A Pilot Study to Assess the Role of Accelera Stochastic Resonance Wearable Technology to Assist Gait and Mobility in the Older Adult

10/5/2025

PROTOCOL TEMPLATE FOR INVESTIGATOR-INITIATED STUDIES

INSTRUCTIONS:

- Sections will expand to fit your responses.
- Keep an electronic copy to modify when making changes either as directed by the IRB, or for amendments/modifications.
- Mark sections “NA” if they are not applicable to your research.
- Please use lay language, avoid professional jargon and define all abbreviations when they first appear.

PROTOCOL TITLE:

Response: A Pilot Study to Assess the Role of Accelera Stochastic Resonance Wearable Technology to Assist Gait and Mobility in the Older Adult

PROTOCOL VERSION/AMENDMENT # AND DATE

Response: Version 4 - 10/05/25

PRINCIPAL INVESTIGATOR:

Response: Principal Investigator: Randeep Jawa, MD
Co-investigator: Jennifer Hensley, MD

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research. Specifically, explain why it is important to do the study.

Response: This research aims to evaluate the impact of subtle vibrations applied to the ankles, on gait and mobility in older adults. Participants will not consciously perceive the vibrations after initial set-up. More specifically-

- Impact of device on gait and mobility

- Older adults' perception of device function, wearability, and impact on mobility confidence

2.0 Background

2.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute/fill in gaps to existing knowledge.

Response: The research protocol outlines the evaluation of stochastic resonance (SR) ankle bracelets in improving mobility in older adults. The concept is that improved mobility would be associated with reduction in falls. Falls in the elderly are a significant public health concern, being the leading cause of injury, hospitalization, and death in this population. Although the elderly make up about 12% of the U.S. population, they account for 75% of deaths related to falls. Approximately one in four individuals over the age of 65 experience a fall annually, with many falling more than once. The healthcare costs associated with falls are staggering, with current estimates of combined direct and indirect costs exceeding $80 billion. Contributing to these costs are hospital stays, medical equipment, and rehabilitation, which underscores the need for effective preventative measures. The risk factors for falls among older adults include vision problems, muscle weakness, and a decline in somatosensory function. Among these, the loss of tactile and proprioceptive sensations has been identified as a critical predictor of falls. Stochastic resonance (SR) is a phenomenon where the addition of a certain level of noise can enhance sensory signal detection. In this context, SR-based devices, such as vibrating insoles, have been explored for their potential to improve balance and reduce postural sway, which could ultimately reduce fall risk in elderly populations.
Previous studies have shown promising results. For example, SR has been shown to enhance tactile sensation in human subjects. Later studies extended this work, demonstrating that SR could reduce the sensory detection threshold in elderly individuals and those with conditions like diabetic neuropathy and stroke. Further investigation of SR insoles participants found that the insoles reduced postural sway in the elderly. These results suggest that SR could be an effective tool for enhancing mobility and in association reduce falls in older adults. Despite these promising findings, important questions remain unanswered.

2.2 Include complete citations or references:

Response:

1. Center for Disease Control and Prevention. Falls Among Older Adults: An Overview. December 8, 2010. Accessed October 24, 2024. http://www.cdc.gov/HomeandRecreationalSafety/Falls/adultfalls.html.

2. Collins JJ, Imhoff TT. Noise enhanced tactile sensation. Nature. 1996;383:770-771.

3. Fuller GF. Falls in the elderly. Am Fam Physician. 2000;61(7):2159-2168. Accessed October 24, 2024. http://www.aafp.org/afp/20000401/2159.html.

4. Galica AM, Kang HG, Priplata AA, et al. Subsensory vibrations to the feet reduce gait variability in elderly fallers. Gait Posture. 2009;30(3):383-387.

5. Hawryluk M. Fall-related injuries cost Medicare billions. Amednews.com. December 16, 2002. Accessed October 24, 2024. https://www.ama-assn.org.

6. Liu WM, Lipsitz L, Montero-Odasso M, et al. Noise-enhanced vibrotactile sensitivity in older adults, patients with stroke, and patients with diabetic neuropathy. Arch Phys Med Rehabil. 2002;83:171-176.

7. Owens PL, Russo CA, Spector W, Mutter R. Emergency department visits for injurious falls among the elderly, 2006. HCUP Statistical Brief #80. Agency for Healthcare

8. Research and Quality. October 2009. Accessed October 24, 2024. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb80.pdf.

9. Priplata A, Niemi J, Harry J, Lipsitz L, Collins J. Vibrating insoles and balance control in elderly people. Lancet. 2003;362(9390):1123-1124.

10. Priplata A, Patritti B, Niemi J, et al. Noise-enhanced balance control in patients with diabetes and patients with stroke. Ann Neurol. 2006;59:4-12.

11. United States Census Bureau. Sixty-Five Plus in the United States. May 1995. Accessed October 24, 2024. https://www.census.gov.

12. Haddad YK, Miller GF, Kakara R, Florence C, Bergen G, Burns ER, Atherly A. Healthcare spending for non-fatal falls among older adults, USA. Inj Prev. 2024 Jul 19;30(4):272-276.

