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Consent to Participate in a Research Study and
Authorization for Release of Health Information for the Research Study Purposes

Jefferson Office of Human Research

Department:	Department of Rehabilitation Medicine Moss Rehabilitation Research Institute (MRRI)
Research Study Title:	Word Retrieval in Aphasia
Research Study Sponsor:	National Institutes of Health (NIH)
Principal Investigator:	Erica Middleton, Ph.D. 215-663-6967

Key Information about this Research Study

This section gives an overview of this research 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.

This study looks at the way people with aphasia produce and understand speech. You are invited to join this study because you have had a stroke that causes aphasia. Alternatively, you are invited to join this study because you have never had a stroke or aphasia.

There are no clinical services offered as part of this research project. You may or may not directly benefit from taking part in this study.

The study will start with 1 or 2 research sessions but may take 50 sessions or more. You will be asked to do different language tasks like naming pictures and repeating words. Your participation in this study is voluntary. You do not have to join this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you do not participate.

General Information

This form has important information about this research study that will be done at Moss Rehabilitation Research Institute (MRRI), part of Thomas Jefferson University and Jefferson Health.

'You' refers to the person who takes part in the research study. You will have a chance to read over the information and think about it before you are asked to decide if you want to take part. A member of the research team will talk to you about taking part in this research and answer any questions that you may have.

What is some general information you should know before joining a research study?

- Someone will explain the research study to you. You can ask all the questions you want before you decide.
- You volunteer to be in a research study. Whether you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you or change the care you receive.
- If you do not understand something about the research study, ask for an explanation before you agree to take part and sign this form. You can continue to ask questions even after you have made your decision at any time during the research study.
- You get a copy of this form once it is signed and dated.

How is being in a research study different from your regular healthcare?

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.

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.	215-663-6967 erica.middleton@jefferson.edu
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Jefferson Center City Institutional Review Board (Ethics Committee)	215-503-0203 215-503-8966 215-955-4239

Study Specific Information

How is this study funded?

This study is funded by the National Institutes of Health (NIH). The NIH is a public agency that promotes and funds health related research.

Why is this study being done?

Scientists who work at Moss Rehabilitation Research Institute (MRRI) 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.

Do we use your medical information?
Yes, but only if it concerns research about 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 MRRI 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 Confidentiality Section of this form.

About how many people will take part in this research study?
About 250 people will be in this study.

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:

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.

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 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 Health.

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.

Could taking part in this research study put you at risk or cause any discomfort?
It is not likely. 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 are or become pregnant, there are no additional risks to you or your baby.

Could taking part in this research study help you or others in any way?
This research study may or may not help you. You should not expect to get better just from being in this study. The information we get may help people with aphasia in the future.

Could your taking part in this research study end early or be stopped for any reason?
Your participation in the research study can end early or stop at any time. Some of the reasons this might happen include:

- If you decide you no longer want to take part in the study
- If you are not able to or do not do the things that the study requires
- If the study is too easy for you, or too hard for you
- If your health or other circumstances change and the research team feels that it is no longer in your best interest
- If the study is ended by the sponsor

Is there any cost to you for taking part in this research study?
Neither you, nor your insurance provider, will be charged for research visits related to this study. However, your standard medical care remains your responsibility or the responsibility of your insurance provider.

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.

Payment will be made using a pre-paid debit card, called a ClinCard. The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, and date of birth. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating. You will be given an informational brochure about how to use Clincard.

You will be asked to fill out a W-9 form that asks for your name, address, and social security number. The information will be given to our accounting department and will be used to meet tax reporting responsibilities.

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 session (credited to your ClinCard).

What happens if you get hurt or get sick from taking part in this research study?
It is important that you report any illness or injury that may result from your participation in this study to the research team.

In the event of an injury or illness resulting from your participation in this research project, you will be provided with clinically appropriate medical care for that injury or illness within the capabilities of Jefferson. However, Jefferson cannot assure that the medical care and treatment will be provided without charge, and the costs incurred may, ultimately, be your responsibility.

Confidentiality (privacy) Of Your Personal Information

This study is covered by Certificate of Confidentiality from the National Institutes of Health. The Certificate means that we do not have to give out identifying information about you even if we are asked by a court of law. We will use the Certificate to resist any demands for identifying information, but there are some limits to this protection. We may voluntarily provide the information to authorities if we learn of child abuse, elder abuse, or the intent to harm yourself or others. We will also share your research information with your written permission. You or a member of your family can share information about your part in this research if you wish.

