

Northeastern University, Department of Electrical and Computer Engineering**Name of Investigator(s):** Sumientra Rampersad, PhD; Michael (Misha) Pavel, PhD; Maciej Kos**Title of Project:** FOCI Study**Informed Consent to Participate in a Research Study**

We are inviting you to take part in a research study. This form will tell you about the study, but the researcher will also explain the contents of the form to you during your first session. You may ask this person any questions that you have. When you are ready to make a decision, you may tell the researcher if you want to participate or not. **You do not have to participate if you do not want to.** If you decide to participate, the researcher will ask you to sign this form. They will then scan it and return it to you.

Key Information

- Your consent is being sought for participation in a research project and **your participation is voluntary.**
- The purpose of this research is to **develop a new mobile technology for monitoring changes in memory and attention.**
- The study consists of:
 - **Three in-person meetings** in our lab, of 3 to 4 hours each.
 - The first in-person session will take place after you sign this form. The second meeting will take place after 6 months. The third meeting will take place after 12 months.
- The procedures that you will be asked to complete include:
 - Allowing researchers to **export your Android activity data**, i.e., your movement data, what apps you use and when from your Google account, and to **install a data collection app** on your smartphone.
 - During the 3 lab visits, you will be asked to answer brief demographic questions and complete a series of **thinking and movement tasks.**
 - During visits 1 and 3, you will also **have a magnetic resonance imaging (MRI) scan of your brain.**
 - Throughout the 12 months of the study, you will receive, on average, one message every two days, and no more than two messages per day, **on your phone asking you to respond to a brief question.**
- The possible risks or discomforts of the study are minimal. Please note that some subjects have experienced claustrophobia while in the MRI. If at any time you wish to discontinue the scan, you may do so by notifying the experimenter.
- There are **no direct benefits to you from participating** in this study.

Why am I being asked to take part in this research study?

We are asking individuals with and without mild cognitive impairment to participate. You have shown an interest in helping us develop a new mobile technology for detecting and monitoring mild cognitive impairment. You are between 45 and 65 years of age, right-handed, able to speak and read English, you own and use an Android smartphone with a data plan, you are not pregnant or planning on becoming pregnant, are not diagnosed with dementia or any condition preventing you from leaving home or undergoing magnetic resonance imaging (MRI), you are not diagnosed with sleep apnea that you do not treat (if you have such a diagnosis you are planning treatment in the next six months), you are not diagnosed with major depression (not including postpartum related), anxiety disorder, epilepsy, seizures, multiple sclerosis, traumatic

brain injury, post-traumatic stress disorder, psychosis, bipolar disorder, Alzheimer's disease, Parkinson's disease, vascular dementia, schizophrenia.

Why is this research study being done?

The research goal is to develop a **new mobile health technology to detect and monitor changes in memory and attention.**

What will I be asked to do?

You will be asked to come to our lab. Before entering the lab, we will ask you some basic health questions, we may take your temperature using a touchless thermometer, and may ask you to wear a face mask covering your mouth and nose. If needed, the research staff will wear a mask. During your first lab session, a member of our research team will take you through the consent process and we will ask your age, gender, sex at birth and additional demographic information. We will also ask you to tell us your height and weight. We are asking for this information because we would like to calculate two things. First, we would like to calculate how many calories you burn per day. Second, we would like to calculate how tiring physical activities may be for you. Knowing your height and weight would help us in these calculations. Then we will ask you to do a few memory and thinking tasks, and some simple movement exercises. The researcher will also ask you for an email address or address where we can send you a gift card.

We will ask you to undergo an MRI session, which takes approximately 30 minutes. MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. You will be asked to lie still on a long narrow bed inside a large magnet while the machine gathers data. You will not feel the magnetic field, but you will hear repetitive tapping noises from the scanner. We will provide earplugs and headphones that you will be required to wear. The space within the magnet in which you lie is somewhat confined.

We will also ask you to allow us to export your Android activity data, i.e., your movement data, what apps you use and when, from your phone. We will not export any emails, messages, photos, videos or browsing history. You will log into your Google account on our secure lab computer. We will export your Android activity data using Google's service called Google Takeout. We will encrypt and save the data on the computer and log out of your Google account. To ensure nobody can access your account, we will clear the browser's cache and cookies.

Next, we will install our research data collection app on your phone. The app collects the following data:

- the time when the device is on or off
- the time when the device locked or unlocked
- the time when the screen is on or off
- the device's location and mode of transportation (standing, walking, biking, car/train/bus)
- time and name of mobile application used
- time you answered a call
 - we do not record who participated in the conversation
 - we do not record the calls
- how quickly you type, how often you tap the delete key and the space key, how often you use autocorrect
 - we do not record what text you type
- what apps send you notifications; the time you receive them and when you dismiss them (if you do)

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- we do not record what the notifications are about or what they contain; for example, if you received a notification about a new text message, we wouldn't know who this text message is from or what it says.
- device's battery status and whether the device is charging

To respect your privacy:

- we do not access and do not record web browsing and search history
- we do not access and do not record information about who you call and what you say
- we do not access and do not record what you type
- we do not access and do not record who you message and what the messages are
- we do not access and do not record your message history
- we do not access and do not record any videos or sounds
- we do not access and do not record any videos or photos you take
- we do not access and do not record what you do using the apps installed on your device, e.g., we do not record if you tap "like" on Facebook or if you buy any products using the Amazon app

Our research app will also ask you short questions, e.g., "Were you shopping yesterday?" On average, you would receive one question every two days and no more than three questions per day. By default, the questions will be sent between 11 am and 9 pm. However, you can change delivery times to be between the hours that you specify.