3.0 Study Design

3.1 Describe and explain the study design (e.g., case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, and observational). Indicate if there is randomization, blinding, control group, etc. If randomizing, explain how this will be achieved.

This is a pilot, observational study with 20 volunteers at Jefferson's Ferry Independent Living. Before the Accelera ankle bracelets are applied, participants will complete a pre-study questionnaire. They will then complete 3 tests that the Centers for Disease Control (CDC) recommends for fall risk assessment, namely the chair stand test, 4-point balance test, and timed up and go test, while using their usual mobility assist devices. If the participants provide optional consent, they will undergo video-based gait/mobility analysis of information derived from the HIPAA compliant Onform video recording app, while they are using their usual mobility

assistance devices, if any. In other words, a video recording is made with the app and stored on the apps' HIPAA compliant platform. With the faces obscured, measurements of their gait/mobility will be performed using additional programs as indicated in the Data section. After bracelet application, volunteers will then be encouraged to resume their normal ambulation (while using their usual mobility assistive devices) for about 30 minutes at the study location as described below. The same 3 tests will be repeated after 30 minutes, along with a post-study questionnaire, and if they consented to video recording above, then repeat videorecording with the Onform video recording app would be performed. With the faces obscured, measurements of their gait/mobility will be performed using additional programs as indicated in the Data section. At this point, the ankle bracelets will be removed – with the subjects having worn them for about 1 hour total. There will be an additional up to 1 hour for completion of the pre- and post-study questionnaires, for a total study session duration of about 1.5 - 2 hours. At each session, we will apply these bracelets to a minimum of 1 patient per session. These sessions will occur at the Wellness Center/gym or other designated area at Jefferson's Ferry 1x per week, with a minimum of one patient for up to 8 patients/week if no holidays, until 20 patients have completed the study. To address infection control, a disposable sock will provide a physical barrier between the device and patient, while still allowing the patient to feel the stochastic resonance.

3.2 Include the number of subjects and the power analysis. If applicable, indicate your screen failure rate, i.e., how many subjects you expect to screen to reach your target sample.

Response: 20 volunteers will be enrolled. The study would continue until 20 volunteers are enrolled and complete all non-optional parts of the single study session.

3.3 Indicate the duration of the subject participation including long-term follow-up.

Response: A single study session. There is no long-term follow-up in this study.

3.4 Indicate whether you are specifically recruiting or targeting any of the following special populations in your study using the checkboxes below.

Response: n/a

☐ Minors (under 18 years old)

☐ Adults unable to consent

☐ Pregnant women

☐ Prisoners

3.5 Indicate if you will include minorities (American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic) as Federal mandates require that you include minorities unless you can justify their exclusion.

Response:

☒ Yes

☐ No, Justify:

3.6 Indicate whether you will include non-English speaking individuals in your study. Provide justification if you will specifically exclude non-English speaking individuals. Review https://www.stonybrook.edu/research-compliance/Human-Subjects/sops for the SBU policy on inclusion of non-English speakers (section 17.8). Following approval of the English version, you must submit the translated version of the materials with the attestation of the translation.

Response: Non-English speakers will be excluded to assure understanding of verbal instructions in English as well as enable completion of the survey.

3.7 Describe the data analysis plan, including any statistical procedures.

NOTE: If we are a lead site for a multi-site study include the total number of subjects that will be enrolled, or records that will be reviewed across all sites. This section applies to both quantitative and qualitative analysis.

Response: The data of participants who meet the inclusion criteria will be collected during study visits and recorded directly by study staff. Only the consents will have the participant's names. There will be no linking of the participant to subject ID. Hence, all data will be de-identified and stored using unique study identifiers to protect participant privacy. The data will be securely stored on password-protected, encrypted servers at Stony Brook Medicine to ensure compliance with privacy and confidentiality standards.

If the participants choose to have their mobility evaluated by the research team with the video recording app, then their videos would be uploaded to the HIPAA compliant platform of the app. The first name used for the app would be the 1st digit of their assigned code and the last name would be the last digit of their assigned code. Their faces would be obscured by taking a video from the chin/neck down.

Descriptive Analysis:

Descriptive univariate statistics will be conducted to summarize the demographic and performance characteristics of the study population, including device sensory thresholds, gait/mobility using a mobility videorecording app (optional, see below) before and while wearing the ankle bracelets, pre- and post-study questionnaires, and performance before and while wearing the ankle bracelets on the 3 CDC STEADI tests (the chair stand test, 4 point balance test, and timed up and go test). Multivariate analysis would also be performed.

Videos uploaded on the Onform app with participants' faces obscured would then be analyzed with additional feature extraction, analytics, and statistical programs. This would include optical character recognition programs to analyze the joint angles numbers that the video recording provides. Outside of the app, parts of the video will be cropped, the stick figure that the Onform app generates will be highlighted, and the contrast and lighting of the video will be adjusted to make the subject look like a shadow, ie s no features of the subject (such as clothing, gender, skin color, etc.) can be recognized. Programs such as ImageJ will be used for feature extraction. Python/R will be used to pull the data from the videos/cropped images. Python/R/excel will be used for statistical analysis of gait/mobility parameters, such as joint angles, stride time, stance time, swing time, cadence, stride length, step width, and foot angle, etc

4.0 Inclusion and Exclusion Criteria

NOTE: If your study is more than minimal risk, you must also upload (in the myResearch IRB smartform) a copy of your inclusion/exclusion checklist to be completed at time of enrollment of each subject.

