The University of Texas at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research Project: NEURAL BASES OF VOCAL SENSORIMOTOR IMPAIRMENT IN APHASIA

Investigators: **Contact:**
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Invitation to be Part of a Research Study: You are invited to be part of a research study. This consent form will help you choose whether to participate in the study. Feel free to ask questions if anything is not clear on this consent form.

Key Information: You are invited to volunteer for a research study conducted by Dr. Roozbeh Behroozmand. Dr. Behroozmand is an Associate Professor in the Department of Speech Language and Hearing at the University of Texas at Dallas. This research is being conducted at UT Dallas Speech Neuroscience Lab located in the Callier Center for Communication Disorders and the Brain Health Imaging Center (BHIC) and is sponsored by the University of Texas at Dallas and the National Institute of Health (NIH). In addition, this research is in collaboration with the University of South Carolina and the University of California at Irvine, and the data will be shared with our collaborators at these other institutions. The purpose of this study is to investigate how stroke-induced damage to the brain impairs speech function. You are being asked to participate in this study because you have suffered from stroke or are part of a healthy control group for this study. This study is being done in the Speech Neuroscience Lab and will involve 100 volunteers. The study involves a maximum of six sessions (each approximately 1-3 hours). During the first session, you will be asked to submit informed consent and will complete a series of questionnaire and safety screening forms to determine your eligibility for the study. In addition, a series of preliminary assessments will be conducted to evaluate your speech and hearing. If you are determined to be eligible, you will be asked to attend follow-up sessions for data collection using a series of behavioral speech and audio-visual feedback training tasks while your brain activity is recorded by placing Electro-Encephalo-Graphy (EEG) electrodes on your scalp, electromyogram (EMG) electrodes on your face and neck to measure muscle activity or recording your neural activity in a Magnetic Resonance Imaging (MRI) scanner. Specifics related to feasible risks and discomforts as well as expected benefits for this study are outlined in the following sections.

Purpose: This research project is part of a broader communication disorders program to study the brain mechanisms of speech disorders in individuals with aphasia due to chronic left-hemisphere stroke and an age-matched healthy control group. We aim to record your speech and your brain activity using Electro-Encephalo-Graphy (EEG) electrodes placed on the surface of your scalp and magnetic resonance imaging (MRI). You will be asked to wear a microphone and headphones or insert earphones and follow visual or auditory cues or read instructions on a computer monitor to perform speech production and listening tasks including steady vowel

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sound vocalizations, word production, sentence reading, object naming, and speech identification while different parameters of your real-time speech auditory feedback are changed (e.g., loudness [or volume], pitch [tone of voice], formant [or quality], and timing). You will also be asked to perform speech imagination (e.g., saying a word in your head) and/or silently produce speech (e.g., move your lips and other speech muscles without producing any sounds). In addition, you will participate in visual feedback training sessions in which you learn to change your speech output by controlling the position of a visual cursor on the computer screen. The goal of this research is to understand how the brain helps with speech production and how the ability to produce speech can be impaired due to brain damage resulting from stroke. The outcome of this research will help develop new technologies for diagnosis and treatment of speech disorders in stroke-induced aphasia and other neurological conditions.

Description of Study: Study activities will take place at the UT Dallas Speech Neuroscience Lab in Callier Center Richardson and/or the Brain Health Imaging Center (BHIC). If you agree to participate, you will be asked to participate in maximum six sessions to complete the following tasks:

