PROTOCOL TITLE: Efficacy of a Coupler-Based Fitting Approach for Experienced Users Receiving Replacement Hearing Aids

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Purpose
The overarching purpose of this project is to develop an accurate coupler-based fitting model for experienced hearing-aid users obtaining replacement hearing aids of any style that will result in positive patient outcomes while mitigating a face-to-face fitting visit.

The proposed project addresses three aims:

Specific Aim 1. Develop vent correction factors for testbox fittings of in-the-ear (ITE) and traditional behind the ear (BTE) with custom earmold hearing aids, which will be used to evaluate the real ear to complete difference (RECD)-fitting approach in a sample of experienced users receiving replacement hearing aids. Hypothesis 1a. RECD coupler-based fittings will accurately meet prescriptive targets and expected aided audibility for ITE and traditional BTE styles. Hypothesis 1b. Subjective outcomes from RECD coupler-based fittings will meet or exceed published norms.

Specific Aim 2. Develop correction factors for RECD coupler-based fittings of hearing aids with non-custom coupling (i.e., mini-BTEs with slim tubing and noncustom open canal coupling—open fits). Hypothesis 2. Correction factors will be developed to account for RECD coupler-based fittings with open canals.

Specific Aim 3. To determine if the open-fit RECD-fitting approach is equivalent to the standard of care (SoC) open-fit fitting approach. Hypothesis 3a. Derived REARs from open-fit RECD-fittings will accurately meet prescriptive targets and expected aided audibility and will be equivalent to in situ REARs in SoC fittings of open-fit styles. Hypothesis 3b. The subjective outcomes will not significantly differ between the experimental RECD-fitting group and the SoC group for open-fit styles.

Background and Significance
1a-Introduction. In the VA system, hearing loss is the second-most common service-connected condition affecting 933,182 Veterans, exceeded only by tinnitus which affects 1,121,709 Veterans (data from Veterans Benefit Report for Fiscal Year 2016). In FY 2016, the VA dispensed 750,075 hearing aids at a net procurement of nearly $270 million (report generated from VA Denver Acquisition and Logistics Center [DALC] Remote Order Entry System [ROES]). Between November 2015 and October 2016, the VA dispensed 461,862 receiver-in-the-canal (RIC) behind-the-ear (BTE) hearing aids; 103,314 BTEs with open-fit coupling or custom earmolds; and 187,952 in-the-ear (ITE) style hearing aids (VA DALC, 2017). It is estimated that 50.1% of Veterans being fitted with new amplification are experienced VA hearing-aid users (Dennis, 2014). The Office of the Inspector General (OIG) recently audited the VA's hearing-aid services and found that the "VA was not timely in issuing new hearing aids to veterans" (OIG, 2014, p. i). One way to improve the timeliness in which Veterans receive their new amplification, without increasing the resources spent, is through an alternative hearing-aid fitting approach. We propose such an alternative fitting approach that aims to increase efficiency of hearing-aid

delivery to experienced users whilst maintaining the quality of the service provided via a standard-of-care approach.

1b-Hearing aid fittings and verification in VA. Veterans Health Administration (VHA) Handbook 1170.02 describes the scope of audiology and speech-language pathology services in VA, which is comprehensive in nature and promotes best practice. This proposal narrowly focuses on verification and validation of an experimental hearing aid fitting approach for experienced users. This experimental approach incorporates verification and validation specified by best practice, but in an alternative method. If the experimental fitting approach is effective and efficient, then it may be incorporated in VA practice for some Veterans, and be an additional service in the collection of comprehensive services available. Probe microphone real-ear measurements are the gold standard method of verifying real-ear hearing-aid performance to maximize aided audibility and ensure that the maximum output of the hearing aid does not exceed uncomfortable loudness levels of the patient (e.g., Mueller, 2001; Valente, Abrams, Benson, Chisolm, Citron, Hampton, & Sweetow, 2006). With in situ real ear aided response (REAR) measurements, the REAR is matched to a validated prescription derived from pure-tone thresholds referenced to the real-ear sound pressure level (SPL) in the patient's ear. Research shows that accurate fittings (i.e., a close match between hearing aid gain/REAR and prescription) result in improved speech intelligibility (quiet and noise) and better subjective outcomes relative to inaccurate fittings (Aazh & Moore, 2007; Abrams, Chisolm, McManus & McArdle, 2012; Baumfield & Dillon, 2001; Byrne & Cotton, 1988; Mueller, 2005; Moore, Alcántara, & Marriage, 2001). Thus, VA advocates the use of probe microphone measures when verifying hearing aid fittings.

1c-Coupler-based fittings. Not all patients, however, can tolerate in situ REAR measurements. In such cases, prediction of the in situ REAR from real ear coupler difference (RECD) values has long been advocated as a viable and accurate alternative. Although rarely used with adult listeners, this method represents the standard, clinically-accepted protocol for fitting hearing aids in younger children and infants (e.g., Moodie, Seewald, & Sinclar, 1994; Mueller, 2005; Tharpe, Sladen, Huta, & Rothpletz, 2001). The RECD is the dB difference, across frequency, between the SPL measured in the patient's real ear for a specified sound coupling (i.e., foam insert or earmold/tubing) relative to the SPL measured in a testbox coupler. In average adult patients with normal middle ear function, RECDs obtained from foam inserts are relatively consistent and thus average RECD values measured with this coupling are not highly variable (e.g., Benter & Pavlovic, 1989; Sinclair, Beauchaine, Moodie, Feigin, Seewald, & Stelmachowicz, 1996; Munro & Hatton, 2000; Munro & Millward, 2006). Earmold venting and tubing length, however, can affect RECDs values (e.g., Gustafson, Pittman & Fanning, 2013). For example, venting can cause leakage of amplified sounds that results in negative low frequency RECD values (e.g., Galster, McCreery, & Irey, 2014). The tubing length also can affect the RECD such that with increasing tubing length, there can be a 7-8 dB decrease at 4000 Hz (e.g., Gustafson et al., 2013). Given that the effects of earmold coupling (i.e., vent size and tubing length) are known, the average RECD values (based on foam insert coupling) can be corrected to better account for individual differences in earmold coupling. Such correction values readily are available (e.g., Dillon, 2012; Scollie, Seewald, & Jenstad, 1998; Vonlanthen, 1996). On the other hand, the effects of coupling differences with earmolds can be accounted for by actually measuring the RECD using the patient's own custom earmold (e.g., Hoover, Stelmachowicz, & Lewis, 2000; Munro & Buttifield, 2005). Indeed, research comparing measured REARs to derived REARs using RECDs with the patient's custom earmolds has shown good agreement (± 5 dB) and are appropriate for clinic use (e.g., Bagatto, Scollie, Seewald, Moodie, & Hoover, 2002; Galster et al., 2014; Moodie et al., 1994; Munro & Hatton, 2000). Thus, RECD-based, hearing-aid verification has been proven effective and a clinically

