Framingham Heart Study
Offspring Exam 10, Omni 1 Exam 5
Brain Health Study

RESEARCH CONSENT FORM ADDENDUM

Basic Information

Title of Project: Multidimensional Assessment of Brain Health as a Marker of Dementia Risk and Resilience

IRB Number: H-40757

Sponsor: National Institute on Aging (NIA), National Institutes of Health (NIH)

Principal Investigator: Sudha Seshadri, MD
Seshadri@UTHSCSA.edu
University of Texas Health Sciences Center, San Antonio, TX

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

The PI of the Brian Health Study is Dr. Sudha Seshadri who is Professor of Neurology at the University of Texas Health Sciences Center, San Antonio, TX and also an adjunct Professor of Neurology at Boston University School of Medicine. The Program Manager supervising this effort at the Framingham Heart Study site is Mr. Timothy Kowalczyk and the PI of the Framingham site for this study is Dr. Vasan Ramachandran, MD who is also the PI of the overall Framingham Heart Study.

Study Phone Number: 857-389-2359 (Dr. Seshadri)
508-935-3410 (Study Manager, Timothy Kowalczyk)

Overview of the Brain Health Study
We are interested in finding a way to define brain health beyond the evaluation of cognitive testing. We will ask you to participate in a number of sensory motor tests that capture your brain health, including testing your vision, hearing, and motor function. You will have eye testing (without dilatation); hearing testing (using an iPad and headphones); and motor function testing (includes gait speed assessment on an electronic gait mat, during normal walk and while doing a mental task like counting.) As described in the main consent form, we may also report some routine research test measurements to you and/or your health care provider at the time of the exam or after your exam

The Brain Health Study within the Framingham Heart Study Offspring Exam 10, Omni 1 Exam 5 is conducted in collaboration with The University of Texas Health Science Center at San Antonio.

All procedures described below will be performed for research purposes only.
A. Vision Testing:

Optical Coherence Tomography Angiography (OCTA):
This exam will be performed without dilating eye drops. You will be asked to rest your chin and forehead on a support that is attached to the OCT machine. You will be asked to fixate your eyes on a target for a few moments and as a camera scans and takes images of the retina, the back of your eye. It also measures blood flow in the eye and is a completely non-invasive measurement that is approved by the U.S. Food and Drug Administration (FDA) as a rapid method of assessing retinal capillary density

B. **Motor Testing**

In ***Gait Testing***, you will be asked to walk on a gait mat (that appears like a regular rug or mat) that has pressure sensors below it. A computer and software connected to the mat will capture the different aspects of the walk including speed, step length, step width, etc. You will be asked to walk at your usual pace, fast pace and while doing cognitive tasks like counting backwards.

C. Hearing Testing
Using a portable tablet-based system and earphones we will present a **pure tone** to the **ear** measuring the lowest intensity in decibels (dB) at which this **tone** is perceived 50% of the time. This measurement is called **threshold**.

Risks of Participation in this research

Informational risks related to the study
Your data will be assigned a code number. Your name, medical record number, or other information that easily identifies you will not be stored with your samples or data. The key that links your identifying information to the code number will be stored securely in a separate file and will not be shared with researchers that are not part of our study team.
The main risk of allowing us to use your data for research is a potential loss of privacy. This risk is serious but rare because we take many steps to protect your information. We protect your privacy by coding your data and removing personal identifiers. Research results obtained in this study will not be placed in your medical record unless we contact you with a finding of high medical importance. We do not think that there will be further risks to your privacy by sharing your data with other researchers; however, we cannot predict how this data will be used in the future.

Risks of Study Procedures
There is also minimal risk of falling during the gait testing, but we will take the same precautions described above to prevent falls by walking behind and to the side and assisting if required.

For more information about risks and side effects, ask one of the researchers or study staff. We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks and we expect no injuries from these studies. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. in the event of a research-related injury or if you experience an adverse reaction, please immediately contact study staff. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We do not offer a program to provide compensation for the cost of care for research related injury. The study staff can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study

Information about how this study will use your Protected Health Information (PHI)
Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out who the person is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this research study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for the study. In carrying out this research, the health information we will see and use about you will include:

- your medical history and blood work,
- results of eye, ear and gait assessment tests,
- information from interviews or from questionnaires,
- demographic information like your age, sex

We will get this information from the data collected today and over the years at the Framingham Heart Study

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your

study records, and other study materials containing health information that are sent outside the institutions listed above for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail, fax, or other secure means of transmission. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be shared with other Researchers?
Because it is research, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in conducting and overseeing this research study including:

- the following collaborators at other institutions that are involved with the study: The University of Texas Health Science Center at San Antonio, Boston University School of Medicine, Massachusetts Eye and Ear Infirmary and University of Southern California
- the members of the local research team;
- the Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out; and
- the Research offices at the University of Texas Health Science Center at San Antonio

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information for research purposes. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in this research study.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the Brain Health Study portion part of the Framingham Heart Study Examination.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you must provide this in writing and send your letter to ***Vasan Ramachandran, Principal Investigator, Framingham Heart Study, 73 Mt Wayte Ave, Suite 2, Framingham, MA 01702.*** If you tell the researchers to stop using your health information, your participation in this part of the Framingham Heart study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. If you ask for research information that is not in your medical record, we might not

provide it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of this study; at this time we do not have any specific end date and will continue using your data until it is no longer of scientific value.

Contact Information
If you have questions now, feel free to ask us. If you have additional questions later or you wish to report a problem or complaint which may be related to this study please contact:

FHS Neurology Study Manager, Timothy Kowalczyk at 508-935-3410.

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date

Surrogate Signature Section

- You are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You are authorizing the collection, use and sharing of another person's protected health information as described in this form.

Printed Name of Subject	Signature of **Subject**, indicating Assent *(If incapable of signing, person obtaining consent should initial here)*	Date
Printed Name of Legally Authorized Representative (LAR)	Signature of Legally Authorized Representative (LAR)	Date

Researcher

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent & Authorization	Date

BMC and BU Medical Campus IRB
IRB NUMBER: H-32132
IRB APPROVAL DATE: 07/21/2021