Preliminary Screenings: For the first session, you will be invited to visit the Speech Neuroscience Lab at Callier Center Richardson to complete preliminary screenings. During this session, you will be asked to fill out a questionnaire form in order for us to collect data on your name, date of birth, contact information, age, gender, race/ethnicity, handedness, native language (and language competence if other than English), educational background, music and/or singing trainings, scalp sensitivity, and medical history including any history of neurological conditions and/or speech- language, hearing, cognitive, and developmental disorders. You will also complete a standard MRI screening form provided by the BHIC to determine your eligibility for MRI scanning. In addition, we will administer an audiometric hearing screening to determine your hearing ability at different frequencies as well as the Montreal Cognitive Assessment (MoCA) for the presence and severity of cognitive deficits to determine your eligibility for participation in follow-up study sessions. The MoCA is a brief test with 30 questions to evaluate performance on a variety of tasks such as following sequential patterns, drawing a clock, naming animal pictures, as well as tasks involving memory, attention, and language skills. If you are a participant in the stroke group, your speech-language function will be assessed using the standard Western Aphasia Battery-Revised (WAB-R) to determine the severity of aphasia symptoms resulting from left-hemisphere stroke. The WAB-R test includes specific modules to evaluate your verbal fluency, spontaneous speech production, speech repetition, naming, and auditory-verbal comprehension abilities. In addition, if you are in the stroke group, you will undergo screening for symptoms associated with dysarthria and/or apraxia of speech. Audio recordings of your speech samples will be taken to assess speech fluency, apraxia and dysarthria symptoms.

EEG Recording: Following preliminary screenings, you will be invited to visit the Speech Neuroscience Lab to attend a second session for resting-state and task-specific EEG data collection during speech production and listening tasks under normal and altered auditory feedback conditions. Before starting data collection, you will receive brief training to familiarize yourself with the task and will be given time to ask questions. For these tasks, you will be comfortably seated in a chair inside a sound booth and a microphone will be positioned near your lips to record your speech. You will also be asked to wear headphones or insert

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earphones will be placed in your ear canals so that you can listen to auditory feedback stimuli. You will be asked to follow visual or sound cues or read instructions on a computer monitor to perform a variety of speech tasks including steady vowel sound vocalizations, word production, sentence reading, object naming, and speech identification while receiving changes in loudness, pitch (tone of voice), formants (or quality), and timing of your speech auditory feedback. You will also be instructed to follow visual cues to perform speech imagination and/or silent speech production tasks. Audio recordings of your speech and video recordings of your face and mouth will be taken during these tasks. In addition, you may also be asked to press a button for registering your responses to different speech/auditory sounds or triggering visual or auditory stimuli. During these tasks, your brain activity will be recorded by placing an EEG electrode cap on your scalp. The connectivity between scalp and electrodes will be established by gently scrubbing your scalp for each electrode and then filling each electrode with conducive gel. In addition to EEG electrodes, we will place electromyogram (EMG) electrodes on your face and neck to measure muscle activity during speech tasks. EMG electrodes will be placed on your skin using double-sided tape after cleaning using alcohol pads and gently scrubbing the area with abrasive gel and applying conductive electrode gel. After speech and EEG data collection, the microphone, headphones (or insert earphones) EEG cap and EMG sensors will be removed. You will be given tissues to remove any remaining gel from your scalp and hair and we advise you to rinse your hair on the same day, so that any remaining gel does not harden.

MRI Recording: If you are eligible for the MRI procedures, you will be invited to participate in an MRI session at UT Dallas Brain Health Imaging Center (BHIC). During this session, you will be screened again for MRI safety and, if there are no concerns, you will be scanned for MRI data collection during the speech production and listening tasks under normal and altered auditory feedback conditions. To ensure your safety and the accuracy of MRI data, we may need to contact a family member or caregiver to confirm relevant medical information. This may include retrieving the name and contact information for a trusted caregiver or family member from you. You may opt to decline sharing this information with us; however, if we are unable to obtain accurate and complete medical information, you may not be able to complete the MRI session. Designated contact information will be stored on a secure contact sheet on a UTD encrypted server. You can request to change or remove this information at any time. If you have any metal, surgical implants or medical devices in your body, our team may ask you to provide official documentation from a medical provider that includes identifying information (e.g., manufacturer and model number) to determine MRI compatibility. For any life-sustaining devices (e.g. pacemakers, stents, shunts, valves etc.) or devices in sensitive areas (e.g. the brain or heart), an implant card stating the manufacturer and model number will be required prior to your scheduled MRI session. This information is necessary to verify MRI compatibility for your safety; without it, your MRI session will be canceled. With your permission, lab members may need to follow the protocol for your medical facility in order to receive the documentation; this may include contact with medical records departments and/or healthcare professionals via phone, email or web portal. You will be informed of or included in any contact made with your care team. De-identified copies of this documentation will be sent to the MRI technologists at BHIC to review prior to your session, to assess MRI compatibility. The de-identified copies will then be securely stored in our records. You may opt not to share this medical information with us. For any participant unwilling or unable to provide the necessary information to verify

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MRI safety, they will be excluded from the MRI session, but will be able to complete all remaining sessions. Only participants who pass screening will be scanned for MRI data collection.