4.1 Describe, in bullet points, the criteria that define who will be included in this study.

Response: Please see inclusion/exclusion attachment for details. In brief, however:
• Adults aged 65+ years who reside at Jefferson's Ferry independent living.
• Express interest in the ankle wearable device.
• Individuals who can communicate in English and provide written consent.
•They must have capacity as measured by being alert and oriented to person, place, and time.
• Participants are able to walk and stand unsupported by others and feel ankle vibrations from the Accelera device at maximum amplitude.

• Answer Yes to at least one: worry about falling, had a fall within last year, feel unsteady when walking, limit activity due to fear of falling, enrolled in a fall prevention program, or use or have used assistive devices for ambulation (e.g. canes or walkers).

4.2 Describe, in bullet points, the criteria that define who will be excluded from this study.

Response: Please see inclusion/exclusion attachment for details. In brief, however:

• Patients diagnosed with neurodegenerative diseases (such as Parkinson's, Alzheimer's, or ALS)
• Any lower extremity amputation other than one toe
• Disability from a stroke or other major neurologic disorder resulting in leg paralysis
• Active ulcers/rashes/infections on feet or legs, or using orthotics other than arch supports or over the counter knee/ankle supports
• Significant lymphedema/peripheral edema/or large ankle size that prevents ankle wearable device application or functionality
• Unable to participate due to other medical or cognitive reasons.
• Cannot give written consent.
• Cannot walk today or generally use wheelchairs
• On anticoagulants or antiplatelet agents other than aspirin
• Age under 65 years

** Individuals with any active infection and/or currently receiving prescribed antimicrobial agent(s) will be asked to return when infection is resolved.

4.3 Describe how individuals will be screened for eligibility. Upload all relevant screening documents with your submission (screening protocol, script, questionnaire). Identify who will certify that subjects meet eligibility requirements. (Upload these documents in the myResearch IRB smartform.)

Response: Participants who are interested will be able to sign up at their discretion after the study is presented to the Jefferson's Ferry community.
To be included, please see detailed inclusion/exclusion criteria attachment. However, in brief they will need to:

- Answer Yes to at least one: worry about falling, had a fall within the last year, feel unsteady when falling, enrolled in a falls prevention program (past and/or present), or use in the past year of assistive devices for ambulation (e.g. canes and/or walkers)
- Are you willing to wear a device on both ankles for up to 1 hour at a time?
- Are you able to commit to completing the pre and post study questionnaire, 3 mobility tests before and while wearing the ankle bracelets.

- The intake form will also contain additional demographic questions (see attached).

5.0 Vulnerable Populations

5.1 For research that specifically recruits/targets minors (under 18 years), review, complete and upload Supplemental Form F: Minors.

☐ Confirmed

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

5.2 For research that specifically recruits/targets adults who cannot consent for themselves, you will be asked additional information in Section 25 (“Informed Consent”).

☐ Confirmed

☒ N/A: This research does not involve this population.

5.3 For research that specifically recruits/targets pregnant women, review, complete and upload Supplemental Form A: Pregnant Women, Fetuses, Non-Viable Neonates, or Neonates of Uncertain Viability.

☐ Confirmed

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

5.4 For research that specifically recruits/targets neonates of uncertain viability or non-viable neonates, review, complete and upload Supplemental Form A: Pregnant Women, Fetuses, Non-Viable Neonates, or Neonates of Uncertain Viability.

☐ Confirmed

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

5.5 For research that specifically recruits/targets prisoners, review, complete and upload Supplemental Form B: Prisoners.

☐ Confirmed

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

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

Safeguards include:

☒ N/A: This research does not involve these populations.

6.0 Recruitment Methods

☐ N/A: This is a records review only, and subjects will not be recruited.

NOTE: If you select this option, please make sure that all record review procedures and inclusion/exclusion screening are adequately described in other sections, including date range for records that will be reviewed.

6.1 Describe source of subjects: When, where, and how potential subjects will be recruited. In order to approach patients in the clinic/hospital setting you must have a treatment relationship with these individuals.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study.

Response: Participants for this pilot study will be older adults (age>=65 years) living at Jefferson's Ferry Independent Living, who use or have used an assistive device for ambulation in the past year, who are interested in trying this technology, and meet detailed inclusion/exclusion criteria evaluation as per the checklist. Before enrollment, as a part of Jefferson's Ferry monthly meeting calendar, it will be indicated that an in-person educational session on this proposed study will be held. Study team members will then provide an educational session at Jefferson's Ferry to describe the study and invite eligible residents to participate. As the plan is to conduct enrollment and study sessions on one day of the week

(tentatively Mondays), excluding holidays or other institutional/researcher obligations, those interested would also be advised that they can stop in on study days for screening/enrollment.

6.2 Describe how you will protect the privacy of prospective subjects during the recruitment process.

NOTE: Examples of appropriate responses may include: “participant only meets with a study coordinator in a private office setting where no one can overhear”, “the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.”