acceptable alternative to in situ REAR verification during face-to-face appointments (e.g., Munro & Hatton, 2000; Munro & Toal, 2005).

1d-Fitting appointments and access. Although each VA audiology clinic has their own scheduling practice, it is not uncommon for experienced hearing-aid users to be scheduled for a 30-minute fitting appointment when receiving replacement hearing aids. One purpose of the fitting appointment is to orient the patient to the hearing aids. For experienced users, an in-depth orientation on care (i.e., cleaning, battery, troubleshooting), operation, (e.g., volume control, manual program control), and use (e.g., insertion/removal, expectations) is unnecessary. Thus, at least for experienced users, a comprehensive face-to-face orientation typically is not conducted at this fitting appointment, although they are still provided with the manufacturer user manual and the VA Hearing Aid Booklet. The main purpose of the 30-minute fitting appointment is instead to ensure that the hearing aid has a good physical fit; addresses the patient's listening goals and preferences; and is programmed appropriately for the patient's hearing loss based on a validated prescriptive method using in situ real-ear measurements (e.g., American Academy of Audiology, 2006). Thus, the patient must be physically present for the in situ REAR measurements.

Access to care is of utmost importance to VA, but it remains a challenge. If Veterans cannot obtain an appointment within 30 days of the clinically indicated or desired date or the closest VA is >40 miles from the Veteran's home, then Veterans can opt into the Choice Program to have their hearing evaluation, hearing aid fitting, and a follow-up appointment completed by a community partner. At Mountain Home, for example, <20% of Veterans opt into the Choice Program and the majority would rather wait longer than 30 days if needed. Thus, having an alternative fitting approach that would circumvent a scheduled visit for Veterans obtaining replacement hearing aids may free up appointments for other Veterans who desire a face-to-face visit.

In addition to the longer than desired wait time for the fitting appointment, Veterans and their family members also are inconvenienced with travel to the medical center. Many service-connected Veterans, however, are compensated for travel costs. Travel compensation costs for just the Mountain Home VA Medical Center last year (for all visits, not just audiology) totaled over $8 million. Once the Veteran arrives at the medical center, s/he is often burdened with parking, navigating to the clinic, or finding a wheelchair or escort to facilitate navigation to the clinic. An efficacious RECD-based fitting approach that could bypass patient travel (and associated costs), a face-to-face appointment, and long wait-times for appointments would be highly desirable for many Veterans receiving replacement hearing aids and would have a significant impact on Veteran-Centric outcomes and VA resources. This project will evaluate an experimental coupler-based fitting procedures designed to greatly improve the efficiency of hearing-aid delivery to experienced hearing-aid wearers. Because the proposed model assumes that tubing length and earmold impressions (when applicable), as well as RECD measures are completed during the initial fitting, no visit is necessary for replacement hearing aid services.

Design

This project contains three separate experiments, one experiment for each aim.

Study 1 will use a quasi-experimental design. Two groups of experienced hearing aid users will receive replacement hearing aids using an experimental service-delivery approach. One group will be receiving replacement behind-the-ear (BTE) hearing aid style and the other group will be receiving replacement in-the-ear (ITS) hearing aids styles. The outcomes of the new hearing aids of both groups will be compared to the previous hearing aids and between groups.

Study 2 will use a quasi-experimental design. One group of subjects will receive 12 mini-BTE hearing-aid fittings (with both open and closed coupling) in one ear. The ears across subjects will be counter-balanced. Hearing aids from 3 different manufacturers and configurations will be fitted using a randomly assigned simulated audiogram. The output of these fittings will inform correction factors for hearing aid fitted in Study 3.

Study 3 will use a quasi-random design. Participants receiving replacement receiver in the canal (RIC) mini BTE hearing aids and will be randomly assigned to one of four groups based on hearing-aid coupling (open vs closed domes). The standard of care (SoC) group receiving open coupling (SoC-open) or closed coupling (SoC-closed) or the experimental group receiving the experimental (EXP) hearing aid service delivery approach (EXP-open or EXP-closed). The outcomes of the experimental fittings will be compared to the respective SoC fitting.

Risk/Benefit Assessment

The procedures used in the proposed study produce minimal risks. There are no known social, legal, physical, psychological, genetic or financial risks associated with participation. All participants in Study 1 or Study 3 will receive a standard, comprehensive hearing evaluation. Some participants may find this boring or may be frustrated when repeated words that might be difficult to hear or listen for soft beeps. This is a common clinical procedure that is not invasive. All participants in Study 1 or Study 3 will obtain a cognitive screening test. This screener may cause people to feel uncomfortable having to be asked to remember things or if they find the test difficult. All participants will receive in situ real-ear verification of hearing aid fitting(s). There may be slight discomfort during these measurements, but they should not be painful and they are routine, taking only a few minutes to complete for each ear.

Participants in Study 1 only will have earmold impressions made of their ears so custom replacement behind-the-ear and in-the-ear hearing aids can be ordered for each ear. There is a rare, but small chance of ear injury during this routine clinical procedure. All standard clinical safeguards associated with obtaining earmold impressions (otoscopy, use of otoblocks) will be used.

