protocol and ICF. Participants who withdraw from the study must return certain study equipment and materials.

The reason for participant withdrawal from the study will be documented in the relevant tracking database(s). The PI or designee(s) will inform the participant of the reason for withdrawal, as well as recommend steps for seeking additional care from their physician, when applicable.

4.9. Lost to Follow-up

A participant will be considered lost to follow-up if the Study Staff are unable to contact the participant after 3 failed attempts for study assessments.

Participants who do not complete study visits during the assessment windows will be handled on a case-by-case basis.

The following actions will be taken if a participant fails to respond to the Study Staff to schedule a required study visit:

- The Study Staff will attempt to contact the participant, reschedule the missed visit, counsel the participant on the importance of maintaining the assigned visit schedule, and ascertain if the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the PI or designee(s) will make reasonable effort to regain contact with the participant (where possible, telephone calls/emails). These contact attempts will be documented in study tracking database(s).
- Should the participant continue to be unreachable, he/she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

4.10. Participant Operational Definitions

A Screened Participant is one who has signed an ICF. An Enrolled Subject is one who signs the ICF and meets all of the inclusion criteria and none of the exclusion criteria. A Completed Subject is defined as one who has satisfactorily completed all study visits outlined in the protocol. A Usable Dataset is defined as a dataset that meets all of Sponsor's data requirements (i.e., complete study endpoint data from a subject to enable inclusion in the analysis).

[redacted]

5. Study Materials

5.1. Devices

The devices utilized for this study do not meet the definition of a significant risk (SR) device under 21 CFR 812.3(m). Therefore, the study can be classified as a Non-Significant Risk device study:

Does the investigational device meet the definition of an SR device under 21 CFR 812.3(m)?	**Yes/No**
Is it intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a participant?	No
Is it purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant?	No
Is it for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a participant?	No
Does it otherwise present a potential for serious risk to the health, safety, or welfare of a participant?	No

5.1.1. Pure Tone Audiometry – [redacted] clinical reference system capable of measuring air conduction thresholds in 1 and/or 2.5 dB steps (0.25, 0.5, 1, 2, 3, 4, 6, 8 kHz). Annual calibration on test system required ahead of study start.

5.1.2. Bone Conduction Audiometry – [redacted] clinical reference system capable of measuring bone conduction thresholds in 2.5 dB steps (0.5, 1, 2, 4 kHz). Annual calibration on test system required ahead of study start.

5.1.3. Tympanometer [redacted] - Diagnostic system capable of performing standard 226 Hz tympanometry. Annual calibration on test system required ahead of study start.

5.1.4. Real Ear measure system

Diagnostic system capable of measuring the frequency-level dependent gain that a given ear receives relative to the acoustic targets defined for a chosen fitting formula (i.e. NAL-NL2 [National Acoustic Laboratories for prescribing nonlinear gain]) This is achieved by placing a probe microphone in the participant's ear canal, after which an expert with headphones in situ will assess the precise level of amplification at every frequency and at different input levels.

5.1.5. Speech-In-Noise (QuickSIN) assessment system

Method of testing a participant's functional hearing ability. The participant's hearing is tested in the presence of background noise.

5.2. Smartphone app

Digital medium through which participants with hearing difficulties will be able to interface with the enabled hearing program.

5.2.1. Self-Tuning in clinic

Hearing aids are fitted by the participants using them. Participants will be randomly sorted into either this group or the Pro-Tuning group.

5.2.2. Pro-Tuning in clinic

Hearing aids are professionally fitted. Participants will be randomly assigned to this group or the Self-Tuning group.

5.2.3. Self-Tuning at home (both groups)

Both groups will be instructed in-clinic on how to modify hearing aid settings to preference during Home Intervals.

