Permission to Take Part in a Human Research Study

Georgetown University

Title: ReadMap: Reading in stroke alexia and typical aging (Patient Consent)

Location: Georgetown University Medical Center and *MedStar National Rehabilitation Hospital*

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you had a stroke, are at least 18 years old, and learned English at 8 years or younger.

You may not participate in this study if you:

- Have had other brain conditions that could impact interpretation of results (such as multiple sclerosis, dementia, head injury with loss of consciousness, tumor)
- Have a severe psychiatric condition that would interfere with participation in the study
- Have a history of a diagnosed learning disorder
- Have hearing or vision loss that interferes with performance on behavioral tests even after correction with glasses or hearing aids

You may not participate in the MRI portion of the study if you:

- Have metal in your body (except titanium; examples include cochlear implants, cardiac pacemakers, implantable medical pumps, implanted shunts, deep brain stimulators, intracardiac lines, shrapnel)
- Are claustrophobic (afraid of enclosed spaces)
- Are pregnant

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research will help us to understand the brain and behavioral basis of reading. By examining people with stroke, we can learn how strokes affect reading and other cognitive and language functions. We can also learn how their brains adapt in response to a stroke.

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We hope that gaining this knowledge will benefit other stroke survivors.

How long will the research last and what will I need to do?

Your initial participation will include about 4 sessions to test your reading, speech, language, and other abilities and 1 session for an MRI. These will take place over a 2-6 week period. You may be asked to repeat these same procedures once or twice in approximately 3-12 months. The researchers may ask if you are willing to participate in additional sessions to conduct further tests, which you may decline at your choosing. We may contact you about future studies and send you periodic updates on the research outcomes in our lab. You can choose to opt out of this at any time.

You will be asked to complete behavioral testing, including paper and pencil tasks, computer tasks, and questionnaires. You may be asked to have an MRI.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

Behavioral testing

You may find certain tasks difficult or irritating. You may be asked to answer questions that you find embarrassing. You do not have to complete tasks or answer any questions that you do not wish to.

MRI

There are no known significant risks with the MRI procedure at this time because the radio waves and magnetic fields at the strengths used are thought to be without harm. The exception is if you have a cardiac pacemaker or certain metals in your body. It is important that all metallic objects be removed from your person prior to approaching the high field strength magnet, as these objects may be attracted to the magnet. We will take reasonable safeguards to minimize known and potential risks but unknown and/or unanticipated side effects might occur.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, a possible benefit includes learning more about your abilities and difficulties from your stroke. Possible benefit to others includes improved diagnosis of reading deficits after stroke, which may help guide treatment.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. Peter Turkeltaub at (202) 784-1764 or the Department of Neurology fellow on-call at (202) 405-1110. You may call Dr. Turkeltaub 24 hours a day. Be sure to inform the physician of your participation in this study.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (202) 687-1506 or irboard@georgetown.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 300 people will be in this research study worldwide; all subjects will be recruited at this site.

What happens if I say yes, I want to be in this research?

Behavioral testing:

You will be asked to perform a number of behavioral tasks, which will include tests that require spoken answers (e.g., repeating words), paper and pencil tests (e.g., completing questionnaires) or computer tasks (e.g., reading comprehension). Testing sessions may last a few hours, but you will be given as many breaks as you need, and can choose to stop at any time. You and your study partner (if needed) will also complete questionnaires that may help us better understand factors that impact stroke recovery, such as your quality of life, ability to communicate, and your mood. Some of these questionnaires will be distributed via Qualtrics, and others will be using paper and pencil.

MRI:

You may be asked to have an MRI as part of this study.

MRI takes advantage of the magnetic properties of your body's tissues to take pictures of your brain. You will be asked to lie on a long narrow bed while the machine gathers information. During scanning, you will be exposed to a magnetic field and radio waves, but you will not feel either. You will hear repetitive tapping noises and you must wear headphones to reduce the noise. You will be asked to lie very still for a resting "anatomic" MRI scan. You will hear a knocking noise when the scanner is on. You may be asked to perform a behavioral task during a "functional MRI" scan, which examines the activity of your brain. You may take a break at any time during the MRI by simply asking one of the researchers. All researchers will make every effort to assure your comfort and safety.

Please advise the researchers of any medications you are taking. In addition, if you are taking any over-thecounter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers. During the study, please tell the researchers if you have any changes to your medications.