The participants in the experimental groups in Studies 1 and 3 will not have face-to-face contact with the study audiologist when their hearing aids are verified and issued. This verification procedure will be completed in a testbox and their hearing aids mailed to them. Thus, sound quality complaints and fit issues, should they arise, will not be addressed at the time of the hearing aid fitting. We anticipate this risk to be minimal because of the careful protocol we have in place to fit (program via the information obtained from the intake form) and verify the hearing aids in the testbox. We anticipate few problems related to the physical fit of the patients' earmolds or hearing aids. Participants in Study 1 and 3 will be asked to complete a battery of questionnaires to determine their hearing aid outcomes. They may find these questions boring or frustrating. Breaks will be offered and any item they don't want to answer can be skipped.

Participants in Study 2 will have 12 hearing aids fitted on one ear, with real ear verification completed on each fitting. Occasionally, there may be slight discomfort during these measurements, but they should not be painful and they are routine, taking only a few minutes to complete for each fitting. The probe can be readjusted in the ear for more comfort.

Participants will be informed that their participation is voluntary and they can withdraw from the study or cease a research session at any time. Further, if for some reason they participants

cannot wear their replacement hearing aids (Study 1 and Study 3), they will still have access to their current hearing aids and can revert to them if needed.

Participants may directly benefit from this protocol. They all will receive a comprehensive audiologic evaluation and those results will be placed in their medical record. For those in Study 1 and 3, their current hearing aids will be evaluated to ensure proper function and best fit. If in need of repair, maintenance, or adjustment, these will be made. Their replacement hearing aids will be carefully fitted and verified to best practices and they will receive close follow-up regarding them. They may enjoy the benefit of obtaining hearing aids without having to come into the clinic for a face-to-face visit (experimental groups only). If the results between the SoC and experimental groups are equivalent, then this study would provide an evidence-based, RECD fitting approach that will improve Veteran-Centric care. Specifically, the RECD-based delivery model reduces the number of visits required to fit a replacement hearing aid compared to the SoC delivery model and, therefore, should result in greater patient satisfaction and reduced costs. In addition, the reduction in the number of clinic visits for established hearing aid patients may produce a reduction in wait times (greater access to care) for new patients seeking audiology services. The risks to participants is less than minimal and the anticipated benefits outweigh the minimal risk.

Selection of Subjects

Study 1 and Study 3: Inclusion Criteria:
Participants will be included in the study if the following criteria are met:

1. aged 18-85 years
2. experienced hearing-aid users who are obtaining replacement VA-issued hearing aids of the same style as their current hearing aids
3. competent hearing aid skills as demonstrated via the checklist (See appendix)
4. no more than a moderate sensorineural hearing loss (defined as less than or equal to 60 dB HL pure-tone average at 500, 1000, and 2000 Hz AU)
5. symmetrical hearing between the ears as defined as no more than a 20 dB difference in pure-tone thresholds at two consecutive frequencies
6. >/=50% word-recognition abilities in quiet as measured during the diagnostic audiologic evaluation
7. Study 1: An education-adjusted score of >21 on the Montreal Cognitive Assessment (MoCA; Nasreddine et al, 2005) to rule out dementia. We are NOT excluding individuals who may have mild cognitive impairment because we intend to include a representative sample of clinical patients and not only include the highest cognitive functioning individuals. Note: All participants in study 1 will complete the MoCA while wearing their current amplification to ensure audibility of orally presented instructions and stimuli (Dupuis et al., 2015).

   Study 3 participants will complete the PROMIS Item Bank v2.0, Cognitive Function, Abilities Subset, Short Form 8a, with a t score of 40 being the cut off for eligibility.
8. ability to read and write in English as determined by reading a few sentences from the informed consent document aloud so that self-report measures can be completed

Exclusion Criteria: Participants will be excluded if they do not meet the inclusion criteria or if any of the following additional criteria are true:

1. outer or middle ear pathology as determined by otoscopy, immittance, and/or audiometric testing (e.g., conductive or mixed losses)

2. a significant change in hearing on audiogram obtained during the current study and that obtained when fitted with the current (to-be replaced) hearing aids as defined by a 15 dB decline in thresholds at three consecutive octave frequencies in either ear
3. lack of phone or non-use of the phone as the participants will be required to conduct a telephone interview after they obtain their replacement hearing aids as determined by a demonstration phone call with current hearing aids
4. unwilling or unable to be mailed hearing aids
5. co-morbid condition that would preclude their participation as determined by a chart review of the VA integrated medical health record (e.g., dementia/memory loss, visual impairment/legal blindness)

Study 2 Inclusion/Exclusion Criteria: One group of Veterans with hearing loss, aged 18-85 years, will be recruited. Participants will have normal outer and middle ears and ear canals free from cerumen. The type and severity of hearing loss will be similar (no more than +10 dB on average) to the simulated hearing loss they will be randomly assigned. They will be free of other comorbid conditions that may affect participation as determined by a chart review (e.g., infectious disease, dementia, etc.).

For Study 2, we are interested in making measures with these non-custom RIC and RITA hearing aids across a variety of ears of representative audiograms of open fit hearing aids. After further consideration, we decided to use the mean audiometric configurations from our previous multisite RR&D Merit Review examining open-fit hearing aids for the current Study 2. The participants do not have to have the actual loss for which we are fitting and verifying in this laboratory-based study, but have hearing loss similar to the audiogram they are assigned to reduce the risk of discomfort.

Vulnerable populations will NOT be recruited.

All studies will continue screen and consent until the targeted sample size of usable data is obtained (accounting for attrition) including 58 Veterans for Study 1; 106 Veterans for Study 2; and 88 Veterans for Study 3. See sample size estimates below.

Subject Recruitment

All subjects will be from the Durham VA audiology clinics. All potential participants will have an equal chance of being selected to participate in the study should they meet the inclusion/exclusion criteria (determined via preliminary chart review). Several recruitment methods will be utilized including through the audiology clinicians, letter, flyers, and signage.