For these tasks, an MRI-compatible microphone will be placed near your lips in the scanner and MRI-compatible headphones or insert earphones will be placed in your ear canals so that you can listen to auditory feedback stimuli. You will be asked to follow visual or sound cues or read instructions on a projector screen in the scanner to perform a variety of speech tasks including steady vowel sound vocalizations, word production, sentence reading, object naming, and speech identification while receiving changes in loudness, pitch (tone of voice), formants (or quality), and timing of your speech auditory feedback. You will also be instructed to follow visual cues to perform speech imagination and/or silent speech production tasks. In addition, you may also be asked to press a button for registering your responses or triggering visual or auditory stimuli. Before starting data collection, you will receive brief training outside of the scanner to familiarize yourself with the task and will be given time to ask questions. You will then be asked to remove all metal items and/or electronic devices (e.g., keys, cell phone, watch, jewelry, hearing aids, etc.) before entering the MRI scanner room. If you have issues with movement or balance, research personnel will escort you to the room. In addition, an MRI-compatible wheelchair is available and can be used, if needed. MRI scanning includes obtaining your brain scans as well as your brain activity during resting-state and speech auditory feedback tasks. MRI-compatible microphones and headphones or insert earphones will be used to record your speech and deliver auditory feedback stimuli to your ears during scanning. You will be instructed to uncross your arms and legs and will be given a squeeze ball for any emergencies. Once sounded, we will cease all scans and communicate with you over the speaker and, if needed, will remove you from the scanner as quickly as possible.

Visual Feedback Training: You will be invited to attend a maximum of three visual feedback training (VFT) sessions on different days. During these sessions, you will be trained to work with a computer program that tracks your speech output and helps you learn to control your loudness (or volume), pitch (tone of voice), formants (or quality), and timing by moving the position of a visual object on the screen. In addition to auditory feedback, the VFT will provide a secondary source of sensory input via the visual system (your eyes) to help you monitor and control your speech by achieving visually defined targets on the computer screen. The VFT training is aimed to improve speech function via compensating for the impaired auditory feedback mechanisms in individuals with post-stroke aphasia. Your ability to control your speech will be evaluated under altered auditory feedback condition with EEG data collection before, during and after VFT training to assess the effect of training on your speech production.

Number of Participants: If you decide to participate in this study, you will be one of approximately 100 people in this research study.

Duration of Participation: Participation in the study involves a maximum of six experimental sessions on different days. Each experimental session will last approximately 1-3 hours. You will be actively participating in completing informed consent, questionnaire, and safety screening forms as well as undergoing preliminary assessments for your speech and language

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ability (session 1), performing speech task during EEG and MRI data collection (sessions 2 and 3), and undergoing visual feedback training (sessions 4-6). For any session, if data collection cannot be completed (e.g., due to technical issues, time limitations, etc.), you will be rescheduled for another session to complete data collection.

Inclusion / Exclusion Criteria: A total of 50 individuals with aphasia due to chronic left-hemisphere stroke (more than 6 months after stroke) and 50 healthy control individuals with no history of neurological conditions and speech-language disorders will be recruited in this study. All participants will be 21-75 years. You will be excluded from this study if you have a history of severe hearing, cognitive, or developmental disorders. You will also be excluded from this study if you do not have the ability to provide informed consent and/or do not have the ability to verbally communicate with the investigators, understand study instructions, or perform the tasks required for completion of this research study. *For MRI only:* if you are unwilling or unable to provide medical documentation about any implants, metal or devices in your body, you will be excluded from the MRI session for your own safety. You will still be able to complete the additional sessions.