Response: During the recruitment and screening process, participants' privacy will be protected by ensuring that all recruitment activities occur in a confidential manner. This includes discussion of recruitment and consent in a private consultation room at Jefferson’s Ferry. Interested individuals will contact the study staff directly to express interest. Personal discussions regarding the study will take place in private settings, in person, to ensure privacy. Only authorized research staff will be involved in the recruitment and screening process. There is only 1 educational session planned. We would have a sign-up sheet for those who are interested at the end of the session and provide them with information about when the study sessions will be taking place so they can further assess interest and eligibility. People interested can also come to the Wellness Center on days that the study is being performed to express their interest.

In addition, all participant information collected during the subsequent screening process will be de-identified and stored securely. The research team will use a unique identifier for each participant, and all identifiable information (i.e. the consents) will be kept in locked cabinets accessible only to designated research personnel until it and the other forms can be uploaded to the University’s secure share drive system. At that point, the physical copies will be destroyed. Furthermore, electronic records will be stored on password-protected, encrypted Stony Brook Medicine servers to prevent unauthorized access.

7.0 Research Procedures

7.1 Provide a detailed description of all research procedures or activities being performed on the research subjects. **This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research.** For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response. Be sure to include:

· Procedures being performed to monitor subjects for safety or to minimize risks.

· All drugs and devices used in the research and the purpose of their use, and their regulatory status

Response: The intervention involves the collection and analysis of data from older adults (age 65+) living at Jefferson's Ferry independent living to evaluate the effects of stochastic resonance (SR) ankle wearables on gait and mobility. The device will be applied during a study session lasting about 1.5-2 hours, where about 1 hour is spent on completing the pre- and post-study questionnaires on pen/paper. The other 1 hour is spent on the various gait and mobility evaluations before and while wearing the device, as detailed below.

At the visit, after completing the pre-study questionnaire, participants will perform 3 tests validated by the CDC for fall risk screening: the timed up and go test, 30-second chair stand, 4 stage balance test. If the participants opt in to mobility analysis performed with the Onform iPad/iPhone video recording app without the participant's name, rather than with a code, then this would be performed. As indicated above, participant's faces will be obscured. The ankle bracelets will then be applied. After about 30 minutes of resuming their usual ambulation in the observation area as below, the same 3 tests would be repeated as well as if they had opted in above, repeat mobility video recording with the Onform app, all while the ankle bracelets are in place. The ankle bracelets will be removed after completion of the session. Before application of the Accelera device and while they are wearing the Accelera device, the participants will be asked to continue to use their usual mobility assistive devices as they usually do. The post study questionnaires will then be completed. All questionnaires will be completed with pen/paper.

There will generally be 1 session per week at Jefferson's Ferry, at the Wellness Center/gym or other designated area at Jefferson's Ferry, with a minimum of one patient for up to 8 patients/week if no holidays, until 20 patients have completed the study. It is currently tentatively planned for Mondays, excluding holidays and other institutional/researcher availability requirements. However, this may be adjusted in coordination with Jefferson's Ferry.

Possible participants will be able to sign up at the educational session for additional information. Additionally, they will be advised that they can come sign up at any date that we are having a study session. They would only complete the screening/survey questionnaires at a study session.

If the participants opt in, then the app that will be used for mobility analysis during the study is called Onform, from Onform Inc. It is a HIPAA compliant video recording and analysis App. The video recording that is saved will be saved as per the app specifications using a first and last name, however the first name will be the 1st digit of the subject ID code, and the last name will be the last digit of the subject ID code. As indicated above, participants' faces will be obscured. Analysis will be as described in section 3.7 above. Please see the attached app privacy policy.

7.2 Describe what data, including long-term follow-up data, will be collected.

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

Response: The data being analyzed includes participant pre and post study questionnaires, including demographics, sensory thresholds for the Accelera device, 30-second chair stand, 4 stage balance test, and timed up and go (TUG) task outcomes. There will also be mobility/gait/posture analysis performed via an iPad/iPhone App without the participant's name before and while wearing the ankle bracelets. Researchers will provide basic prompts regarding participants' stability and gait. Participants will also complete a self-reported health/exercise/fear of falling questionnaire at the start of the visit and at the end of the visit as well as a post questionnaire. We will also evaluate for falls with or without the device at the study session. There is no long-term follow-up.

7.3 List any instruments or measurement tools used to collect data (e.g., surveys, scripts, questionnaires, interview guides, validated instruments, data collection forms). Upload these materials in the myResearch IRB smartform.

Response: Participants will complete a self-reported health/exercise/fear of falling/mobility questionnaire as detailed above during the index visit and at the start and end of the study session. Their performance on the above 3 CDC tests (the chair stand test, 4-point balance test, and timed up and go test) will be measured and recorded using the CDC defined evaluation tool before and while wearing the ankle bracelets. If the participants opted in, then we will also perform gait/mobility analysis with the HIPAA compliant Onform app, as indicated above in section 3.7, before and while wearing the ankle bracelets. We will also measure sensory thresholds for the Accelera device. Finally, we will also evaluate for falls with or without the device at the study session.

7.4 Describe any source records that will be used to collect data about subjects (e.g., school records, electronic medical records) and include the date range for records that will be accessed.