The audiology clinicians will be informed of the study requirements for all three studies. If the clinician thinks the patient is a potential candidate for the study, then the clinician will ask if the patient wants to talk to a member of the study staff to learn more about the study. If the study staff member is available, then s/he will speak to the patient then. They potential participants can be consented at the VA at this time. If not, then the patient will be provided the recruitment letter and flyer and asked to contact the study staff. If the patient would like to be contacted by phone by the study staff, then the clinician will document their agreement to be contacted by phone in the clinical note.

Patients who are experienced hearing aid users scheduled in the audiology clinic to be considered for new amplification may be mailed the recruitment letter and flyer. In addition, Veterans who are eligible for new amplification (i.e., current hearing aids are > 4 years old)

based on a review of the hearing-aid ordering system (ROES) in CPRS, can be mailed a recruitment letter and flyer. These experienced hearing-aid users are required for Study 1 and 3.

For Study 2, experienced hearing-aid users are not required. They just need to be Veterans with sensorineural hearing loss. A recruitment letter and flyer may also be mailed to patients who are scheduled for an upcoming hearing evaluation.

We also will post flyers in the audiology clinic area and on the digital signage in the audiology waiting room. In these instances, the patient will contact the study staff.

Consent Process
All participants will undergo an informed consent process. The informed consent discussion via use of the approved informed consent document (ICD) will occur by an approved study staff member in a private location. The study staff member will review and discuss each page of the ICD, answering potential participant questions and obtaining participant initials and signatures where indicated on the ICD. The participant will be offered a copy of the signed ICD for their records.

For participants recruited directly from the VA audiology clinic, they will be consented at the VA Audiology clinic. For those recruited through a recruitment letter or flyer, then they can be consented at VA or at the MOSCH Duke lab. In any case, consenting will occur in a private office/lab, with only the participant and research staff present.

Study Interventions
All of the procedures in all studies in this project are routine clinical procedures and the research personnel will be responsible for all aspects of both the research and the usual care.

Study 1.
Session 1 (Baseline, Pre-Fitting). All testing will be completed separately in each ear for both groups. Otoscopy will be performed. The standard audiometric evaluation including air- and bone-conduction pure-tone audiometry; word-recognition in quiet (NU-6 words) and in noise (Words-in-Noise test; Wilson et al., 2003; Wilson, 2003; Wilson and Burks, 2005) will be completed. Tympanometry and aural acoustic reflexes also will be measured. These results will be compared to the audiogram for the original fitting to rule out a significant change in hearing. The current hearing aids will be maintained and the fit will be verified via real-ear measurements. The Client Oriented Scale of Improvement (COSI) will be completed to obtain the listening goals of the participant and to facilitate programming needs of the replacement hearing aids (e.g., whether or not manual programs are needed/desired) along with outcome measures for their current hearing aids (presented in random order). Obtaining subjective outcomes from their current hearing aids will provide baseline scores for which to compare outcomes from the replacement hearing aids to ensure the outcomes from the replacement hearing aids are at least equivalent. In addition, an intake form (See Appendix) will be completed for both groups to determine other device options and function (e.g., volume control options such as yes/no or unlinked/linked; removal filament or not; earmold style from previous order form; etc. The participant will be asked to demonstrate hearing aid skills with their current hearing aids. If questions or concerns arise, then they will be re-oriented during this session or disqualified. Earmold impressions will be taken for replacement hearing aids. For the BTE group, only acrylic earmold material will be used.

For both groups, RECD values will be obtained separately for each ear with the foam insert following the ANSI S3.46 (2013) standard as implemented in Audioscan Verifit 2 system. In

short, the test box reference microphone will be calibrated. The probe tube will be inserted 25-27 mm from the intertragal notch in order to ensure placement within approximately 2-5 mm from the eardrum. The foam insert will be placed in the ear canal and care will be taken not move the probe tube during insertion. The RECD transducer will be coupled to the foam insert and the real-ear response will be obtained. The difference between the HA-1 coupler and real ear response is the measured RECD. Clinical application of the proposed model assumes all necessary pre-fitting procedures (e.g. earmold impression, tubing length, RECD) are completed at this session.

Session 2: The Testbox Fitting 'Visit'. Within five business days of receipt of the replacement hearing aids, the testbox fitting 'visit' will occur. The participants will ***not*** be present during the fitting. The vent size of each hearing aid will be measured. For both groups, the BTE earmold/ITE hearing aid will be attached to the 0.4cc coupler with putty ensuring that the eartip is flush against the opening of coupler and the vent sealed, as is standard with this procedure. The right and left hearing aids will be programmed separately to the NAL-NL2 prescription generated from the Verifit 2 using the measured RECD from Session 1 of each ear. The derived REAR of the hearing aids will be verified to the 50-, 65-, and 75-dB SPL prescriptive targets generated by the Verfit 2 system using the speechmap stimulus. The criterion for an appropriate fitting would be ± 3 dB between the output and the prescriptive target from 250 Hz to the frequency in which the unaided threshold crossed the 65-dB SPL target. We will then apply the refined vent size correction factor we previously determined. The real ear aided response (REAR85) will be measured using an 85-dB SPL swept pure-tone to ensure that the maximum output of the hearing aids does not exceed the predicted uncomfortable loudness levels of the participant (feedback manager deactivated during this measurement only). The programming options will be optimized based on the information obtained on the intake form (Appendix). After programming and verification, the hearing aids will be mailed to the patient along with the manufacturer brochure and programming report from the manufacturer software. A signature will be required to accept the delivery and the delivery will be tracked.

Two-Day Follow-Up Phone Call. All participants will receive a 2-day follow-up phone call after the delivery of the hearing aid is confirmed with the delivery receipt. A telephone script (See Appendix) will be used to ask questions about the physical comfort of the device, sound quality, and any other hearing-aid problems or questions.

