Jefferson
Thomas Jefferson University

Office of Research Administration

833 Chestnut Street, Suite 900
Philadelphia, PA 19107
T 215-503-6976
F 215-503-2365
resadmin@jefferson.edu

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Thomas Jefferson University
Consent Form for a Research Study
And HIPAA Authorization Form

Department: Department of Rehabilitation Medicine
Jefferson Moss Rehabilitation Research Institute

Research Study Title: Word Retrieval in Aphasia

Sponsor/Funding Agency: National Institutes of Health (NIH)

Principal Investigator: Erica Middleton, Ph.D.
215-663-6967

What Is the Key Information You Need to Know About This Study?

The information in this section will give you an overview of key information to help you decide whether or not to participate in this study. There is a more complete description of this study in the pages that follow. Please read this description carefully and be sure to ask any questions you have.

- You are invited to participate in a study about the way people with aphasia produce and understand speech. We expect about 250 people at Jefferson will join this study.
- Your participation in this study will start with 1 or 2 sessions but may take 50 visits or more that will last 1-3 hours each. You may be asked to participate in follow-up sessions, but you are not required to return for additional sessions.
- Participation in this study may involve naming or pointing to pictures and repeating words. We may ask you to listen to words or sentences. For some of the tasks, we will use a special camera to track the position of your eyes as you look at picture scenes on a computer screen. Many of the tasks you complete will be audio and/or video recorded.
- Most studies involve some risk. Risks of this study are minimal and will be closely monitored. These risks are described in detail later in this document.
- You may or may not personally benefit from participation in this study. Other people may be helped by what is learned.
- You should carefully consider the reasons you may or may not want to participate in this study. This would include:
    - the length and frequency of study visits and overall duration of the study
    - your ability to follow all study requirements, like properly following instructions provided by experimenter or completing all requested tasks
    - your experience of potential physical and non-physical risks
    - your comfort and understanding of study procedures

- Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

How Is This Study Different From Standard Medical Care?
Research is different from medical treatment. Medical treatment tries to make *you* better. Research tries to learn more about medical problems and treatments for a *group of people*. Research may or may not help you or make you better.

This study will have no influence on any medical care you are receiving. Tests during this study are solely for research purposes, not medical care.

Will you be paid or receive anything for taking part in this study?
Yes. We will give you $20 per hour for your time and effort. Because you can work at your own pace, the total amount may vary from person to person. Most people will earn from $40 to $300 for completing all sessions.

You will be paid with a pre-paid debit card called a Clincard. A company outside of Jefferson manages this debit card system. To set up the card, the company will receive your name, address, and date of birth. They will only use this information as part of the payment system. Your information will not be sold or shared with other companies. The company will not receive any information about your health status or the studies in which you participate. You will get a brochure that explains how to use the Clincard.

If you earn enough money from Jefferson in one calendar year, you may need to fill out a tax form from the Internal Revenue Service (IRS). This form will ask for your name, address, and Social Security number. Jefferson uses this form to meet tax reporting responsibilities. The amount of money that requires reporting at Jefferson is based on the amount set by the IRS, and may change. You may not reach this amount by participating in only one research study, but you could reach it if you join more than one research study at Jefferson.

What Happens if You Leave the Study Early?
There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the study personnel will discuss the reason if this becomes necessary.

What Happens if New Information Becomes Available?
New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete. You will be given any research results that could affect your health.

Why is this study being done?
Scientists who work at Jefferson Moss Rehabilitation Research Institute and study stroke are called the Brain Behavior Relationship (BBR) Research Group. Our research enrolls people who have had a stroke, as well as those who have never had a stroke. We study how the brain works and how problems caused by stroke affect people. We study behaviors like speech, attention, memory, and movement to find out what therapies work best and how the brain recovers.

After a stroke or other type of brain injury or condition, people may have aphasia. This means that they may have trouble talking and sometimes understanding what people are saying to them. This study wants to understand the different kinds of aphasia that people have after a stroke.

Why are you being invited to take part in the research study?
We are asking you to be in this study for one of the following reasons:

- You have aphasia.
- You had aphasia at one time and have recovered from it.
- You had a stroke but never had aphasia.
- You never had a stroke.

Where will your research visits take place?
Your visits will take place at:

Jefferson Moss Rehabilitation Research Institute
Medical Arts Building
50 Township Line Road
Elkins Park, PA

A friend or family member can come with you. If it's impossible for you to make it to this location, we may be able to offer you a home visit or other options.