5.3. Wireless Headphones

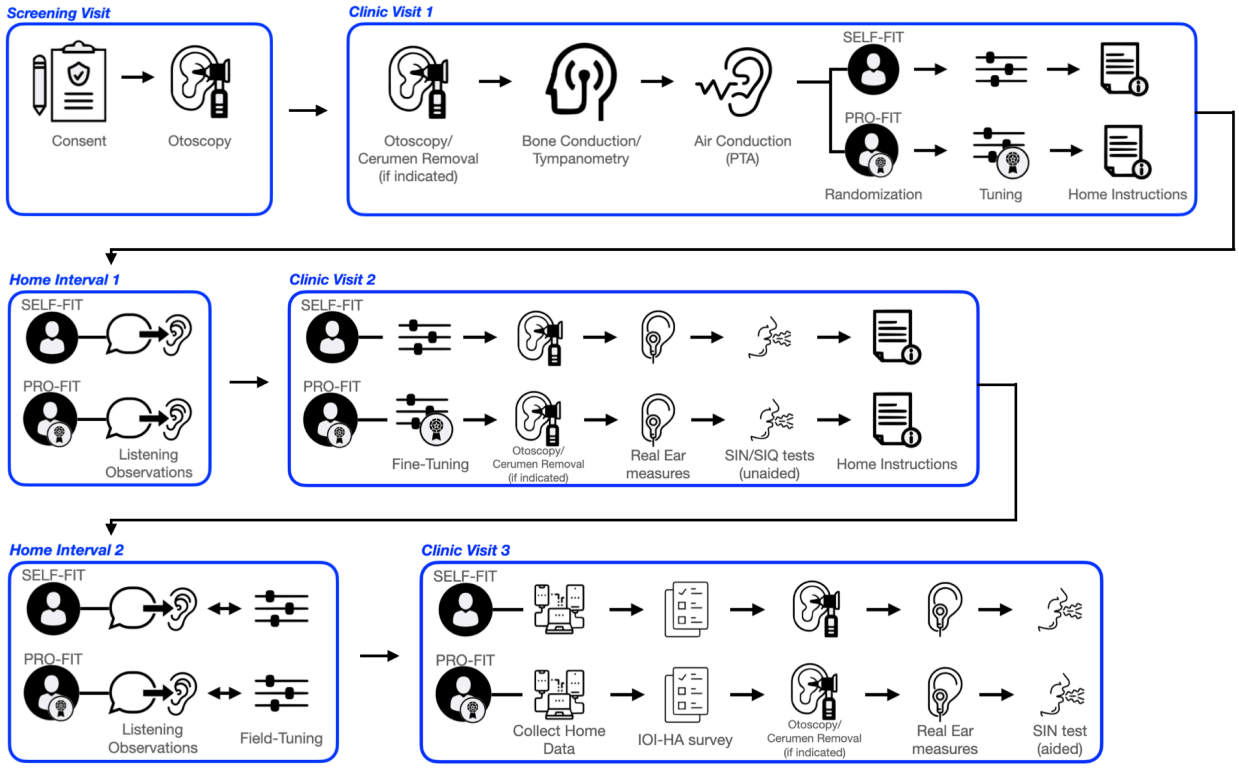
The Sponsor will provide the study site with sufficient quantity of wireless headphones and iPhones to complete the study. Subjects will be instructed to return all equipment at the end of the study.

5.4. Device Accountability

Each participant's study device ID number will be recorded in the study database(s). All study equipment will be returned to the Study Staff at the end of the study.

6. Study Assessments

6.1. Figure 1: Diagram of Study Assessments and Procedures



7. Participant Safety

7.1. Anticipated Risks to Participants

Participants may have risks or discomforts while in this study. Precautions will be taken to minimize risks, and the participant will be encouraged to talk to the Study Staff if he/she experiences any injuries, side effects, or discomfort during this study.

Potential risks and discomforts may include:

- **Previously unknown hearing loss:** Participants may experience symptoms of stress and anxiety related to objective finding of hearing loss. They will have access to the study Audiologist who can address frequently asked questions.
- **Discomfort or injury with ear exam and ear wax removal:** Clinic visits include examination of the ears by an audiologist who may remove ear wax if deemed required and consented to by participant. Some participants may experience discomfort with ear exams. Removal of ear wax is

common in audiology practices and considered safe but does have potential risks of eardrum perforation, a laceration in the ear canal, dizziness, and/or inability to remove ear wax.