Session 3 (One-Month Post-Fitting). One month after the hearing-aid fitting, both groups will return to complete subjective outcome measures based on testbox fittings of replacement hearing aids. The COSI outcomes will be measured to determine if the hearing aids are meeting the patient-nominated goals. The Aided 2 portion of the Abbreviated Profile of Hearing Aid Benefit (APHAB), International Outcomes Inventory for Hearing Aids (IOI-HA), and Satisfaction with Amplification for Daily Life (SADL) will be completed. An exit survey (See Appendix) also will be administered to gain insight into the perceptions related to service delivery, access, and convenience. In addition, in situ REARs will be obtained from both groups using the current testbox programming from the replacement aids. These in situ REARs will allow within and between group comparisons regarding the hearing-aid function and determine the accuracy of the experimental fittings.

Study 2.
All testing will be completed on one test ear of the participant in an effort to increase the variability associated with ear geometry, etc. Otoscopy will be performed. Tympanometry will be conducted to ensure normal middle ear function. RECDs will be measured individually for the randomly assigned test ear. Because real ear unaided responses (REUR) also might affect gain

in open fittings, REURs for the test ear will be measured as this data may facilitate refinement of correction factors. The test ear will be measured such that the appropriate slim tube/RIC receiver length and dome size prior to each fitting using manufacturer specific clinical tools and procedures. Each participant will be randomly assigned an audiogram for their open versus closed fittings. The audiograms selected for open versus closed coupling will be based on the fitting range of the device and that represent the configurations typically seen in open-fit hearing-aid users. The selected audiogram will be entered into the fitting software and Verifit, along with the average RECD for the test ear. The hearing aids will be programmed and verified to NAL-NL2 targets in the testbox. Because the instruments will be sealed in the coupler, initialization of feedback suppression processing will lead to erroneous results for open fitted instruments. Therefore, feedback suppression processing will be activated for all testing; however, the feedback initialization routine, which helps determine the maximum amount of stable gain on an individual ear, will not be run. After which, the output of the hearing aid will be measured in-situ with measured RECDs, and real ear aided responses (REUR) will be measured for all RICs and RITAs with both open and closed coupling for the assigned audiogram. It is estimated that each participant will require ~90 minutes of testing which will be completed in 1 session (with breaks).

Study 3.

Session 1 (Baseline, Pre-Fitting). The baseline testing for Session 1 of Study 3 is nearly identical to the procedures in Session 1 of Study 1. See Section 3g. Thus, only the minor differences will be described here. The comprehensive hearing evaluation, completion of the intake form (Appendix), and reorientation that is needed will be completed with the participant's current hearing aids. Their current hearing aids will be maintained and re-verified to ensure an accurate fit to prescriptive targets. The self-report outcome battery on the current hearing aids will be assessed (COSI, SADL, IOI-HA, and the aided portion 1 of the APHAB). Individual RECDs and REURs will be measured for each ear of each participant. The choice in replacement open vs closed domes will be made following routine clinical procedures. The receiver length will be measured and the dome size (open vs closed) will be estimated using manufacturer measurement tools. The replacement hearing aids will be ordered in ROES.

Session 2-The Intervention 'Visit'.

SoC-open and SOC-closed Group Fittings. These groups will receive the SoC, 30-minute face-to-face fitting appointment 4 weeks after Session 1, the average wait time for a fitting appointment. The right and left hearing aids will be programmed separately to the National Acoustics Laboratory Non-Linear 2 (NAL-NL2) prescription. The REAR of the hearing aids will be verified to the 50-, 65-, and 75-dB SPL prescriptive targets generated by the Verifit 2 system using the Speechmap™ stimulus. The criterion for an appropriate fitting would be ± 3 dB between the output and the prescriptive target from 250 Hz to the frequency in which the unaided threshold crossed the 65-dB SPL target. The real ear aided response for an 85 dB SPL input (REAR85) will be measured using an 85-dB SPL swept pure-tone to ensure that the maximum output of the hearing aids does not exceed the predicted uncomfortable loudness levels of the participant (feedback manager deactivated during this measurement only). The programming options will be optimized based on the information obtained on the intake form (Appendix). The participant will be provided with the manufacturer brochure and programming report from the manufacturer software. Consistent with current SoC, no orientation will be provided.

EXP-open or EXP-closed Group Fittings. The participants in these groups will **not** be present during the fitting. These fittings will follow the same procedures as the testbox fittings in Study 1.

The only difference is the correction factors used will be determined from Study 2, and the measured RECD will be corrected as determined from study 2.

Two-Day Follow-Up Phone Call. All participants will receive a 2-day follow-up phone call after the hearing-aid fitting (either in situ fitting for SoC groups, or after delivery of hearing aid is confirmed with the delivery receipt for EXP groups) using the same telephone script (Appendix) as in Study 1.

Session 3-One-Month Post-Fitting. Session 3 procedures will be the same as in Session 3 in Study 1. In short, the self-report outcomes and exit interview will be assessed based on the patient experience of the replacement fittings. In addition, in situ REARs will be obtained from all groups using the current programming from the replacement aids. These in situ REARs will allow within and between group comparisons regarding the hearing-aid function and determine the accuracy of the experimental fittings relative to the SoC fittings. The repeat in situ REAR measurements in the SoC group (i.e., Sessions 2 and 3) will serve to assess the inherent variability with in situ REAR measurements and will facilitate interpretation of REAR data when comparing the accuracy of the in situ and derived REARs in the experimental groups.

Adverse Events

Given the study population (healthy Veterans with no more than a moderate sensorineural hearing loss), who are obtaining replacement hearing aids (Study 1 and 3), there are very few unexpected or anticipated serious events. In rare cases, ear injury during an earmold impression procedure could occur (Study 1 only), or occasional mild discomfort during probe microphone measurements (Studies 1, 2, and 3). Otherwise, participants may experience boredom or frustration with the taking a hearing test, listening to speech, or completing study questionnaires. All adverse events will be reported per Durham VAMC requirements. All Serious, Unanticipated and Related adverse events will be reported to IRB within 5 business days of hearing of the event. All other adverse events will be reported at continuing review.

