Version Date: 12/17/2021	R&D Stamp: VA R&D	COMIRB Approval Stamp/Date:

Subject Name: _____ **Date:** _____

Title of Study: Acceptability and Feasibility of Apollo Wearable Device, Tuned Vibroacoustic Stimulation (TVS) in Veterans with a History of Post-traumatic stress disorder (PTSD)

Principal Investigator: [redacted] **VAMC:** [redacted]

VA Investigator: [redacted] **COMIRB#:** 20-2268

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about the use of the Apollo Wearable System (Apollo) in Veterans with post-traumatic stress disorder (PTSD).

The Apollo is a non-invasive and non-habit-forming device that delivers gentle wave-like vibrations to the body that are believed to impact how the nervous system responds to stress.

You are being asked to be in this research study because you are a Veteran between the ages of 18 and 65 with PTSD.

Other people in this study

Up to 100 people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to meet with members of the study team at least twice. Also, there will be weekly surveys emailed to you by a member of the study team. You may also be called by members of the research team regarding these surveys. You will be asked to use the Apollo, as well as a device to measure your heart rate (for 24 hours) twice during the study. You will be asked to provide blood samples (twice), which we are collecting to learn about inflammation and DNA. You will also be asked to provide stool samples (twice), which we are collecting to learn more about the gut microbiome.

Time 1. During this visit you will be asked to complete surveys on the computer and respond to interview questions. The surveys and questions may include information about your thoughts, feelings, and physical and mental health symptoms. It is estimated that this appointment will take approximately 3 hours. You will be asked to provide a stool and blood sample. You will also be asked

to monitor your heart rate for 24 hours by putting an EKG lead on your rib cage. A kit with instructions for the stool sample collection as well as the EKG device will be provided to you with a stamped return envelope to mail the sample back, or they may be delivered to your home by a member of the study team. The sample and the EKG device may be picked up from your home by a member of the study team or you may be asked to send them back to the study team (postage will be provided).

After 24 hours' worth of heart rate data is collected a member of the research team will work with you to get you the Apollo device (e.g., mail, delivery) and communicate with you about how you should use the device and whom you should call if you have questions. You will be asked to wear the Apollo device for 10 +/- 2 weeks and be asked to install the Apollo application on your mobile phone. You will use the Apollo device for at least 60 minutes after waking up in the morning and at least 120 minutes before bed using the recommended settings for that time of day. You will use the app on your phone to help facilitate. In addition, in collaboration with our partners at Apollo Neuroscience, Inc., the study team will record usage including all modes used, the intensity, physical position, and usage patterns.

Between Time 1 and Time 2. Between Time 1 and Time 2 you will also be asked to complete weekly surveys via the computer. A member of the research team may contact you by phone call to see how you are doing with the study and address any questions or concerns with the device or side effects, as well as challenges you may be having completing the surveys.

Time 2. Prior to the Time 2 visit, we will ask you to start measuring your heart rate again for 24 hours. We will also work with you to collect a stool and blood sample. During the final meeting you will be asked to complete surveys on the computer and respond to interview questions. The surveys and questions may include information about your thoughts, feelings, and physical and mental health symptoms. We will also ask questions regarding your experience with the Apollo device and app. The final appointment is expected to last approximately 3 hours. You will be asked to return the Apollo device and heart rate monitor devices after this final appointment. The final sample, EKG device, and the Apollo device may be picked up from your home by a member of the study team, or mailed.

This research study is expected to last approximately 5 years. Your individual participation in the project will require 2 visits and weekly check-ins/surveys. As well as wearing the device, daily, between visits. In total, your participation will be approximately 34 hours over the course of approximately 10 +/- 2 weeks. We may also access your medical record before and after your participation.

What are the possible discomforts or risks?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Discomforts you may experience while in this study include feeling uncomfortable answering questions about your experiences. It is possible you may get frustrated, tired, or upset during the appointments or while answering survey questions.

The Apollo device is not approved by the Food and Drug Administration and is considered experimental. Any side effects associated with the Apollo device are usually mild and most often include discomfort where the device is worn, which can be relieved by removing the device and cleaning it gently with an alcohol wipe (provided). It is also possible that you may feel restless if you set the intensity on your Apollo too high. In this scenario, the restlessness is temporary and can be alleviated by turning down the intensity on the Apollo device to where it is just barely noticeable using the buttons on the device or the mobile app.

Minimal physical risks for specimen collection are listed below:

- Stool specimen: Contamination of skin with feces from the collection container could occur.
- All blood draws will be conducted by trained professionals. You may experience dizziness, fainting, light-headedness, bruising, slight bleeding and/or pain during or after the blood sample is taken.

While we maintain the highest level of confidentiality with study data and personal information, there is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed. A number of protections are in place to maintain the confidentiality of your records.

In response to some of the assessments or in response to information that you may share with the study staff, we may contact a VA clinician to discuss possible treatment options. If a member of the research team is concerned about your safety, they will consult with a licensed provider and you may be assisted in obtaining mental health or primary care depending on your needs.