- **Discomfort with headphone wear:** Some participants may find it uncomfortable to wear the wireless headphones in *Home Interval 1* and in *Home Interval 2*. If comfort prohibits a participant from this wireless headphone wear, they will be withdrawn from the study.
- **Loss of confidentiality due to study data breach**: To minimize this risk, the Study Staff will adhere to rigorous standards to protect the data. All data collected from participants will be coded and separated from any directly identifiable information (DII). Although the Study Staff will take precautions to protect the participant's identity, such as keeping study records in a secure location with restricted access and removing information traditionally used to identify participants when their study data is shared, we cannot guarantee that their identity will never become known to the Study Sponsor. It is possible that there could be unauthorized access to, or security breaches of, the systems used to store information, and there may be other privacy risks that are not foreseen.
- **Loss of confidentiality related to storing health data on an app:** Participants will be reminded not to share their mobile device login information with others and receive training on best practices on preventing the infiltration of DII into the study app. Only the Study Staff will have access to the primary study crosswalk.
- **Provided device configuration changes:** Participants may make changes to the provided smartphone, either intentionally or inadvertently, that compromises the ability of the study software to function properly. The Study Staff will be available to handle usability issues participants experience during the course of their participation. If the Study Staff notice a gap in the data, they may attempt to contact participants to troubleshoot the problem(s).
- **Discomfort associated with being asked personal questions about health history and the completion of questionnaires:** (Infrequent likelihood of risk) Any participant who becomes distressed while completing questionnaires will be encouraged to seek clarification of any questions that he/she find to be unclear or troubling. The participant may skip any question which he/she finds distressing and will be told that he/she do not have to tell us why he/she are not answering question(s).

7.2. Study Risk Assessment

The devices utilized in this study do not meet the definition of an SR device under 21 CFR 812.3(m) included in device Section 5.1. Therefore, this study can be classified as a Non-Significant Risk device study.

7.3. Adverse Events

7.3.1. Adverse Event Definitions

Adverse Event (AE)

Any untoward medical occurrence in a clinical investigation participant which does not necessarily have to have a causal relationship with the study procedures.

An AE can therefore be any clinically significant sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the study procedures, whether or not considered related to the study procedures.

Any abnormal laboratory findings, abnormal safety assessments, or anticipated day-to-day fluctuations which are associated with a pre-existing disease or condition, are not considered an AE, unless judged by the investigator to be worsening or more severe than expected.

Serious Adverse Event (SAE)

A serious adverse event (SAE) is defined as any AE that is fatal, life-threatening, results in persistent or significant disability, requires medical or surgical intervention to prevent permanent impairment or damage, or results in hospitalization.

Any SAE, including death, due to any cause (related or unrelated to the study or a study device) will be documented on the AE form and will be reported immediately (within 24 hours of learning of the event) by Study Staff to the Sponsor.

7.3.2. Categorization of Adverse Events

The severity of an AE will be categorized as follows:

Mild:	The event is transient, easily tolerated by the participant, and does not affect the participant's daily activities.
Moderate:	The event causes the participant discomfort and interrupts the participant's usual daily activities. May require treatment but not extended hospitalization for the participant.
Severe:	The event is incapacitating, causing inability to do work or usual activities; signs and symptoms may require medical evaluation and/or treatment, and may require additional prolonged hospitalization.

7.3.3. Causal Relationship Assessment

The assessment of causal relationship to study procedures is required for the purposes of reporting AEs. When determining the relationship of study procedures to an AE, to promote consistency, the following guidelines should be taken into consideration, along with good clinical and scientific judgment:

The relationship of each AE to study procedure(s) will be assessed using the following categories:

Probably Related:	There is a strong temporal relationship to the study or device, and an alternative etiology for the AE is unlikely.
Possibly Related:	The event is not readily explained by the participant's medical condition, concomitant therapy, or other causes, and there is a plausible temporal relationship between the event and participation in study procedures.
Probably Not Related:	An event for which an alternative explanation is more likely (e.g., concomitant medications or ongoing medical conditions) or the temporal relationship to study procedures and/or exposure suggests that a causal relationship is unlikely.
Not Related:	An AE that does not follow a reasonable temporal sequence from participating in study procedures and/or that can reasonably be explained by other factors, such as underlying diseases, complications, concomitant drugs, and concurrent treatments.