Costs and/or Payments to Subjects

Participants will be compensated $50 for each face-to-face test session. The participant payment will help offset the cost of travel to the VA (Duke lab via off-site wavier) and to encourage participants to complete the multi-session protocols lasting ~2 hours each. For these reasons, a $50 payment/session to participants is deemed to be reasonable with the expected effort and demands of the visit(s). Two sessions are proposed in Study 1 for each participant. For Study 2, there will be a single session lasting ~90 minutes. For Study 3, the two active control groups [SoC] will undergo 3 test sessions and the two experimental groups will undergo 2 test sessions. Thus, some participants will receive an additional payment for an additional face-to-face test session compared to other participants (Study 1 and Study 3), but these assignments are random. In an effort to make the payments equitable, payments will only be offered for face-to-face visits. There will be no partial payments. All participants will be paid via direct deposit (if available) or mailed a check after each face-to-face test session.

Data and Safety Monitoring

The current study does not have any appreciable safety risks. All the procedures are standard clinical procedures related to hearing evaluations, hearing aids fittings, and questionnaires. At each study visit, we will monitor the safety of the participant during procedures and report SAEs to the IRB in accordance to stated policy. All data, either paper or electronic, will be stored and/ or transferred according to stated policy and what is approved for the study. The PI will provide oversight related to data and safety monitoring.

Withdrawal of Participants

Participants can be withdrawn from the study by the PI if they cannot correctly complete the study procedures or do not return for the follow-up visits.

If a subject self-withdraws from the study, there are no consequences to them, although they may not realize the full potential benefits from participating in the study (especially Study 1 and 3 where direct benefit may be obtained). They can obtain their normal audiology care, if needed, through the Audiology clinic at the VA.

Data Analysis and Statistical Considerations

This project contains three separate experiments, one addressing each aim.

Study 1 Power Analysis. The primary outcome of interest is based on fitting accuracy of each ear (i.e., deviation of REAR from prescriptive target across frequency). A power analysis for a repeated measure ANOVA with an effect size ηp2= 0.10, power (1-β) = 0.80, and α = 0.05 requires a sample size of 100 ears (total of 50 participants) over the two groups. A small effect size is expected, as a small effect size was found in the preliminary data (ηp2 = 0.10). Considering 15% attrition, then 8 additional participants will be needed (N = 58) resulting in 29 participants per group.

Study 1 Data Analysis Plan. A generalized linear model will be applied to examine fitting accuracy. This analysis will examine differences (in dB SPL) for in situ REAR (based on testbox fittings) across frequency between the groups relative to the prescription. Because it is expected that differences within the two ears of the same subject will be smaller than differences across subjects, inclusion of both ears in the same analysis may over inflate the statistical power. However, it is also of interest to ensure that all data are considered. Therefore, we propose to complete separate analyses for the left and right ear, even though we expect the pattern of results to be very similar for each ear. These analyses will determine (1) in situ REARs of the testbox fittings matched the prescription within each group, and (2) if there was an effect of fitting accuracy as a function of style. A generalized linear model will be conducted to compare the expected (from prescription) and actual aided SII within and between groups. Finally, separate mixed model repeated measures ANOVA will be applied to examine group differences among the outcome measure subscales (i.e., SADL subscales, IOI-HA items/subscales, and for the APHAB subscales) to examine differences in outcomes between groups and between current hearing aid fittings and the replacement testbox fittings. For the COSI, the percentage of ‘better’ and ‘much better’ responses and the average of the final ability will be calculated across goals and compared between groups via a paired-sample t-test. The subjective outcomes of replacement hearing aids (Session 3) from testbox fittings will also be compared to normative data for each group by comparing our mean, standard deviation, and sample size to those same variables from the published outcome respectively via a Welch test. This will inform whether our outcomes for testbox fittings of replacement hearing aids from each group were consistent with the published norms or not. For the IOI-HA, the IOI-HA norms from the VA ROES DALC database that contains over 100,000 IOI-HA records will be used. In the same fashion, we can select IOI-HA norms from ROES by based on degree of hearing loss and hearing aid style. A

logistic regression also will be conducted to examine if the proportion of responses differ between the groups on the specific telephone and exit survey items of interest.

Study 2 Power Analysis. The sample size for this aim is based on having 12 monaural hearing aid fittings (3 manufactures of 1 open RIC, 1 closed RIC, 1 open RITA, and 1 closed RITA) per participant (ears counterbalanced across participants such that odd-numbered subjects obtain fittings in the left ear and even numbered in the right ear). To ensure a wide range of RECDs and the expected variability in slit leak venting with closed domes, our target sample size is now 96 participants. See randomization Table in Appendix 6 in the grant application for details. For this single session study, we will account for 10% attrition due screen failure and thus will recruit an additional 10 participants for a total of N = 106.

Study 2 Data Analysis. The data from this study will not be analyzed in the usual manner as the purpose of this study is to develop correction factors for open and closed dome fittings of RIC and RITA style hearing aids from several manufacturers. First the frequency-specific gain deviations for each ear as a function of vent size will be calculated. Second, Linear and nonlinear modeling of these data with the goal of developing a best fit model of the relationship between physical vent size and the frequency specific change in gain. The model will also be adjusted as a function of hearing loss, if necessary, to account for cases when the model correction would erroneously lead to negative gain.

Study 3 Power Analysis. A power analysis based on the same expectations as Study 1 regarding fitting accuracy was conducted. For a mixed model repeated measure ANOVA with an effect size $\eta p^2 = 0.10$, power $(1-\beta) = 0.80$, and $\alpha = 0.05$ requires a sample size of 100 ears (total of 50 participants) over the four groups, or 13 participants per group. A small effect size is expected, as a small effect size was found in the SPiRE data ($\eta p^2 = 0.10$). Nonetheless, considering increased variability due to venting and to obtain robustness required by clinical standards, we will increase the sample size to achieve higher power of $(1-\beta) = 0.95$. This would bring the sample size of ears to 152, or 76 participants in total (19 per group). Considering 15% attrition, then 12 additional participants will be needed (N = 88) resulting in 22 participants per group.