Response: Participants will be asked to list their medical histories in the questionnaire indicated above, assistive device use, and fall history/fear of falling. The study team will not access any patient medical records. Please see attachment for detailed intake form questions.

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

Response: The participants will be advised of their performance on the 3 CDC tests (the chair stand test, 4-point balance test, and timed up and go test) before and while wearing the ankle bracelets, their responses on the pre and post questionnaires as well as mobility/posture/gait analysis app findings if participants want to review these.

8.0 Research Setting

8.1 Describe all facilities/sites/locations where you will be screening and conducting research procedures.

Example: “A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software,” “The angiogram suite at Stony Brook University Hospital, a fully accredited tertiary care institution within New York State with badge access,” etc.

Response: Jefferson’s Ferry Independent Living at the Wellness Center/gym or other area as designated by Jefferson’s Ferry

8.2 For research procedures being conducted internationally), Supplemental Form C must be completed and uploaded.

Response:

☒ N/A: This study is not conducted outside of SBU or its affiliates.

8.3 For research procedures conducted externally to Stony Brook University (e.g. other institutions, schools, other states), attach applicable approval letter(s) in the myResearch IRB smartform.

Response: Please see attached approval letter from Jefferson’s Ferry.

9.0 Resources and Qualifications

9.1 The Principal Investigator (PI) must confirm, in consultation with Chair and Dean as applicable, that adequate resources are present to conduct and complete the study compliantly and safely. Specifically:

☐ NO ☒YES The proposed subject population(s) are available in sufficient numbers to meet the study requirements.

☐ NO ☒YES Sufficient funds are available to conduct and complete the study compliantly and safely.

☐ NO ☒YES The PI and study team have sufficient time to conduct and complete the study compliantly and safely.

☐ NO ☒YES The PI has determined that the named study team is qualified to conduct the research compliantly and to monitor the safety and welfare of the enrolled research subjects effectively.

☐ NO ☒YES The PI ensures that the study team is fully aware of his/her involvement in this study and the details of the study protocol.

☐ NO ☒YES The PI ensures that the study teams will only be involved in research procedures for which they have been trained, and are currently certified and/or licensed, if required.

☐ NO ☒YES The PI ensures that all study team members are updated on the progress of the research and the regulatory requirements (including enrolled subjects, unanticipated problems, etc.).

Response:

10.0 Other Approvals

10.1 List approvals that will be obtained prior to commencing the research (e.g., University Hospital signoffs per the UH Application, Cancer Center Scientific review, external site, funding agency, laboratory, Radiation Safety, IBC, SCRO, IACUC, RDRC).

Response:

☒ N/A: This study does not require any other approval.

11.0 Provisions to Protect the Privacy Interests of Subjects

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

NOTE: Privacy refers to an individual's desire/right to control access to or to place limits on whom they interact with or whom they provide personal information. Privacy applies to the person. Examples of appropriate responses include: "participant only meets with a study coordinator in a private office setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: The participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering. Participants will only meet with a study coordinator in a private consultation room at Jefferson's Ferry.

12.0 Confidentiality

A. Confidentiality/Security of Study Data

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

NOTE: Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

12.1 Where and how will all data and records be stored? Include information about locked cabinet/locked office, authorization of access, certificates of confidentiality, and separation of identifiers and data, as applicable. Include physical (e.g., paper) and electronic files (e.g., storage of data in REDCap) password protection, encryption.

Response: All data and records will be stored locally on secure Stony Brook Medicine networks. The only identifying data is the consent form. However, this will not be linked to the unique random study code/participant id number. The data will be collected during study visits and de-identified, with participant identifiers being replaced by unique study codes. The de-identified data will be encrypted and securely stored on Stony Brook Medicine encrypted servers, which meet institutional security standards. Access to the data will be restricted to authorized personnel, with password-protected systems and encryption in place to ensure data security. Additionally, all identifiable information, such as consent forms will be uploaded to a secure

Stony Brook Medicine shared drive and then disposed in the secure Health Sciences Center (HSC) discard bin.

The optional Onform app video recordings will be stored on the apps HIPPA compliant platform. The face will be obscured.

The physical forms (i.e. pre and post questionnaires, performance on the app, CDC tests, device sensory thresholds) will be transported to SBUH by research personnel and will be stored separately in a secured, locked file cabinet until they can be uploaded (scanned) into the secured shared drive, at which point all physical forms will be discarded in the Stony Brook Medicine HSC secure bins. Answers to the study questionnaires, performance on the 3 CDC tests as well as gait analysis app findings, Accelera device sensory thresholds, will also be entered into an excel sheet on the Stony Brook Medicine shared drive.

12.2 Who will have access to the data?

Response: Access to the data will be restricted to the Principal Investigator and the designated research staff involved in the study, including research assistants, data managers, and statisticians. Accelera company will only have access to the aggregate data from the study.

NOTE: If there are plans to share datasets with unrestricted access, adjust language in the consent form to reflect this. Consider including the phrase: "*Your data and biospecimens will be shared in a way where anybody around the world can gain access to them without review."*

12.3 How will the data be transported/transmitted (if applicable)?

Response: Data will be transported and transmitted securely using password-protected, encrypted spreadsheets. De-identified electronic files will be stored on Stony Brook Medicine networks. For data sharing with collaborators, including the study sponsor Accelera, deidentified data will be transmitted via encrypted emails.