If you experience the risks/discomforts listed above and need help, please contact the study doctor, or your VA provider. If you need immediate assistance, urgent care is always available at the [redacted] VA Medical Center and can be accessed via the Emergency Room or by calling [redacted]

Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

The study may include risks that are unknown at this time.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the safety and feasibility of Tuned Vibroacoustic Stimulation (TVS) delivered by the Apollo device for Veterans. There are no direct, guaranteed benefits to you for being in this study. This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section above describing the discomforts or risks.

Are there alternative treatments?

Although this study includes a device for an intervention, this is not a treatment study. The device used in this study is commercially available wearable wellness device and is not intended to treat or cure any diseases.

You should talk to your doctor about your choices regarding evidence-based treatments for PTSD. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

Support for this study will also be provided through pilot project funding from the Rocky Mountain Mental Illness Research Education Clinical Center (MIRECC).

Will I be paid for being in the study?

You will be paid $45 for the Time 1 visit. You will be paid $45 for the Time 2 visit. You will also be paid $10 for completing weekly surveys between Times 1 and 2. This will add up to a total of $210 if you complete all of the visits and complete all surveys between visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

Will I have to pay for anything?

There will be no cost to you for participation in this study. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed, for research-related interventions or procedures that are required by the protocol.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission, if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

Every reasonable safety measure will be used to protect your well-being. The VA Eastern Colorado Health Care System (ECHCS) will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans in accordance with applicable federal regulations (38 CFR 17.85). Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, call [redacted] If your injury requires emergency medical attention, the [redacted]

Who do I call if I have questions?

The researcher carrying out this study at the VA is [redacted] You may ask any questions you have now. If you have any questions later, you may call [redacted] You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call the Colorado Multiple Institutional Review Board (COMIRB) office at [redacted] This is the Board that is responsible for overseeing the safety of human participants in this study. If you want to verify that this study is approved or if you would like to obtain information or offer input, please contact the VA Research Office at [redacted]

How will my private information be protected?

Identifiers might be removed from the identifiable private information data or identifiable biospecimens that are collected. After that removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Some things we cannot keep private: If you tell us you are going to physically hurt yourself or someone else, we have to report that to the VA or Colorado State Police. Also, if we get a court order to turn over your study records, we will have to follow the court order.

Who will see my research information?

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, HIV status, drug or alcohol treatment, or mental health treatment.

We will try to keep your medical records confidential, but it cannot be guaranteed. Records that identify you (including your medical records and the consent form signed by you), may be looked at or portions of your records copied that identify you by others. These include:

- Federal agencies such as the Food and Drug Administration (FDA), the General Accountability Office (GAO), the Office of the Inspector General, Office for Human Research Protections (OHRP), and the Office of Research Oversight (ORO) that protect research subjects like you, may also copy portions of records about you.
- Specific title 38 USC 7332 protected information (drug abuse and alcoholism or alcohol abuse).
- People at the Colorado Multiple Institution Review Board
- The investigator and research team for this study
- The sponsor (group paying for the study), study monitors or agents for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Our local VA Research and Development Committee
- University of Colorado Anschutz Medical Campus
- University of Colorado Hospital Clinical & Translational Research Centers (CTRC)
- Apollo Neuroscience, Inc.
- Icahn School of Medicine at Mount Sinai
- James J. Peters VA Medical Center

I understand that by signing this consent form, a copy of limited data about me, restricted to deidentified survey data, that is collected as part of this specific VA research study will be stored in the REDCap database at the University of Colorado Denver's (UCD's) Colorado Clinical and Translational Sciences Institute (CCTSI). These data will be used solely for the purposes defined in this consent form and for this specific study. Data collected about me for this study placed on the

CCTSI REDCap Database will not be accessed or used for any other study or purposes and will only be accessed by VA-credentialed personnel. The CCTSI REDCap database is a highly secure, nationally utilized data management system, and it is housed within the highly secure environment at the University of Colorado Denver.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted] and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

What happens to data collected?

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data".

Is there other information I need to know? If you are interested, [redacted] or her designee may also contact you in the future regarding participating in other studies. If interested, you will be given a separate consent and VA HIPAA B authorization to sign to be enrolled in [redacted] protocol #10-0554 "VISN 19 MIRECC Research Database". I choose to allow my personal contact information (address, telephone number, and emergency contact) to be kept by this investigator for possible recruitment in future studies.
I have been told that I do not have to make my data available for future recruitment. I may withdraw from future recruitment at any time without penalty or loss of VA or other benefit to which I am entitled by contacting [redacted]

☐ Yes, I am interested in being contacted to participate in future studies. ____Initials

☐ No, I am not interested in being contacted to participate in future studies. ____Initials

Agreement to be in this study

I have read this form, or it has been read to me. A member of the research team has explained the study to me. I have been told about the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this form below, I voluntarily consent to participate in this study. I will receive a copy of this consent after I sign it. A copy of this consent form will be placed in my medical record.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____