7.3.4. Anticipated Adverse Device Effects

There are no Anticipated Adverse Device Effects from the provided smartphone or wireless headphones.

The following occurrences are not to be regarded as AEs:

- Hearing symptoms or diseases (including tinnitus)
- Cerumen impaction
- Abnormal audiogram findings
- Complaint about smartphone or comfort of headphones
- Discomfort or injury with ear exams and/or with removal of ear wax
- Study app functionality issues

7.3.5. Unanticipated Adverse Device Effects

An Unanticipated Adverse Device Effect is defined as any serious adverse device effect on health or safety or any life-threatening problem or death caused by or associated with the device that was not previously identified in nature, severity, or degree of incidence in the investigational plan (including the protocol, the ICF, the PI's brochure, or other study-related documents).

7.4. Reporting

7.4.1. Adverse Events

Throughout the entire study period, once participants have signed the ICF, the PI and/or designee(s) will evaluate participants at each study visit, record all AEs (whether or not they are considered to be related to the study procedures), and determine if any AEs are device- or study-related. Signs and symptoms of each AE should be described in detail and include approximate onset time and date, approximate offset time and date, description of event, severity, relationship to study procedures, action taken, outcome,

and (if applicable) the PI's opinion of the causal relationship between the event and the study procedures.

AEs will be collected as reported by participants and reported as observed by study staff. All AEs will be documented on the AE form and will be reported within 10 working days of learning of the event by Study Staff to the Sponsor. If deemed necessary by the Sponsor, the CRO or Study Staff will notify the Institutional Review Board (IRB).

7.4.2. Serious Adverse Events

The IRB will be notified of SAEs as soon as possible and according to current applicable regulations and specific IRB requirements, but in no event later than 10 working days after the PI first learns of the event. The PI will be requested to complete a separate SAE reporting form, in addition to the information in the source documentation. The site study staff should report all SAEs to the Sponsor as soon as possible but no later than 24 hours of becoming aware of the event.

7.4.3. Pregnancy

Pregnancy is not reported as an AE and is not an exclusion event even if pregnancy is reported while enrolled in the study.

7.4.4. Follow-up

A participant experiencing an AE will be monitored until the symptoms subside, resolve, or stabilize to a pre-existing condition; the PI concludes that further follow-up is not necessary; or the participant is lost to follow-up. In the event a participant does not return to a study visit, the outcome of this event will be recorded as lost at follow up.

A participant experiencing an SAE will be monitored until there is a resolution for the symptoms; permanent outcome of the event; or the PI concludes that further follow-up is not necessary. The timelines and procedure for follow-up reports are the same as those for the initial AE report.

7.4.5. Actions Taken

Action taken will be defined as:

- None;
- Study procedures interrupted;
- Study procedures stopped.

7.4.6. Outcomes

Outcome will be defined as:

- Resolved;
- Ongoing or stabilized and followed by private healthcare provider;
- Lost to follow up.

7.5. Safety Assessment Plan

The Study Staff are responsible for the ongoing safety and well-being of the participants while they are enrolled in the study. In the case of an emergency, the local 911 system will be activated.

The management of all medical complications that arise during the course of each study visit will be managed by the PI or designee(s), as deemed appropriate.

In addition:

- The Study Staff will be trained to identify potential AEs and follow-up immediately with participants.
- AE information will be collected and documented at every time point.
- PI or designee(s) will follow-up with participants and/or refer participants to their primary care provider, as necessary.
- Participants who are diagnosed with tinnitus during their participation in the study may be withdrawn per PI discretion.

8. Device Handling and Management Plan

Both subjective and objective data will be acquired from several instruments for this study. Participant data will be confidentially acquired and managed at all times throughout the study. All data will be collected and maintained by the PI and designee(s) and secured against unauthorized access and stored in a secure, access-controlled location

Each participant screened will be assigned a unique participant ID at the time of consent. The unique participant IDs will be associated with study data for all data storage, transfer, processing, analyses, and presentation by the Sponsor. An encrypted primary list of participant names with their respective IDs (cross-walk) will be maintained by the Study Staff and accessible to only the PI and designee(s). The PI and designee(s) will have access to the cross-walk for the purposes of contacting individuals who require follow up (e.g. the occurrence of incidental findings) or administrative tasks. Additionally, all signed ICFs will be stored in a secure, access-controlled location.