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 sees the information collected about you?
Your information may be viewed by the individuals involved in conducting this research, including those collaborating, funding, and regulating the study. We share the minimum amount of information necessary on a need-to-know basis (only when we have to) and ask anyone who receives it from us to protect your privacy. Even though we are very careful,

there is a chance that if we share your information with someone else, it could then be used or shared in a way that it will no longer be protected like we protect it here.

We cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to others who may or may not be part of the research study.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we create, collect, or use as part of the research. This permission is called an Authorization. If you sign this form, the following people may access, use, store or share your research and personal health information collected as part of this study:

- Members of the MRRI research team
- Other MRRI staff members: Other researchers who work here can sometimes help us understand the information we get from you during the study. They also help us plan future studies. Sometimes these researchers may know you, if you have been in their studies. Sometimes the researchers may not know you.
- The Study Sponsor: The National Institutes of Health (NIH) pays for this study and may need to look at your study record.
- Regulatory Agencies: The Office of Human Research Protections is a government agency that provides research oversight. The Institutional Review Board at Thomas Jefferson University looks over the results of this study every year to make sure all the rules are being followed. Regulatory agencies may conduct audits that look at your study records and may photocopy records that have your name listed.
- Government officials and representatives of Thomas Jefferson University and its Affiliates who need to see this information as part of their job.
- The MRRI 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 MRRI 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.

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.

What research and personal health information will be collected as part of this study?
If you sign this form, you are authorizing (allowing) the study's team members to collect certain kinds of information:

- We collect your contact information so we can get in touch with you by phone, letter, text or email.
- We collect general information, such as if you're male or female, your age, work experience and education.
- We collect research information, such as notes that the research team makes about you during this study and results of any surveys, questionnaires or tests you did for the study.
- We collect health information, such as images of your brain and information about stroke-related problems that you may experience. This information includes findings from tests you complete for medical or research purposes. Information may collected be from your past, present or future medical and research records.

How is your research and personal health information protected?
The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we create, collect, or use as part of the research. This permission is called an Authorization. Jefferson follows the rules of the federal law (HIPAA) and all other related laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected.

Will your authorization ever expire?
This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over. A review of your research or medical records may also take place after the study is over.

May you take back your authorization?
You have the right to take back (revoke) your Authorization at any time by writing to:

Erica Middleton, Ph.D.
Moss Rehabilitation Research Institute
Medical Arts Building
50 Township Line Road
Elkins Park, PA 19027

If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of this study. If you revoke your Authorization, you can no longer continue to participate in the study.

What if the information from this study is published?
We may publish reports about this study that describe results of this study. In those reports, we will not use your name, and there will be no way to identify you.

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.

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.
- 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.

Will your information be used for other research?
Information obtained about you in this study may also be used for other research studies here at Jefferson. Your information may also be shared with institutions outside of Jefferson for other research projects. Before your study record is shared with other institutions for further research, information that identifies you will be removed. The individuals performing the additional research will not know who the information came from. You will not be asked for additional consent to use your information for such research projects.

What else do you need to know if you decide to take part in this research study?

- You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.
- You have the right to see and get a copy of your health information that is used or shared as part of this research study. Tell the person in charge of this research study if you would like this information.
- You have a right to refuse to sign this form. If you do not sign the form, you may not be in the research study, but refusing to sign will not affect your health care outside the study.
- Signing this form does not mean that you are giving up your legal rights.

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.

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

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.

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

_____
Email address

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

How do you indicate your decision about taking part in this research study?

If you decide you want to take part in this research study, you must sign and date this form. By signing this form, you are indicating that:

- You are voluntarily making the decision to take part in this research study.
- The information in this consent form has been explained to you and all your current questions have been answered.
- You have been encouraged to ask questions about this research study to the investigator(s) listed on the first page of this consent form or another qualified member of the research study team at any time.
- You have been told that by signing this form you are not giving up any of your legal rights.

By signing this form, you agree to participate in this research study and give authorization to use the information collected for this research as explained in this consent form. Your signature documents your permission to take part in this research. A copy of this consent form will be given to you.

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**