

[Insert greeting],

My name is **[insert name]** from Washington University in St. Louis.

Thank you for your interest in our research study.

-OR-

I received your name and telephone number from colleagues at Washington University. I am calling you about a research study because you may be eligible to participate. The purpose of this study is to understand how the brain learns and retrieves information using behavioral and neuroimaging techniques.

Would you be interested in learning more about the study? Please feel free to ask questions at any time.

[If the individual states, “no”]

Thank you for your time and consideration. **[End the call]**

-OR-

[If the individual states, “yes”]

This is a research study conducted by Zachariah Reagh and the Complex Memory Lab having to do with learning and memory. If you agree to participate, you may be asked to complete cognitive tasks on a computer, participate in magnetic resonance imaging scans, and complete questionnaires.

This study involves (pick either)

- A) Behavior sessions only
- B) Behavior and imaging sessions
- C) Imaging sessions only

A) (# SESSIONS) at Washington University’s Danforth campus. You will be asked to complete several questionnaires and tasks on a computer. The session(s) will last (# HOURS). You will be paid \$10/hour for completing this study.

B) (# SESSIONS) which will be completed on different days. In (# SESSIONS), you will need to come to Washington University’s Danforth campus. You will be asked to complete several questionnaires and tasks on a computer. The session will last (# HOURS). You will be paid \$10/hour for completing the session. In the remaining (# SESSIONS), you will need to come to the Washington University School of Medicine. You will be asked to complete a task while in the MR scanner. This task could be a computer task where you will push buttons on a keypad, or a verbal task where you will

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EXPIRATION DATE: N/A

speak into a microphone. You will be paid \$25 per hour for your time. You may also be asked to complete questionnaires. You are free to skip any question that you prefer not to answer.

- C) (# SESSIONS) at the Washington University School of Medicine. You will be asked to complete a task while in the MR scanner. This task could be a computer task where you will push buttons on a keypad, or a verbal task where you will speak into a microphone. You will be paid \$25 per hour for your time. You may also be asked to complete questionnaires. You are free to skip any question that you prefer not to answer.

In order to determine if you are eligible for this research study I need to ask you a few questions about demographics, physiological information, and contraindications for magnetic resonance imaging, which will include current and previous health conditions. This is called a phone screen. The phone screen is for research purposes and could last about 5-10 minutes. If you prefer to do this at a more convenient time please let me know.

Identifiers may be removed from your private information collected during this phone screen and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

A risk of participating in this phone screen is that confidential information about you may be accidentally disclosed. You will not benefit from participating in the phone screen.

We will keep the information you provide confidential by using an ID code number for the information collected. We will destroy the link between the ID code and your name if you are not eligible to participate in the study or decide that you do not wish to participate at any point. Any report or article that we write will not include information that can directly identify you. However, federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records pertaining to this research activity.

Your participation in this phone screen is completely voluntary. You may choose not to take part at all. If you decide to participate in the phone screen you may stop participating at any time. Any data that was collected as part of this phone screen will remain as part of the study records and cannot be removed. If you decide not to take part in the phone screen, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If, after completing this phone screen, you are eligible for the research study you will be asked at a later date to sign a separate consent form that includes more detailed information about the study.

Your answers to the screening questions will create Protected Health Information (PHI) that

identifies you. Your health information is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). Because of this law, you will need to give the research team permission to use and share your protected health information from the phone screen for this research.

When possible, the research team will make sure information cannot be linked to you. Once information doesn't identify you, it may be used and shared for other purposes not discussed during this phone screen.

The information collected today during the phone screen may be seen by people making sure the research is being done right. This may be people at Washington University, or people from the federal Office for Human Research Protections.

- If you agree, you are giving permission for us to use of your PHI for this research, and your permission will not expire.
- If you do not agree to allow us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in the phone screen for this study.
- Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.
- If you change your mind and do not want the research team use or share your information, you will need to provide a written letter to the research team cancelling your permission. Please contact the Human Research Protection Office for more information on how to revoke your authorization or contact the research team to request the withdrawal letter. If you do this, the research team may only use and share information already collected for the study. You will not be allowed to continue to participate in the study.
- If you have questions or concerns about your privacy and the use of your protected health information, please contact the University's Privacy Officer at 866-747-4975.