At the end of the first in-person meeting, we will schedule a phone call with you for three weeks later. This phone call is meant to see how you are doing with the app and whether you have any questions. We will check in again 2 months later and then schedule the second lab visit, 6 months after the first. The third lab visit will happen 12 months after the start of the study. The second and third lab visits will be similar to the first (thinking + movement tasks). The third visit will also have an MRI session and we will remove the data collection app from your phone.

As a token of our gratitude, after every session you will receive a gift card from a store of your choice: Amazon, Target, Bed Bath and Beyond, Walmart, Star Market, Stop&Shop or iTunes.

The values of the gift cards will be:

- 1) Lab Visit 1, ca. 3 hours, \$50
- 2) Lab Visit 2, ca. 2 hours, \$50
- 3) Lab Visit 3, ca. 2 hours, \$50
- 4) Completion bonus, \$70

If you complete the study, you will receive a total of \$220 in gift cards.

Where will this take place and how much of my time will it take?

The lab sessions will take place in our lab at 805 Columbus Avenue in Boston. The study will last 12 months from your first lab session to completion. Each of the three lab sessions will take between 3 and 4 hours.

Will there be any risk or discomfort to me?

The likelihood and degree of risk to participants is minimal. You are also free to stop your participation at any time.

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The possibility of feeling uncomfortable working with the app is very low. If you feel the questions sent by the app are annoying or distracting, you can place your phone on “silent” mode, or ignore them if they come at inconvenient times. You should ignore all questions while driving a vehicle.

You may feel fatigued or frustrated during the thinking and movement tasks in the lab. You will be allowed breaks at several points during each session.

The MRI scanner uses a strong magnet that will attract some metals and affect some electronic devices. If you have a pacemaker, metal implants, bullet pieces, insulin pumps or any other metal such as metal clips or rings inside your body, you cannot have an MRI. During the scan, you will lie in a small closed area; you should not participate if you are scared or anxious in small places. The MRI scanner makes loud banging noises while taking a measurement, so earplugs and headphones will be used to reduce noise. Tattoos could become warm or irritated during the scan and remain so for several days. There is a small possibility that you experience a localized twitching sensation due to the magnetic field changes; this is not unexpected and should not be painful. Dizziness or nausea may occur if you move your head rapidly within the magnet. Most people experience no ill effects from these scans, but some people do report claustrophobia (fear of being in enclosed small spaces). While the MR images in this study are not formally reviewed by a radiologist, if in the course of processing the images we notice any abnormality that would be possibly important to your health, we will notify you.

Will I benefit by being in this research?

There are no direct benefits to you from participating in this study. However, the data you provide may help develop a technology for detecting and monitoring mild cognitive impairment as well as advance our understanding of this condition. Your participation will likely help this research and technology reach its full potential.

Who will see the information about me?

Your information in this study will be confidential. Only the researchers on this study will see the information about you. No reports or publications will use information that can identify you in any way as being a participant in this project. All recordings will be destroyed following transcription and analysis.

Future Use of Data

Your **de-identified** information could be used for future research **without additional informed consent**.

If I do not want to take part in the study, what choices do I have?

Your participation in this study is voluntary. You do not need to participate.

What will happen if I suffer any harm from this research?

No special arrangements will be made for compensation solely because of participation in this research.

Can I stop my participation in this study?

Your participation in this research is completely voluntary. You do not have to participate if you do not want to, and you can refuse to answer any question. Even if you agree to be in the study, you may stop at any time. If you do not participate or if you decide to quit, you will not lose any rights, benefits, or services that you would otherwise have.

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Who can I contact if I have questions or problems?

If you have any questions about this study, please feel free to contact the principal investigator Dr. Sumientra Rampersad via phone (617-379-1112) or email (s.rampersad@northeastern.edu).

Who can I contact about my rights as a participant?

If you have any questions about your rights in this research, you may contact Nan C. Regina, Director of Human Subject Research Protection, Mail Stop: 560-177, Northeastern University, Boston, MA 02115. Tel: 617-373-4588. Email: n.regina@neu.edu. You may call anonymously if you wish.

Will I be paid for my participation?

Participants will receive gift cards in the amounts of \$50 after completing each lab visit and a \$70 bonus for completing the entire study. If you complete the study, you will thus have received a total of \$220 in gift cards.

Will it cost me anything to participate?

There will be no costs to participation, excluding miscellaneous fees. If you come to our campus by car, we will pay for on-campus parking. Be aware that the use of the apps on your smartphone will transfer a small amount of data to the research server and may drain your phone battery slightly faster than usual. In addition, standard data fees and rates may apply based on your plan with your mobile phone carrier.

Is there anything else I need to know?

The investigator may withdraw the subject at any time (i.e., when it is in the subject's best interests, there are untoward side effects, or there is failure to comply with the study protocol). Any completed study visit will still be rewarded with a gift card.

Agreement to take part in this research.

I agree to take part in this research.

Print full name of person agreeing to take part

Date

Signature of person agreeing to take part

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I Agree to be contacted for follow up or for future research studies

Contact Information (email and phone)

Signature of researcher who explained the study to the participant above and obtained consent

Date

Printed name of person above

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