Do you have to take part in this research study? What happens if you say no?
You do not have to take part in this research study. If you decide you do not want to take part in the research study:

- There is no penalty or change to any benefits that you are otherwise entitled.
- Your medical care and the relationship you have with your healthcare team or Jefferson will not change.

What choices do you have if you decide not to take part in the study?
There are no clinical services offered as part of this research project. Whether or not you take part in this study has no bearing on the treatment choices available to you. However,

please tell the researcher if you currently receive speech therapy. This could help us understand your responses to this research study.

What can you expect if you join in the research study?
A study team member will work with you one on one. You will be asked to do some or all of the following tasks:

- You will point to pictures.
- You will name pictures.
- You will repeat words and sentences.
- You will listen to tape-recorded words to decide if they are the same word or different words.

Sometimes we will measure how quickly you can do something.

We will examine your face and mouth. We do this to help us understand the way you produce speech.

We may also track the position of your eyes as you look at different pictures or scenes on a computer screen. The eye tracker works by recording your eye movements using a video camera on the table in front of you. The recording of your eye movements does not include an image of your face.

Many of the tasks you complete will be audio or video recorded. More information about how recordings are used, protected and shared can be found in the "**Audio and Video Recording Section"** section of this form.

We may collect medical information for this study if it concerns research about your brain functioning or stroke-related difficulties. For your convenience, we use available records when possible. This includes different types of tests you may have or already had (like memory tests or MRI scans). These results can come from tests done as part of your treatment at a Jefferson facility, or, tests that took place during your participation in institute research projects that study stroke. If your records are from a different facility, you will be asked to sign a separate release form. If we cannot use available imaging records, we may ask you to have a scan of your brain at the University of Pennsylvania; details on this scan study will be discussed with you at a later time if you are eligible and interested. More information about how your medical information is protected and shared can be found in the "**What Happens to the Information Collected About You During the Study?**" section of this form.

How long will your participation in the research study last?
The length of the study may be different from person to person. Some people may come in for just 1 or 2 visits. Other people may come for 50 visits or more. We will let you know after the first or second visit how many times we need you to come in. Each visit usually lasts between 1 and 3 hours.

What if you decide you want to take part in the research study but change your mind later?
If you decide to take part in the research study, you always have the right to change your mind. You can decide you no longer want to take part in the research study at any time. No matter what your choice is, there will be no penalty to you. Your choice will not affect the care that you receive, your benefits or the relationship you have with your healthcare team or Jefferson.

If you agree to take part in the research study and then, at any point think you may want to stop taking part in the study, it is important that you talk to the study team.
If you do change your mind about taking part in the research study:

- Any information that has already been collected about you will remain part of the research records and cannot be removed
- No new information will be collected about you after you tell the research study team you have changed your mind.

What Are the Possible Benefits of the study?
This research study may or may not help you. You should not expect to get better just from being in this study. We hope that one day the information we get from this study may help people with aphasia in the future.

What are the risks or discomforts of the study?
Taking part in this study involves certain risks. There may also be risks that are not known at this time. If we learn about new important side effects or risks, we will tell you.

Research study staff will closely monitor you during the session(s) and help to prevent or minimize any side effects. If at any point you feel too uncomfortable, please inform the research study staff and they will determine how to proceed. They may consult with the Principal Investigator for further directions.

- Task risks:
  There is a chance that you might get frustrated or tired. Sometimes things we ask you to do may be hard for you. But, we will take as many rest breaks as you need.

  If you participate in an eye tracking study, we will place a small sticker on your forehead, which may cause mild skin irritation. If so, this usually resolves within the hour.

- Confidentiality risks:
  If you participate in this study, information about you will be collected and retained on paper and/or stored in computer files. Great care will be taken to safeguard all forms of such information, for example using locks for files with paperwork and using passwords for computer files on secured servers. Despite all efforts to protect your information, there is always the risk that your confidentiality could be lost. You will read more about the protection of your information later in this form.

Please ask the study staff or Principal Investigator if you would like to know more about how your information will be protected while you are in this study.

Are There Risks Related to Pregnancy or Breastfeeding?
There are no known risks for pregnant women, embryos or fetuses while participating in this study.

Will there be any costs to you for taking part in this study?
You may have costs for participating in this study.