All collected data types are outlined in Section 8.1.

8.1. Data Types

Data types to be collected as part of the study include:

8.1.1. Contact/Demographic Data

Contact information (name, phone number, physical address, and email address) and demographic information will be collected as a part of recruitment and screening. Select Study Staff (PI and designee(s)) will use participant names and email addresses to execute administrative tasks, such as scheduling and troubleshooting. Only those Study Staff who require access to such contact information for these study purposes will be provided access. Each participant screened will be assigned a unique participant ID number at the time of consent, which will not be based on any information about the individual. The unique, single-use identifiers will be associated with study data for all data processing, analysis and presentation. An encrypted primary list of participant names and contact info, with their participant IDs, will be kept on a secure server that is accessible only by the PI and designee(s). The PI

will have access to the primary list for the purposes of contacting individuals who require follow up (e.g. with the occurrence of incidental findings or poor adherence to procedures).

Participant names or other DII will be stored securely on a data server separate from the coded data.

8.1.2. Study App Data

Study app data is focused on participant fitting including estimated wear time and settings changes during the home intervals.

8.1.3. Sensitive/Other Health Information

Health information collected during this study may include ear exam findings (otoscopy, tympanometry), hearing ability assessment (PTA, bone conduction audiometry, SIN, software enabled hearing test results), device settings (as tuned by individual and/or audiologist and as assessed by Real Ear measure), and questionnaires/self-assessment about hearing experience. All collected data, regardless of collection method, will be stored on a secure server or cloud-based solution.

8.1.4. Data Collected Outside of the Study App

8.1.4.1. Otoscopy Findings

A healthcare provider will assess general ear health at the Screening Visit by otoscopy including for any ear canal blockage, and record findings.

8.1.4.2. Tympanometry

A healthcare provider will oversee tympanometry at the Clinic Visit #1 and record result classification and any relevant comments.

8.1.4.3. Bone Conduction Audiometry

A healthcare provider will oversee bone conduction audiometry at the Clinic Visit #1 and record results.

8.1.4.4. Pure Tone Audiometry

A healthcare provider will oversee pure tone audiometry at the Clinic Visit #1 and record results. Pure Tone Audiometry in this protocol refers to the measure of air-conduction thresholds via the presentation and detection of pure tone signals.

8.1.4.5. Real Ear Measures

A healthcare provider will oversee Real Ear measures at Clinic Visits 2 and 3 and record results. This includes frequency-level dependent gain that a given ear receives relative to the acoustic targets.

8.1.4.6. Speech-In-Noise

A healthcare provider will oversee speech-in-noise testing at Clinic Visit 2 (unaided), and at Clinic Visit 3 (aided).

8.1.4.7. International Outcomes Inventory for Hearing Aids (IOI-HA) Survey

This survey will be administered at Clinic Visit 3 and results recorded as primary outcome.

8.2. Data Collection, Storage, and Transfer

Data will be assessed for completeness and format by periodic data checks/queries on the database. This will enable the Study Staff to ensure proper functionality and connectivity of the study devices and general participant compliance with study procedures. Any issues, if observed, will be communicated to the PI to be addressed by the Study Staff. If necessary, appropriate corrective actions will be taken.

8.3. Study Record Retention

All data collected or derived from this research study will remain the property of the Sponsor. Participant contact information will be maintained by Study Staff unless a participant asks for it to be removed. All other collected study data will be retained in coded form for 10 years post study completion.

8.4. Data Quality Control

The Study Staff will perform internal quality management of study conduct, data, and documentation and completion.

Quality control (QC) procedures will be implemented as follows:

Informed Consent: The Study Staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with GCP (Good Clinical Practices), accuracy, and completeness.