Videos/data collected via the Onform app platform is maintained on the apps' HIPAA compliant platform.

12.4 Describe if identifiers will be retained, de-identification of the data is not feasible, or whether there are circumstances in which re-identification may be possible.

Response: De-identified data will be stored separately from any identifying information, which will be encrypted and stored in a separate, secure file to ensure confidentiality. Participants'

faces will be obscured in the video recordings on the Onform app. Only authorized study personnel will have access to the data.

12.5 If this study includes data collected from individuals, groups, or populations with unique attributes (e.g., Tribal Nations, international sites) that may increase the risk of re-identification, describe how sensitive information regarding potentially stigmatizing traits, illegal behaviors, or other information that could be perceived as causing group harm or used for discriminatory purposes will be protected.

Response: n/a

12.6 Describe circumstances under which a code key may be used to re-link identifying information to data/specimens?

Response: n/a

B. Confidentiality of Study Specimens

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

☐ N/A: No specimens will be collected or analyzed in this research.

12.7 Where and how will all specimens be stored? Include information about: locked freezers, locked laboratories, authorization of access, and labeling of specimens, as applicable.

Response: n/a

12.8 Are there limits for the future use of biospecimens in any way? Such as controlled access to the data based on laws, regulations, policies, and agreements.

Response: n/a

12.9 Who is responsible for receipt or transmission of the specimens (if applicable)? If you are transporting specimens to another location not affiliated with Stony Brook University, you must have a Material Transfer Agreement.

Response: n/a

12.10 Banking Data or Specimens for Future Unspecified Use

☒ N/A: This study is not storing data or specimens for research outside the scope of the present protocol. This section does not apply.

NOTE: If you are proposing to bank specimens for future use, you may be subject to licensure requirements under the NYS Department of Health and must be covered under the SBU license. See SOPs section 17.2 at https://www.stonybrook.edu/research-compliance/Human-Subjects/sops.

12.11 If data will be banked for research outside of the scope of the present protocol, describe where the data will be stored, how long they will be stored, and who will have access to the data.

NOTE: Your response here must be consistent with the information provided to subjects in your Consent Documents

Response:

12.12 Will specimens be obtained from specific cultural groups? Consider whether your study will include specimens collected from individuals, groups or populations with unique attributes (e.g., Tribal Nations, international groups) that may increase the risk of re-identification. Describe how sensitive information regarding potentially stigmatizing traits, illegal behaviors, or other information that could be perceived as causing group harm or used for discriminatory purposes will be protected.

Also, consider cultural sensitivities around the return and/or destruction of biospecimens when research participants withdraw their consent for the storage and sharing of data and biospecimens or when data and biospecimens need to be maintained.

NOTE:

In general, participants should be given the choice about whether or not they wish to have their data and biospecimens stored and shared for future use. Providing options for participants to agree to data and biospecimen storage and sharing is particularly important in studies that offer the prospect of direct benefit to the participant. Requiring storage and sharing may be considered undue influence if the participant does not want to agree to sharing of data and biospecimens but feels compelled to agree anyway to join a possibly beneficial research study.

If the primary research study offers no prospect of direct benefit, it may be reasonable to consider requiring storage and sharing in the primary protocol (e.g., if the primary protocol is a repository protocol with the sole purpose being to collect data and/or biospecimens for future use). In this case, there is no reason to participate if the participant does not want to provide consent for storage and sharing.

NIH Funded Research: Upload a copy of the Data Management and Sharing Plan

Response:

13.0 Withdrawal of Subjects

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

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

Response: if the participant is unable to participate in the study during the study session for any reason, including inability to walk, they would be withdrawn from the study.

13.2 Describe any procedures for orderly termination.

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

Response: n/a

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

Response: If a subject withdraws on the day of the study before information is deidentified, their data will be removed. This includes removal of data/videos from the Onform app if they had opted in to participate.

13.4 Describe what will happen to data already collected.

Response: Data can only be discarded at the time of the study session if the participant requests. After that, we would not be able discard it as there is no matching between the person who signed the consent and the random participant/subject ID. As we are not keeping any picture of the participants and faces will be obscured on the Onform video recording, after the session, we would not be able to delete the videos.

14.0 Risks to Subjects

14.1 Describe if any subjects will be withdrawn from therapeutic procedures or drugs (e.g., washout periods) prior to, or during, their participation in the study.

Response: n/a

14.2 List the reasonably foreseeable risks, discomforts, to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks.

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

- Response: Mild skin irritation from wearing the device.
- Temporary muscle fatigue from mobility exercises.
- Dizziness or imbalance while adjusting to the device.
- Minimal risk of falling and sustaining any injury from the fall, with or without device. The study will be conducted in a monitored setting with a healthcare provider who is also a part of the research staff available.
- Loss of confidentiality

- Since this is a research study, not all risks may be known at this time; there may be unforeseen risks associated with study participation.

14.3 Describe the probability, magnitude, duration, and reversibility of the risks and the procedures to minimize these risks.