Possible Risks: There is minimal risk associated with participation in this study, though this study may involve risks to the participant which are currently unforeseeable. Participants will be informed about significant findings that provide additional information about risks or that may influence their decision to continue participation in this research.

Speech tasks: You could experience frustration and boredom during the experimental tasks as they are repetitive. Furthermore, data acquisition involves long periods of time spent in relatively confined spaces (e.g., sound booth and MRI scanner). Occasionally, individuals will have a negative reaction to neuropsychological assessment, experimental testing and/or training procedures. For example, this can be caused when individuals realize that their performance on a given task is far worse than they would have expected. We always make sure that ample time is allotted for training and practice before testing, and you will be given time to ask questions to make sure you understand the instructions and are able to perform the tasks properly. During speech production, you may experience dry mouth or slight fatigue in your vocal/speech production muscles but that should not last long. This is often more common during EEG sessions that take longer than MRI scanning. If at any time during EEG recording your throat feels dry or you feel vocal fatigue, you will be asked to stop, take a rest, and have a drink of water. You may do this as often and whenever necessary. We will also communicate with you during MRI scanning and, if needed, will remove you from the scanner during the time between scans and will give you a break and water to drink. However, we don't anticipate this to be a major concern during MRI since the duration of speech production task is significantly shorter compared with EEG sessions.

EEG recording: EEG preparation and recording causes no harm and little to no discomfort and has no long-term side effects. Slight discomfort may be caused by the preparation of electrodes, the pressure of the cap on your scalp, or slight skin irritation from the application of the conductive gel. However, our research team is trained to minimize this discomfort as much as possible. When the cap is removed, gel may remain in your hair but can be washed out easily using water.

EMG recording: The use of surface electrodes for electromyography (EMG) is generally a low-

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risk procedure, and serious complications are rare. However, there are some risks associated with skin irritation or allergic reaction to electrode placement. Some individuals, especially those with sensitive skin, may experience mild skin redness or irritation underneath the electrodes. This is often due to the adhesive tape and/or the conductive/abrasive gel used with the electrodes. Proper skin preparation before and cleaning afterward can help minimize these potential risks.

MRI scanning: Undergoing an MRI involves exposure to a strong magnetic field, which can pose certain risks, particularly to individuals with metal or surgical implants. If you have any metal, implants or devices in your body (such as pacemakers, cochlear implants, aneurysm clips, shunts, valves, orthopedic hardware or other metallic objects), the magnetic field may cause movement, heating, or changes in the implant's function or positioning. These effects could result in discomfort, device malfunction, or injury. Our lab follows strict protocols for safety screening, verification of all your medical history and scanning procedures in order to minimize the risk for adverse effects from exposing you to the magnetic field. Because the MRI machine acts like a large magnet, it could move metallic objects in the MRI room during your examination, which could possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. Having an MRI scan may mean some added discomfort to you. In particular, you may be bothered by feelings of claustrophobia and by the loud scanner noise during the study. Most people report, however, feeling less claustrophobic during functional MRI than during a routine MRI scanning. This has to do with the visual presentation system used in fMRI studies in that the video screen gives the illusion of the scanner tunnel being larger due to 3D effects. Also, temporary hearing loss has been reported from the loud noise. This is why you will be asked to wear headphones and earplugs during MRI scanning.

Please note, the MRI scans at the UT Dallas BrainHealth Imaging Center are designed for research purposes only and cannot be used for a medical diagnosis. The researchers in this study are not medical personnel and will not be looking at your brain scans to find or treat a medical problem. If they do notice something unusual, the scans will be reviewed by a neuroradiologist. If it is determined that the unusual finding should be followed up, you will be notified by the Principal Investigator. You and your doctor should then decide on the next steps.

Breach of Confidentiality: A breach of confidentiality is a common risk in social and behavioral research, despite the steps that will be taken to protect the confidentiality of your records. Specific safeguards to protect confidentiality are described in the following section of this document.