The MRI will not include a contrast agent (injection of dye).

Study Partner:

If you need help transporting yourself to and from the lab or completing some of the questionnaires, you will be asked to select a "study partner". This is someone who you see regularly who can help you get to study sessions. The study partner will also answer questions about your medical history and help you to fill out questionnaires. The study partner will sign a separate informed consent form to be included in the study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for completing behavioral testing and questionnaires. Some subjects will be asked to have an MRI.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. There are no consequences to your health or well-being of withdrawing from the study early. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

Your decision to participate in this study or not will not impact your clinical care from either Dr. Turkeltaub or any other Medstar National Rehabilitation Hospital (NRH) or Georgetown staff member.

Is there any way being in this study could be bad for me? (Detailed Risks)

Risks and side effected related to the procedures we are studying include:

Behavioral Testing

You may be asked to perform a task that you find difficult or irritating. If you find the task too annoying or frustrating, it will be stopped. You may be asked to answer questions that you find embarrassing. You do not have to answer any questions that you do not wish to.

MRI

There are no known significant risks with the MRI procedure at this time because the radio waves and magnetic fields at the strengths used are thought to be without harm. The exception is if you have a cardiac pacemaker or certain metals in your body. There is a possibility that you will experience a localized twitching sensation due to magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs. Peripheral nerve stimulation is possible at the higher field strengths used for this study (3.0 Tesla). It is important that all metallic objects be removed from your person prior to approaching the high field strength magnet, as these objects may be attracted to the magnet. In addition, such objects as watches and credit cards should also be removed as these could be damaged (these items will be watched for you while you are being tested). The effects of the scan on a fetus are unknown, and therefore, if you are or could

be pregnant, we will not perform the scan at this time. Please take note that some subjects have experienced claustrophobia in the magnet; if you feel this discomfort you may discontinue the scan at any time. We will take reasonable safeguards to minimize known and potential risks but unknown and/or unanticipated side effects might occur.

For more information about risks and side effects, contact the investigator at (202) 784-1764.

Pregnancy

The safety of MRI in pregnant women has not yet been fully studied, and therefore pregnant women are not permitted to participate in the MRI portion of this study. Women of childbearing age who report that they are or may be pregnant will be excluded from the MRI portion of this study.

Avoidance of Pregnancy: The MRI procedure used in this study may be unsafe for a fetus/ unborn baby. If you, as a subject of study, are a woman of child bearing potential, you must agree to avoid pregnancy during your participation in this study. If you do become pregnant during the study, you should immediately notify Dr. Turkeltaub at (202) 784-1764. In addition, if you are already pregnant, you cannot participate in this study.

What happens to the information collected for the research?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of research study participants are stored and kept according to legal requirements. Hard copies and electronic files containing protected health information will be maintained for the duration of the study (expected to be 12 years). Hard copies will be secured in a locked filing cabinet in a locked room within Dr. Turkeltaub's laboratory. Only study staff will have access to these materials. If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage: electronic files will be stored on a password protected computer network only accessed by the investigators. The PI will be responsible for proper destruction of data. De-identified data required for further analysis will be maintained indefinitely.

You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institution(s) conducting this study, organizations that may request to inspect and/or copy your research and medical records for quality assurance data analysis and other research related and operational or administrative purposes, include groups such as:

Georgetown University, Georgetown University Institutional Review Board (IRB), MedStar Health Research Institute IRB, federal research oversight agencies.

Please note that administrative personnel involved in processing your payment for participation will be aware of your identity.

Data without any personal identifiers may be shared with other researchers or uploaded to public data repositories without your additional informed consent.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

HIPAA Authorization

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
- Records about study medication or drugs
- Substance abuse information: *History of alcohol or substance use*
- Mental health information: *History of psychiatric condition*

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or Georgetown University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Georgetown University workforce, who may need to see your information, such as administrative staff members from the Georgetown University Institutional Review Board (IRB) Office and its agents, and members of the Institutional Review Board.
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Other Georgetown University and MedStar National Rehabilitation Hospital research centers and Georgetown University contractors and MedStar contractors who are also working on the study.
- Study monitors and auditors who make sure that the study is being done properly,
- Others*:* The following individuals or organizations may also access, receive, or use your personal health information: University of North Carolina – Chapel Hill.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the study. After the expiration date, Georgetown University may not gather new information about you, or use or disclose your personal

health information collected in this study for any purpose other than the research study described in this consent unless Georgetown University obtains permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Peter Turkeltaub
Institution: Georgetown University Medical Center
Department: Neurology
Address: 4000 Reservoir Rd NW, Bldg D, Suite 165A, Washington, DC 20007

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if your situation changes such that you are no longer eligible based on the criteria mentioned above, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan (e.g., missing scheduled sessions), or if they judge that it is in your best interest to be removed. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

New Findings

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, and any information that may affect your interest in remaining in the study.