There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to any underlying medical condition(s). You will be responsible for these costs. You will have to pay for basic expenses like any childcare, or food. If you are not sure about the costs that may result from taking part in the study, you should talk to a member of the study team. There will be no study related procedures billed to you or your insurance company. However, your standard medical care remains your responsibility or the responsibility of your insurance provider. If you receive a bill that you think is wrong, please contact the study personnel.

Depending on your situation and the availability of funds, our researchers may offer to schedule your transportation to and from study visits. Accepting this service is completely optional. If we schedule your travel, we will provide your name, address and phone number to the transportation company. Payment for the ride service will be made directly to the transportation company by our office. If you use transportation that we schedule, please understand that we are not responsible for anything that may occur during that transportation, just like we would not be responsible if you were to make your own transportation arrangements. If we do not schedule your travel and costs make it impossible for you to attend research sessions, we can offset your expenses up to $25 per visit (funds added to your pre-paid debit card (discussed below) at time of your visit).

What happens if you become ill or are injured while taking part in this research study?
There is a possibility that you could have a research-related injury, which is an illness or an injury that is directly caused by a study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this study. Neither Jefferson nor the study will pay for costs associated with treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan.

To help avoid injury or illness, it is very important to follow all study directions.
• If you have an emergency, call 9-1-1 right away or go to the emergency room.

What Happens to the Information Collected About You During the Study?
Information will be collected about you for this study. The information will be seen by the people involved with this study. Steps will be taken to protect your identity. However, we cannot promise complete confidentiality.

To do this study, we need to collect, use, and share your personal health information. We are committed to respecting your privacy and keeping your personal health information confidential. The federal law known as "HIPAA" (Health Insurance Portability and Accountability Act) that protects your personal health information requires us to get your permission to use the personal health information about you that we create, collect, or use as part of the study. This form will explain why your personal health information is being collected, what information will be collected, and who will have access to it. By signing this form, you are giving us permission to use your information including your personal health information as described in this form.

Your personal health information includes the information in your health care records and information that can identify you. For example, information in your health care record may include your name, address, phone number, and medical information.

The personal health information that may be collected, used, and shared for this study includes:

- Information from your medical records or from the Rehabilitation Research Registry Record
- Demographic Information such as your name, gender, birth date
- Demographic information including race and ethnicity
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research-related injury
- Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information
- Images of your brain and information about any stroke-related problems you may experience
- Notes that the research team makes about you during this study and results of any surveys, questionnaires, or other tests you did for the study

Your personal information will be used by and shared with the following:

- Study Personnel at Thomas Jefferson University and its affiliates for the purpose of this study
- Members of the research team
- Institutional Review Boards (ethics committees that review research) including Jefferson IRB
- The National Institutes of Health (sponsor), which is providing money to the researcher to carry out this research
- Government Agencies like the Food and Drug Administration (FDA)
- Public health authorities who monitor such things as sexually transmitted diseases, HIV, AIDS, child abuse, as required by law

- Groups monitoring the safety of the study, such as a data and safety monitoring committee
- The Rehabilitation Research Registry: If you are a member of the Registry, we will let the Registry team know when you started and finished this study. We will send them updated information about you, such as a new phone number. We will send them results from some of the research surveys and tests you complete.
- Transportation Companies: If you ask that we make travel arrangements for you, we will provide your name, address and phone number to the ride service. We will also let them know of any special travel related needs you may have.
- The Brain Behavior Relationship (BBR) Research Group: Your study records may be also shared with Institute researchers for use in other projects that study brain-behavior relationships and address stroke-related issues. These projects will be approved by an authorized IRB prior to your research information being shared.
- Others as required by law

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. Please inform the investigator in writing if you want to end your permission to collect your personal health information and biospecimens samples. Please note that anything already collected will still be used and you may not be able to continue in this study.

The results from this study may be published in scientific or academic journals or presented at scientific or academic meetings, but you will not be personally identified unless you give us your separate written permission.

Your personal health information, with the personal identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without your additional permission.

We may publish results from this study on a website that other researchers and clinicians can use in their studies. These results may describe what you did in this study. But we will not use your name, and there will be no way to identify you.

Additionally, your research results may be shared with other laboratories or individuals who provide services or analyze health information in connection with this study. The information shared with these researchers will not include your name or other information that can identify you and will be used for one or both of the following specific purposes: (1) to assist the project team in interpreting research information; or (2) to assist the project team in planning future studies.