Response: Participants will be asked to stay in the fixed area at Jefferson's Ferry, e.g. wellness center/gym, for the approximate 1.5 - 2-hour duration of the study.

14.4 Describe procedures being performed to monitor subjects for safety.

Response: Participants will be asked to stay in the fixed area at Jefferson's Ferry, e.g. wellness center/gym, for the approximate 1.5 - 2-hour duration of the study.

14.5 If the study poses risks to an embryo or fetus should the subject be or become pregnant, how will you minimize the risk of a pregnancy occurring during the course of the study? (Select all that apply.)

☐ Counseling on birth control and /or abstinence

☐ Pregnancy test during the study

☐ Pregnancy test prior to initiation of the study

☐ Other _____

14.6 If applicable, describe possible risks to others who are not subjects (e.g., partner of a subject who is administered a study drug).

Response: n/a

14.7 Provisions to Monitor the Data to Ensure the Safety of Subjects

☐ N/A: This study is not enrolling subjects OR is limited to records review procedures only OR is a minimal risk study. See SBU SOPs section 3.6 for a list of the procedures that are

generally considered to be minimal risk: https://www.stonybrook.edu/research-compliance/Human-Subjects/sops).

Response: This study will be performed in a fixed location at Jefferson's Ferry, e.g. wellness center/gym. Participants will remain at this location for the duration of the study and hence will be in a controlled setting for monitoring.

14.8 Provide information about the Data and Safety Monitoring Plan.

Response: This is a pilot study on an FDA exempt class I device that is available over the counter. We will actively monitor and record any falls or other device-related adverse events occurring during study participation. Although the study poses minimal risk, we recognize the importance of safety monitoring. An independent monitor, Dr. Rachel Wong, not part of the research team, will be designated to oversee the safety data, specifically the fall incidence. This individual will receive fall data at regular intervals (e.g. each time 5 participants have completed the study – so they would receive data a total of 4 times, as this would indicate all 20 participants have completed the study) and will recommend pausing or terminating the study if an excessive fall rate is observed or if participant safety is otherwise compromised.

14.9 Provide information if a medical monitor will be used to monitor the safety of the study.

Response: no

14.10 Provide information if a Data and Safety Monitoring Committee/Board will be used to monitor the safety of a study that is greater than minimal risk. Provide justification if a Data and Safety Monitoring Committee/Board will not be used.

☒ N/A:

Response:

14.11 Describe what data are reviewed, including safety data, and efficacy data.

Response:

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

Response:

14.13 Describe the frequency of safety data collection, including when safety data collection starts.

Response:

14.14 Describe who will review the safety data.

Response:

15.0 Potential Benefits to Subjects

15.1 Describe the potential benefits that individual subjects may experience by taking part in the research.

Response: There is no direct benefit. They may find that their mobility transiently improves with the device.

15.2 Indicate if there is no direct benefit.

NOTE: Compensation cannot be stated as a benefit.

Response: There is no direct benefit. They may find that their mobility transiently improves while wearing the Accelera device.

15.3 Indicate if there is a potential benefit to others, future science, or society.

Response: If the study demonstrates improved mobility and/or confidence with the ankle bracelet device then this would be an important finding in geriatric mobility/fall prevention literature. Conversely, if the device fails to improve mobility as assessed above, then that would also be important.

16.0 Economic Burden to Subjects

☐ N/A: This study is not enrolling subjects or is limited to records review procedures only.

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

NOTE: Some examples include transportation or parking, insurance co-payments, study drugs.

Response: none

17.0 Compensation for Participation

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

17.1 Describe the amount/nature and timing/scheduling of any compensation to subjects, including monetary, course credit, or gift card compensation. Describe any prorated payments based on participation. Add IRS tax information to the consent form per template.

Response:

NOTE: If using West Campus Departmental pools, participation in studies may be offered for credit in class but students MUST be given other options for fulfilling the research component that are comparable in terms of time, effort, and education benefit. Please indicate the alternative activity/related contact information in the consent form.

18.0 Informed Consent

18.1 Will you be obtaining consent from subjects?

☒ Yes (If yes, provide responses to each question in this section, and upload your consent documents where indicated in the electronic submission system.)

☐ No (If no, skip to the next section.)

18.2 Describe how the capacity to consent will be assessed for all subjects. Review SBU SOPs section 5.5 for guidance: https://www.stonybrook.edu/research-compliance/Human-Subjects/sops).

Response: These are volunteers in an independent community living setting who are able to provide informed consent. We are only allowing patients who are in the Independent Living section of Jefferson's Ferry and who can consent for themselves to participate in the study. While formal capacity testing is not planned, we will implement a two-step assessment to ensure each participant has the capacity to consent. First, participants must be oriented to person, place, and time. Second, participants must be able to demonstrate understanding of the study by accurately restating (using the "teach-back" method) key elements of the consent form, including the study's purpose, procedures, potential risks, and voluntary nature. Should a participant be unable to meet these criteria, they will not be enrolled in the study.

18.3 Describe the consent process that will be conducted to ensure that the subject is fully informed regarding study details and subject rights. Include where the consent process will take place, with consideration of the need to protect the subject's right to privacy.