Study 3 Data Analysis. We will use a similar data analysis plan as in Study 1 for real ear/fitting accuracy variables. This will determine if derived REARs from open-fit RECD-fittings will accurately meet prescriptive targets and expected aided audibility and if *in situ* REARs of RECD-fittings for are equivalent to *in situ* REARs in SoC fittings of open-fit styles. For statistical reasons, we propose to complete separate analyses for the left and right REAR data as described in Experiment 1. For self-report data, a separate mixed model repeated measures AVONA will be conducted to compare outcomes amongst the groups. This will determine if subjective self-report outcomes across a variety of domains differs as a function of fitting experience and open-fit style.

The data will be analyzed by the PI; her collaborator and co-investigator (Todd Ricketts, Ph.D., at Vanderbilt University—coded data only) who also will develop the correction factors; and the statistical consultant at Duke University (to be determined). A copy of coded data only will be

stored on the Duke University Server. A copy of all electronic data will also be stored at VA on \\v06.med.va.gov\dur\Research\Research\Smith_Sherri_Research.

Privacy, Confidentiality, and Information Security

1. **Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:**

It will be obtained, used, and/or shared for this study includes:

Identifier(s)	Source(s) of Health Information
☒ Names	☒ Medical history & physical exam information
☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: mailing address	☐ Photographs, videotapes, audiotapes, or digital or other images
☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: age, audiology treatment dates (hearing test dates, fitting dates)	☐ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe:
☒ Telephone numbers	☒ Progress notes
☐ Fax numbers	☒ Diagnostic / Laboratory test results
☒ Electronic mail addresses	☐ Operative reports
☒ Social Security Numbers	☐ Imaging (x-ray, CT, MRI, etc.)
☒ Medical record numbers	☐ Discharge summaries
☐ Health plan beneficiary numbers	☒ Survey / Questionnaire responses
☐ Account numbers	☐ Billing records
☐ Certificate and/or license numbers	☐ HIV testing or infection records
☐ Vehicle identifiers and serial numbers, including license plate numbers	☐ Sickle cell anemia information
☒ Device identifiers and serial numbers	☐ Alcoholism or alcohol use information
☐ Web Universal Resource Locators (URLs)	☐ Drug abuse information
☐ Internet Protocol (IP) address numbers	☐ Mental health (not psychotherapy) notes
☐ Biometric identifiers, including finger & voice prints	☒ Psychological test results
☐ Full-face photographic images and any comparable images	☐ Genetic testing
☒ Any other unique identifying number, linked study ID, characteristic, or code, describe: each substudy will have a unique study ID based on group assignment and number of subject entering the study. For example, Study 1: ITE01, BTE 01	☐ Other, describe:

2. **Data and/or Specimen Acquisition:**

Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Provide description of processes: The prospective data will be collected from participants as described above for Study 1, Study 2, and Study 3.

☒ Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.): . Participant demographics (e.g., name, last 4 of social security number, age, gender, previous hearing-aid fitting date, and hearing aid information [make, model, style]), will be collected from CPRS. The prior audiogram and date will be collected from CPRS (Study 1 and 3) to ensure we meet the inclusion criteria.

☐ Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number: .

Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.

3. Level of Data:

The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

☒ Identified (e.g., names, addresses or other identifiers included)
☒ Coded (direct and/or all identifiers removed, but study code/ID included)
☒ De-Identified (all HIPAA 18 and study ID/code removed):
- ☐ Verified Statistically
  OR
- ☒ Verified by Absence or Removal of HIPAA 18 and study ID

☐ Limited Data Set
☒ Other: Describe: data will be de-identified to create a limited data set to be shared with other scientists as outlined in data management plan

4. Location of Data and/or Specimens, and Data Retention Plan:

A. Data and/or Specimen Location: Data will be stored electronically in \\v06.med.va.gov\dur\Research\Research\Smith_Sherri_Research. Data that will be stored electronically include the master study key that will store subject number, first name, last name, last 4 of SSN, consent date, and race/ethnicity. Coded data files will contain subject number, gender, age, fitting date, and all other variables related to the study procedures as listed above (primary hearing test, hearing aid data, and outcome data). A copy of the coded data file only (not master file with PHI) will be saved on a Duke University restricted folder only accessible by the study team (Please see attached approved ORD off-site wavier). For Study 1 and 3, the serial numbers of the hearing aids will be stored in the hearing aid fitting software on the Duke University server. The individual subject hearing aid fitting file will contain the subject code and fitting date, but the

serial numbers cannot be removed. The serial numbers of the hearing aids are also in the Veteran's CPRS record on the VA server and will not be stored in a data file.

Paper records of data include the consent document, HIPPA authorization, and coded participant folders and will be stored the MOSCH Duke lab (temporarily) and then at the Durham VAMC Audiology Clinic, Building #1, Room D3018 (permanently).

Electronic data will also be stored in the VA REDCap server. This would include any collected coded data including but not limited to hearing test data, hearing aid information, subject responses to questionnaires, surveys, or cognitive screeners. This data may initially be collected on paper forms and will then be input by study staff into the REDCap database. No PHI will be stored on the VA REDCap server.

VA REDCap is specifically designed for human subjects research. VA REDCap has the following features:

- Installed and accessible only on a VA network.
- Login requires VA Network ID.
- Housed on a VA Informatics and Computing Infrastructure (VINCI) server at the Austin Information Technology Center (AITC).
- Data is backed-up nightly and every 6 hours.
- Provides data de-identification features
- Captures audit trails and logging with individual user rights management
- Restricts access to Protected Health Information (PHI) at the user-level

Specimens are not collected as part of this research.

☒ Data will be also be placed at the VA Informatics and Computing Interface (VINCI; http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

B. Data Retention Plan

X Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently, destruction of research records (see DAA-0015-2015-0004, section 7.6 "Research Investigator Files" for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager.