Possible Benefits: Taking part in this study is not likely to benefit you personally. However, this research may help researchers understand about brain mechanisms involved in speech production and their impairment due to stroke. The outcome of this research may help develop speech treatment methods for patients with stroke and other neurological diseases.

Alternatives to Participation: Individuals may choose not to participate.

Compensation: Participants will receive $25/hour for participation in this research study. Should you decide to withdraw from the experiment after a session has started, you will still

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receive the payment for the time you participated in the study at $25/hour. Upon session completion, you may request to receive a copy of assessment forms of results from the hearing screening, speech-language-cognition evaluations, and/or anatomical MRI images. All assessments/imaging results are completed for research purposes only and are not intended to be used for diagnosis and/or treatment (personal use only). Requesting a copy of the forms/results will not affect the hourly payment for your participation time.

Participants will receive payment via GalaxyPay, a pre-paid card. Your name, mailing address, and date of birth will be shared with a third-party solely for the purposes of compensation processing.

Initials: _____ I acknowledge that my name, mailing address, and date of birth will be shared with a third-party solely for the purposes of compensation processing.

Voluntary Participation: Participation in this study is voluntary. All individuals have the right to agree or refuse to participate in this study. Individuals who consent to participate also have the right to change their minds at any time during the study. Participants may tell the investigator that they no longer wish to participate. Refusal or withdrawal of participation will not involve any penalty or loss of benefits to which non-participants are entitled. Refusal to participate will not affect participants' legal rights or the quality of health care they may wish to receive at Callier Center.

Removal from Study: Researchers may decide to remove participants from this study if a) they believe participation in the study is no longer safe for you; (b) you are unable to keep appointments to attend experimental sessions or follow the researcher's instructions; (c) The sponsors cancel funding support for the research.

Records of Participation in this Research: All of the information participants provide to investigators as part of this research will be protected and held in confidence within the limits of the law and institutional regulation.

Audio recordings of your speech and video recordings of your face and mouth will be taken during study procedures. These recordings will be stored using a password-protected UTD computer and the lab server. Please initial the section below that indicates your acknowledgement of the audio and video recordings.

Initials: _____ I acknowledge that this study will use audio and video recordings.

Information Available to Others: A description of this clinical trial and, after completion, results from this 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.

Identifiable Private Information: Private information that can be used to identify you will be removed from the data collected during this study. After such removal, the de-identified data could be used by Investigators for future research studies or distributed to another investigator for future research studies without additional informed consent. The de-identified information will be coded alphanumerically and linked to private information in case the participants need to

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be contacted in the future. The alphanumerical codes will be on the participant survey questionnaire form stored in a locked file cabinet in the lab and also stored electronically in REDCap. The key to the locked filed cabinet and password to REDCap will only be accessible by the PI and research personnel in the study.

Would you like us to contact* you with information about future research studies? Please select one of the options below.

___ Yes, I would like to be contacted for future research studies.

___ No, I would not like to be contacted for future research studies.

* Future contact requires our study team to store your name and contact information. This information will be stored separately from the research data collected in this study.

UT Dallas Institutional Review Board (IRB): Members and associated staff of the IRB of The University of Texas at Dallas may review the records of your participation in this research. An IRB is a group of people who are responsible for assuring the community that the rights of participants in research are respected. A representative of the UTD IRB may contact you to gather information about your participation in this research. If you wish, you may refuse to answer questions the representative of the IRB may ask.

Publications Associated with this Research: The results of this research may appear in publications, but individual participants will not be identified.

Contact People: Participants who want more information about this research may contact any of the investigators listed on page 1 of this document. Participants who want more information about their rights as a participant or who want to report a research related injury may contact:

UTD Office of Human Subjects Protections 972-883-4575 or HSP@utdallas.edu
UTD Office of Research and Innovation

Signatures: A participant's signature indicates that they have read, or listened to, the information provided above and that they have received answers to their questions. The signature also indicates that they have freely decided to participate in this research and that they know they have not given up any of their legal rights.

Participant Name (printed) _____

Participant Name (signature) _____ Date: _____

Name of Research Obtaining Consent (printed) _____

Name of Researcher Obtaining Consent (signature) _____ Date: _____

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