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Zachariah Reagh at (314) 935-5176. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number I just mentioned. I can repeat it for you if you would like.

Do you agree to participate in the phone screen?

[If the individual states, “no”]

Thank you for your time and consideration. **[End the call]**

-OR-

[If the individual states, “yes” conduct the phone screen. You may include the screening questions on this document or attach a separate document in myIRB.]

MR SCREENER

1. Demographic Information

What is your biological sex?

What is your age?

What is your height?

What is your weight?

Are you right or left handed?

Are you a native English speaker?

2. Medical Conditions

(If subject responds “yes” to any of these questions, **follow-up probe questions*** (listed below) are asked. A response of “yes” does not necessarily exclude them from the study)

Have you ever had any surgical procedures?

Do you have any implants?

Do you have any heart problems?

Do you have any hearing problems?

Do you have any vision problems?

Is your vision corrected with glasses or contacts?

Are you color blind?

Have you had extensive dental work?

Do you have permanent retainers?

Do you have any implanted orthopedic item?

Have you had prior experience with MRI?

Have you had any neurological trauma (for example, severe concussions)?

Are you claustrophobic?

Do you have any metal such as piercings, filings, splinters, or shrapnel, in your body?

Are you on any medications?

Do you have tattoos or permanent eyeliner?

Do you have a history of seizures?

Do you have or have you had a mental illness?

(If female) Are you pregnant or breastfeeding?

Were you born prematurely (before 37 weeks)?

Do you have any other medical problems which we have not discussed?

If subject is found to be ineligible, the reason they are ineligible is told to them.

An example of such a statement follows:

I'm sorry, we're unable to use you because MRI consists of magnetic signals, which could be dangerous to those with metal in their body. Metal objects could heat up and tug on you while you are in the scanner.

If subject is found to be eligible:

You meet our inclusion criteria. If you are interested in participating, I need to collect demographic information and confirm your contact information to send you confirmation of your appointment and a map of the campus.

What is your full name, first, middle, and last?

What is your preferred method of contact?

What is your full address?

What is your email address?

What is your phone number?

The interview is complete. Please feel free to call me (state your name) at (phone number) if you would like to reschedule or have any questions before your visit. Thank you!

(probe questions follow)

****Probe Questions for more detail about a "yes" response in part 2****

Surgery

What was the nature of the surgical procedure?

Did it involve any type of surgical clips or staples?

Heart problems

Do you have a heart pacemaker or replacement valve?

Do you have an aneurysm clip?

Do you have an implanted cardiac defibrillator?

Do you have an intraventricular shunt?

Do you have sternum wires from open heart surgery?

Do you have a vascular access port?

Do you have a heart valve prosthesis?

Do you have any type of neuro/biostimulator?

Hearing problems

Do you have a hearing aid? What kind?

Do you have a removable hearing aid?

Do you have any type of ear implant?

Do you have a cochlear implant?

Vision problems

Do you have any eye movement problems/trouble fixating on a moving object?

Do you have strabismus? (cross eyes as a child or now)

Do you have orbital/eye prosthesis or cataract implants?

Dental

What is the nature of the dental work?

Were there any screws, pins, metal plates, or braces implanted?

Dentures? Removable?

Orthopedic items

Do you have an artificial limb or joint?

Have you ever broken a bone?

Do you have any metal plates or pins in your body?

Do you have a penile prosthesis?

Do you have a halo vest or metallic cervical fixation device?

Do you have a Swan-Ganz catheter?

Do you have an implanted diaphragm?

Do you have an IUD?

Do you have a pessary?

Do you have pacing wires?

Do you have wire mesh (hernia surgery)?

Do you have any other implants?

Do you have an implanted drug infusion device or insulin pump?

Do you have any type of implant held in place by a magnet?

Metal injuries

Have you ever had an injury to the eye involving a metallic object (metallic slivers, shavings, foreign body)?

Have you ever worked with metals, such as welding?

Medications

What is the nature of the medication?

Are you receiving hormone treatment?

Have you ever had any psychological illnesses?

Any other medical problems which we have not discussed?