For studies involving Center Functional and Molecular Imaging:

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you and any information that may affect your interest in remaining in the study. The investigators for this project are not trained to perform radiological diagnosis, and the scans performed are not optimized to find abnormalities. The investigators are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, Dr. Turkeltaub, a licensed neurologist, will be consulted as to whether the finding merits further investigation, in which case he would contact you and, with your permission, your primary care physician, to inform you of the finding. The decision regarding whether further examination and treatment is clinically indicated lies with you and your physician, and will be provided at the usual charge. The investigators, the consulting neuroradiologist or neurologist, and Georgetown University are not responsible for any examination or treatment that you undertake based upon these findings.

What else do I need to know?

If you agree to take part in this research study, we will pay you $50 per behavioral testing session and $50 per MRI session for your time and effort. The overall amount of testing time for each participant may vary. However, we expect the study to require approximately four behavioral testing sessions, resulting in total compensation of approximately $250. For any additional sessions that are conducted virtually and are not full-length testing sessions, participants will receive $25.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

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I voluntarily agree to participate in the MRI portion of the study.

YES NO _____ Subject Initials

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Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject	
Signature of legally authorized representative	Date
Printed name of legally authorized representative	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of subject assenting	Date
Printed name of subject assenting	

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I voluntarily agree to participate in the MRI portion of the study.

YES NO _____ Subject Initials

_____ Legally Authorized Representative Initials

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STUDY PARTNER INFORMATION & CONSENT

As the subject's study partner, you have important tasks that need to be carried out in order for the study to be conducted in the safest and best manner possible. These responsibilities include:

1) You must have direct contact with the subject at least 2 days per week.
2) You must be able to accompany the subject to all lab visits.
3) You are an important source of information about the subject. You must agree to be asked questions in order to find out whether there are any changes in the subject (e.g. changes in medication, any accidents or surgeries since the last visit, or other questions regarding the subject's health status that may impact his/her participation in the study). You must also agree to help the subject fill out questionnaires regarding his/her medical history, quality of life, communication abilities, and mood. You may also need to help the subject obtain prior medical records needed for the study.
4) You must agree to return with the study subject for the subject's examinations and evaluations.

If you choose not to be the subject's study partner, we will try to find someone else who can be the study partner instead. If for some reason you become unable to carry out your responsibilities after agreeing to be the study partner, please tell the study team immediately. You may be asked, if possible, to select a substitute who can take over your duties. Your contact information (name, phone numbers, address, email address) will be kept on file in electronic or hard copy form. Electronic files will be stored in password-protected files, and hard copies will be kept in a locked filing cabinet in a locked room in the laboratory. We will maintain confidentiality of all your responses.

You have read all the preceding information which describes both the subject's participation in the study and your involvement as the subject's study partner. The study has been explained to you in detail. All your questions have been answered to your satisfaction.

You voluntarily agree to participate.

YES **NO** **Study Partner's Initials** _____

_____	_____	_____
Study Partner's Name (print)	**Signature**	**Date**
_____	_____	_____
Person Obtaining Consent (print)	**Signature**	**Date**

Data Sharing Information & Consent

We are collecting data related to motor speech disorders during this study. We share this dataset with researchers at the University of North Carolina (UNC) - Chapel Hill so that they can investigate the diagnosis of motor speech disorders and advance stroke recovery in this area. UNC also has Institutional Review Board oversight to ensure adherence to privacy and confidentiality guidelines. Secure methods will be used to transfer this data, and all data will be destroyed after use. In order to share this data, we need your permission. The shared data and purpose for sharing data include the following:

- Voice or video recordings without other identifying information in order to learn more about assessment and treatment of Apraxia of Speech

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You voluntarily agree to share data with **The University of North Carolina – Chapel Hill:**

YES **NO**

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

_____

Name of Witness