Research staff may use their personal telephones or devices to contact you. Your contact information and/or text messages will not be saved to the staff member's personal device.

How will the information that is collected from you during the research study be kept confidential?

- Research files and records are not labeled with your name. We use a subject code on all research information. Only the study staff can link that code to your name or other information that can directly identify you.
- Your signed consent document will be stored in a locked file that only the research team can access.
- The 'paper' research record created from your information will be stored in a locked file that only authorized individuals can access.
- Your electronic research information is stored on internal computer systems. Electronic files may also be saved to a secure location through a subscription to a private web-based cloud service.
- Video recordings will be moved from the video camera to a secure location as soon as possible.
- Only authorized members of our research staff will have electronic access to your information. This is true whether the files are saved at our facility or on a web-based platform.
- Any of the automated transcription services that we use will not keep copies of your voice recordings, or the transcript of your speech.
- Your electronic research information is kept safe by password protection and other information security practices.
- Research staff may use their personal telephones or devices to contact you. Your contact information and/or text messages will not be saved to a staff member's personal device.
- Information is kept only as long as necessary and will be destroyed according to hospital policy.

Where Can You Find Additional Information About This Study?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who can you talk to about the research study?

For Questions About:	Person or Office	Contact Information
The Study or Research Related Injury	Main Investigator: Erica Middleton, Ph.D.	Phone: 215-663-6967 Email: erica.middleton@jefferson.edu Mailing Address: Jefferson Moss Rehabilitation Research Institute 50 Township Line Road Elkins Park, PA 19027

An institutional review board (IRB) is an independent committee established to help protect the rights of study participants. If you need to contact someone other than the study personnel about a concern or your rights as a study participant, contact:

- By mail: TJU Office of Human Research
  1020 Locust Street, Ste. M-34
  Philadelphia, PA 19107

- or call: 215-503-0203

- Website/Email: https://research.jefferson.edu/clinical/personnel/human-research/contact.html

Audio and video recording

Audio and video recording are a required part of this research project. Study staff will watch and listen to these recordings in order transcribe your speech and to observe your communication skills. An online service may be used to transcribe your audio recordings.

The recordings are digital. They may be used indefinitely, but will be stored for a minimum of 6 years after the study has ended. The recordings will not use your full name, but since they may include your voice and images of your face, it is possible that you could be recognized by a viewer.

By signing this consent form, you allow us to record your research sessions and to use these recordings for research purposes. These recordings will be shared and protected as described in the Confidentiality Section of this form.

Optional: Additionally, we may present reports about this study for educational reasons and may wish to show recordings of you during these presentations. Use of your video for educational purposes is optional. Please indicate below whether or not we have your permission do so.

_____ initial I allow video recordings created during my research sessions to be shown for educational purposes. I understand that the audience may include health care providers, researchers, and students from inside and outside Jefferson. I understand that I can withdraw my permission for these recordings to be used at any time.

_____ initial I do not allow videos created during my research sessions to be used for educational purposes

Email Communications

Optional: We are asking for your email address so we can arrange appointments and answer your questions about this research project. Email is generally not a secure way to communicate about your health. You should not send sensitive, detailed personal information by email.

You do not have to provide your email address to participate in this study. Please initial one of the lines below.

_____ initial Yes. I agree to the use of email to contact me for this study. I can be contacted at:

_____
Email address

_____ initial No. I do not want to be contacted by email.

Participant:
By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other study personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this study.

Word Retrieval in Aphasia Signature Page

Printed name of research participant	Signature of research participant	Date
Printed name of Legally Authorized Representative (if applicable)	Signature of Legally Authorized Representative / relationship to participant	Date
Printed name of person holding consent discussion	Signature of person holding consent discussion	Date
Printed name of Witness (if applicable)	Signature of Witness	Date

(Witness required if the only language the surrogate/subject speaks and understands is English, but the surrogate/subject cannot read English, or if the surrogate/subject is blind or is mentally capable but cannot physically sign the consent form.)

Assent

- ☐ Not applicable.
- ☐ Verbal assent obtained.
- ☐ Assent not requested given cognitive status of the participant.

By signing below, you the investigator, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

Name of Investigator	Signature of Investigator	Date

☐ **Copy of Signed and Dated Consent Form Given to the Participant or Legally Authorized Representative**