Response: During the recruitment and screening process, participants' privacy will be protected by ensuring that all recruitment activities occur in a confidential manner. Interested individuals will contact the study staff directly to express interest. Personal discussions regarding the study will take place in private settings, either over the phone or in person, to ensure privacy. Only authorized research staff will be involved in the recruitment and screening process.

In addition, all participant information collected during the screening process will be de-identified and stored securely. The research team will use a unique identifier for each participant, and all identifiable information (e.g. consents) will be kept in locked cabinets, until they are uploaded into a secured Stony Brook Medicine shared drive accessible only to designated research personnel. Furthermore, electronic information will be stored on password-protected, encrypted servers to prevent unauthorized access.

18.4 Describe how you will ensure that subjects are provided with sufficient time to consider taking part in the research study. Detail if there is any time period expected between informing the prospective subject and obtaining the consent.

NOTE: It is required that the prospective subject receive sufficient time to have their questions answered and to consider their participation

Response: The study has been approved by Jefferson's Ferry leadership. Prior to initiation of the study, there will be an 'open house' type forum(s) at Jefferson's Ferry, where we will discuss the study. As this is purely voluntary, only interested participants are expected to enroll.

18.5 Describe the process to ensure the subject's ongoing willingness to continue participation for the duration of the research study.

Response: There is only a single study session in the study. The participant may withdraw at any time during the single study session.

Non-English Speaking Subjects

☒ N/A: This study will not enroll Non-English speaking subjects.

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

Response:

18.7 If subjects who do not speak English will be enrolled, describe the process to consent the subjects, as well as the process to be used to ensure their understanding of research procedures throughout the conduct of the study. Review SOPs section 17.8 for important policies in this regard: https://www.stonybrook.edu/research-compliance/Human-Subjects/sops).

Response:

Adults Unable to Consent

☒ N/A: This study will not enroll adults unable to consent.

18.8 Justify why it is necessary to include adult subjects who are unable to consent.

Response:

18.9 Describe how you will identify Legally Authorized Representatives (LAR) for the subjects that will be consistent with the NYS Family Health Care Decisions Act (FHCDA; see SBU SOPs section 5.2 at https://www.stonybrook.edu/research-compliance/Human-Subjects/sops).

Response: n/a

18.10 For research conducted outside of New York State, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research.

Response: n/a

18.11 Describe the process for obtaining assent from the adult subjects

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

Response: n/a

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

Response: n/a

18.13 Describe how you will obtain consent from a subject to use their data if they later become capable of consent. Include information regarding how competence will be assessed.

Response: n/a. This is a single session study.

19.0 Waiver or Alteration of Consent Process

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

Complete this section if:

· Informed consent will not be obtained at all

· Informed consent will be obtained, but not documented, or

· Informed consent will be obtained, but not all required information will be disclosed (e.g., in deception research)

☐ A waiver is requested. Complete and upload Supplemental Form G.

19.1 If the research involves a waiver of the consent process for planned emergency research, please contact the Office of Research Compliance for guidance regarding assistance in complying with federal regulations governing this activity (see: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research

20.0 Drugs and Devices

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

20.1 Does this study involve use of radiopharmaceuticals?

☐ Yes

☒No

20.2 For investigational devices, provide the following information below:

Where will the device(s) be stored? Note that the storage area must be within an area under the PI's control. Describe the security of the storage unit/facility. Provide full details regarding how the dispensing of the device(s) will be controlled (accountability of removal/return of used devices, and disposition of remaining devices at the conclusion of the investigation) and documented (accounting records/logs).

Response: The Accelera ankle bracelets, FDA class I exempt devices, will be stored at a secured location at Jefferson's Ff~~f~~erry where only research staff conducting the study would have access. Please also see supporting letter from Accelera regarding FDA exemption.

20.3 For investigational drugs (including marketed drugs being used off label), will the services of the Investigational Drug Pharmacy be used for storage, dispensing, accounting the drug (required for research conducted at UH, HSC, Cancer Center, and Ambulatory Surgery Center)?

☐ Yes

☐ No → Provide the following information below:

· Where will the drugs/biologics be stored? Note that the storage area must be within an area under the PI's control

· Describe the security of the storage unit/facility:

· Provide full detail regarding dispensing of the drugs(s), how labeled, controlled (accountability, disposition of unused drug at the conclusion of the investigation) and documented (accounting records/logs):

Response:

21.0 Sharing Results with Subjects

21.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.

Response: If the volunteers desire, they will be shown the results of their performance on the timed up and go, chair stand, and 4-point balance test and app-based gait/posture/mobility analysis, before and while wearing the ankle bracelets.

22.0 Collaboration

☒N/A: This study does not include any collaborations.

22.1 Internal Collaboration

Response: n/a

22.2 External Collaboration

Response: Accelera is lending the devices to us for the study and will receive aggregate data.

22.3 Community Based Participatory Research (CBPR)

Does this project include community based participatory research? (Also referred to as community-based research (CBR), CBPR is a partnership-based approach to research that takes place in community settings and involves community members in the project's design and implementation and dissemination of results.)

☐ N/A: This study does not include CBPR.

Response: Yes, we are collaborating with Jefferson's Ferry.