☐ Other data retention plan, describe:

Data Access and Data Recipients: Only members of the Durham VAMC study team will have access to the electronic master study key that will store identifiable information and be saved on the VA server. They also will have access to the participants' CPRS medical records stored on DVAMC servers. The electronic data files will only contain coded data with the direct identifies removed (e.g., name, address, phone number, SSN). The electronic coded data files will be stored on the VA server (\\v06.med.va.gov\dur\Research\Research\Smith_Sherri_Research) and a copy on a restricted Duke University folder (only accessible by the study staff) and shared via Azure with the Duke Department of Surgery statistical support staff member (statistician to be determined) who will facilitate the PI with data analysis. The electronic coded data file will also be shared via Azure with Dr. Todd Ricketts (Vanderbilt University and Co-Investigator on the grant) who is responsible for the development of correction factors and other data analyses. Electronic coded data will also be stored in VA REDCap which is housed on a VINCI server at the Austin Information Technology Center (AITC). This data will only be accessible to study staff who have a VA Network ID login with VA REDCap.

VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins).

Access to study data will be removed for all study personnel when they are no longer part of the research team.

5. Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:

The data collection for all three sub-studies will occur at the MOSCH Lab at Hock Plaza at 2424 Erwin Road, Suite 103, Durham, NC (See approved off-site waiver from RR&D). The VA server will be accessed by the study team from this site remotely (VPN/CAG). Electronic data will be entered into data files via this method too. For participants who are consented at the Duke lab, their paper ICD and HIPAA authorization will be transported to DVAMC Audiology clinic. Coded paper data files will be transported to the DVAMC Audiology clinic when the data are entered electronically and participants are terminated from the study.

I. ☐ Data and/or specimens will not be transported or transmitted outside of Durham VAMC environment.

II. ☐ Data and/or specimens will be transported BETWEEN sites that are under the auspices of the Durham VA Medical Center.

III. ☐ Data and/or specimens will be transmitted to other VA sites using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).

☐ Data are coded or contain identifiers and thus will be sent <chose method of transfer such as: PKI or RMS encrypted e-mail, FIPS 140-2 encrypted disk (with VA-authorized carrier and tracking), or FIPS 140-2 encrypted external drive (with VA-authorized carrier and tracking). You may identify a primary and secondary method>.

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).

☐ Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.

☐ Other, describe:

IV. ☒ Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.

☐ Data are coded or contain identifiers and thus will be sent via <chose method of transfer such as FIPS 140-2 encrypted CD or FIPS 140-2 encrypted hard drive/flash drive> using VA—approved carrier with tracking.

☒ Data are coded or identified and will be sent using Azure file encryption. Todd Ricketts, Ph.D. Vanderbilt University and the statistician at Duke University (to be determined)

☐ Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF) <insert information including sponsor name and URL and the encryption the site uses.>

☒ Other, describe:

1. For participants consented at the MOSCH Duke lab, their original ICD and HIPAA authorization will be transported to DVAMC Audiology Clinic (Building 1, Room D3018) using a lockable VA envelope. Only the study staff will have access to the key. Coded paper participant data files will be transported to the DVAMC Audiology clinic in a locked VA envelope. Electronic coded data will be entered into the study files via a VPN/CAG connection. Electronic coded data will be shared with Dr. Ricketts and the Duke University statistician (TBD) for data analyses.

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:

☐ Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data or specimens released from the Durham VAMC (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or spreadsheet) that includes the participant's name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

C. ☒ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials.

D. ☒ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container) in accordance with VHA Directive 6609:

NOTICE!!!

Access to these records is limited to: AUTHORIZED PERSONS ONLY. Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

V. ☒ We will communicate with veterans enrolled as participants in this research study through MyHealtheVet.

6. Risk Mitigation Strategies:

Interactions with participants during consenting and data collection will occur by approved study staff members in a private location to ensure privacy of the participant.

Paper records that contain PHI or coded data will be kept in a locked cabinet in a locked office. During transport from Duke to VA, a locked VA envelope/suitcase labeled accordingly, will be used by approved study staff members only (after they sign the appropriate memo). Electronic data with PHI will be kept in a separate master file from the coded data to reduce the likelihood of identifying the participant. Unauthorized access will be mitigated by having key control over paper records and by restricted access to electronic folders to approved study staff only. The PI, study staff, collaborator, and statistical consultant will be responsible for overseeing the privacy of the participant and security of the data.

☐ Data are fully de-identified (stripped of HIPAA 18 and study ID/code) before being shared outside of Durham VAMC.

☐ Specimens are fully de-identified (stripped of HIPAA 18 and study ID/code before being shared outside of Durham VAMC.

☒ Direct identifiers will be maintained separately from data and or specimens by using a code to "identify" subjects. In a separate database (i.e., a "linking" or "cross-walk" database) this code will be linked to identifying subject information.

☐ Other, specify:

7. Suspected Loss of VA Information:

Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

8. Reporting of Results:

☒ Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.

☐ Other results reporting plan, describe:

9. Future Use of Data:

☐ Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.

☐ Future Use of data is optional (i.e., not required by the research subject).

☐ Future Use of data is required for participation in the study.

☒ No future use of data is currently planned.

10. Use of Mail Merge Technology

☐ Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research subjects. The study team is aware that to reduce risk of mail merge related privacy incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research subject name and mailing address are properly "matched". If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

11. Use of Non-Standard Software
☒ I do NOT intend to use any new specialized software (i.e. Software that's not already approved OR installed) in this study.

☐ I intend to use specialized software that has not already been installed and it has been approved for use by the VA Technical Reference Model (TRM) Group.
(Note: All new software must be approved by TRM before it can be installed on VA systems.)

☐ I intend to use previously installed software on my VA computer.

12. Use of Cloud Computing Services
☐ Cloud computing services will NOT be used in this study.

☒ Cloud computing services WILL be used in this study as described below and have been approved nationally by the VA Chief Information Officer (CIO). (Note: ONLY cloud computing services that have been approved nationally may be used.)

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