Source Documents and the Electronic Data: Data will be initially captured either in the study app and uploaded via phone network/Wi-Fi or documented by the Study Staff securely on a study-specific computer. To ensure accuracy, study site staff will compare a representative sample of source data against the database, targeting key data points in that review.

Protocol Deviations: The Study Staff will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

9. Statistical Methods

9.1. Statistical Hypothesis

The primary endpoint hypothesis for the clinical validation study is as follows:

H_0: Mean(IOI-$HA_{Pro\text{-}Fit}$) - Mean(IOI-$HA_{Self\text{-}Fit}$) > 3
H_1: Mean(IOI-$HA_{Pro\text{-}Fit}$) - Mean(IOI-$HA_{Self\text{-}Fit}$) $\leq$ 3

where Mean(IOI-$HA_{Pro\text{-}Fit}$) and Mean(IOI-$HA_{Self\text{-}Fit}$) are the average follow-up (i.e., clinic visit 3) total IOI-HA scores for the Pro-Fit and Self-Fit groups, respectively.

[redacted]

9.2. Data Analysis

In general, descriptive statistics (e.g., N, Mean, Std. Dev., Min, Max) for continuous data types and frequencies for categorical data types will be displayed. All analyses will be performed with SAS [redacted] and/or R [redacted]. Analysis results will be presented separately for each of the two randomized groups and overall as appropriate.

Subject accountability (number of enrolled, withdrawn (and reasons), and complete), demographic and baseline characteristics (i.e., age, sex at birth, race, ethnicity, height, weight, BMI, etc.) and medical history will all be summarized using the Full Analysis Set. Baseline ear measures (i.e., PTA, bone conduction, and tympanometry) will be summarized separately for each ear.

All adverse events will be summarized in terms of event type, severity, and relationship to device/study procedures. Serious adverse events will also be summarized. The overall incidence (number of study participants and number of events) will be presented as both frequency counts and percentages.

Details of the efficacy analyses including the primary endpoint and additional exploratory analyses are presented below.

The full analysis set will be used as the pivotal analysis set to test the primary endpoint hypothesis. The methodology and missing data mechanism assumptions will be described in the study Statistical Analysis Plan (SAP). The null hypothesis, H_0, will be rejected and the Self-Fit group will be considered non-inferior to the Pro-Fit group if the one-sided p-value for this test is $p<0.025$ or equivalently, if the one-sided upper 97.5% confidence bound for the difference (Pro-Fit – Self-Fit) of the two group means is no more than 3. The primary endpoint analysis will also be performed on the Per Protocol and Complete Cases Analysis Sets as supportive analyses.

To assess the exploratory objectives, the Speech in Noise (SIN) test scores will be summarized descriptively for each assessment visit (baseline and final) for each of the two randomized groups (Self-Fit and Pro-Fit) along with corresponding 95% confidence intervals for the means based on the t-distribution. Additionally, a two-sided 95% confidence interval for the mean difference between groups of the within-subject differences will be reported. For the real ear measures testing, the REM output values (dB SPL) will be summarized descriptively from all available ears at each frequency and averaged across all frequencies separately for each of the two study arms (Self-Fit and Pro-Fit). The mean absolute difference (MAD) between the Self-Fit and NAL-NL2 targets and the MAD between the Pro-Fit and NAL-NL2 targets will also be computed at each frequency and averaged across all frequencies using all available ears.

9.3. Participant Population for Analysis

Full Analysis Set: All subjects who sign informed consent, meet eligibility criteria, and are enrolled and randomized into the study. This analysis set will be used for the primary endpoint analysis and to summarize subject accountability, demographic and baseline characteristics, and adverse event data. Subjects in this analysis set will be analyzed “as randomized”.

Per Protocol Analysis Set: All subjects who meet predetermined data usability criteria and who do not have any major protocol deviations that would necessitate exclusion from analysis. Subjects in this

analysis set will be analyzed “as treated”. This analysis set will be used as a supportive analysis of the primary endpoint.

Complete Cases Analysis Set: All subjects who have complete data for the efficacy endpoints of IOI-HA, QuickSIN, or Real Ear Measures.

9.4. Sample Size Determination

The approach to sample size determination is based on a two-sample independent t-test comparing group means assuming equal variances between groups. [redacted] a total of N=112 (56 per group) will be enrolled in this study.

9.5. Randomization and Blinding

Eligible subjects will be randomized (1:1) to either the Self-Fit or the Pro-Fit groups using a single pre-determined block randomization schedule. The randomization will not incorporate any pre-stratification. Subjects will not be blinded to their randomly assigned group.

Additional details of the randomization schedule (e.g., block size, etc.) may be found in the study Statistical Analysis Plan (SAP).

9.6. Significance Level

The primary hypothesis tests will use a one-sided significance level of 0.025. Analyses of the exploratory objectives will use 95% confidence intervals. Multiple comparison corrections will not be used.

9.7. Interim Analyses

There are no interim analyses planned for this study.

10. Ethical Considerations

10.1. Ethical Review and Approval

Before the study (including participant screening) commences, this research study will be submitted to a duly constituted IRB for ethical review and approval. The submitted documents will include, but are not limited to:

1. The final protocol
2. IRB application forms
3. ICF
4. Participant-facing material to be used within the study
5. Participant recruitment procedures
6. Any other documents required by the IRB

The submission will clearly identify which documents have been submitted to the IRB with title, date, and version indicated. The study will not begin unless the IRB has given a favorable opinion. An IRB approval letter will be provided to the PI, prior to study initiation.

This study will be conducted in compliance with the protocol, the principles of GCP, all governing IRB requirements, and applicable regulatory requirements.

10.2. Informed Consent

Informed consent will be obtained in accordance with 21 CFR Part 50. The nature of the informed consent will comply with the current version of the Declaration of Helsinki, the current GCP ICH (International Conference on Harmonisation) requirements, and local regulations, whichever provides the greater protections to the participant. Participants will be asked to sign any state-specific forms.

Informed consent will be given freely after the participant has been informed of the nature, significance, implications, risks, and basic procedures of participation in the study. Consent will be evidenced in writing, dated and signed, or otherwise marked by the participant to indicate his/her consent, prior to the start of his/her participation in the study.

During the informed consent process, the PI or designee(s) will explain the purpose, duration, procedures, participation requirements, risks, and potential benefits of the study. The PI or designee(s) will answer any questions the participant may have. Consent will be documented with signatures and dates from the participant and a member of the Study Staff. The participant will be encouraged to retain a copy of the signed ICF.

10.3. Reporting to IRB

During the study, the PI will promptly report the following to the IRB:

- Unexpected SAE where a causal relationship cannot be ruled out;
- Non-substantial and substantial amendments to the protocol;
- Deviations to the protocol implemented to eliminate immediate hazards to the participants;
- New information that may adversely affect the safety of the participants or the conduct of the trial (including new risk/benefit analysis in case it will have an impact on the planned follow-up of the participants);
- Annual reviews of the trial status; and
- Other documents as required by the IRB.

The PI will maintain an accurate and complete record of all submissions made to the IRB. The records should be filed in the study's Trial File.

11. Study Management

11.1. Quality Assurance and Quality Control

In accordance with the guideline for ICH GCP, the Study Staff have the responsibility for implementing and maintaining quality assurance and QC systems. The ultimate responsibility for the quality and integrity of the study data resides with the Study Staff.

11.2. Protocol Adherence

The protocol will be read in its entirety, and its instructions will be followed as detailed. The PI should agree with any deviation(s), with the appropriate written and approved protocol amendment(s) made to

reflect the agreed-upon change(s). Where the deviation occurs for the well-being of the participant, the PI must be informed of the agreed-upon action.

11.3. Documents Necessary for Initiation of Study

Prior to the enrollment of the first participant, the following documents will be available:

- Signed original of the final protocol;
- IRB approval;
- Copy of the constitution of the IRB;
- A list of members of the IRB; and
- A copy of the consent form and participant information to be used.

11.4. Study Closure

This research study will be considered complete:

1. After the final session is completed for the last participant,
2. The collected and annotated data is sent to the Sponsor, and
3. The Sponsor confirms that data is complete and usable.

12. References

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