UNIVERSITY OF PITTSBURGH

School of Medicine / Department of Physical Medicine & Rehabilitation

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: **Mapping of motor and sensory brain activity using functional Magnetic Resonance Imaging (fMRI)**

Principal Investigator:: Jennifer Collinger, PhD
Rehabilitation & Neural Engineering Laboratories
3520 Fifth Avenue, Keystone Bldg., Suite 300
Pittsburgh, PA 15213
Phone: 412-383-1274
E-mail: collinger@pitt.edu

Study coordinator: Alayna Schwerer **412-648-4035**

SOURCE OF SUPPORT: National Institutes of Health, National Institute of Neurological Disorders and Stroke

University of Pittsburgh School of Medicine / Department of Physical Medicine and Rehabilitation

DESCRIPTION:
This imaging study is being conducted in support of a grant to develop and commercialize a brain-computer interface device to help restore quality of life and function for individuals with limited hand function.

KEY INFORMATION:
This is a brain imaging study to locate signals which control movement of body parts such as the hand, arm, mouth, leg, foot, or shoulder. You will watch simple videos of movement of various parts of the body while you imagine or attempt to perform those same movements. The MRI will record your brain activity.

We aim to complete testing with 5 participants with ALS, 5 participants with cervical spinal cord injury (SCI), and 5 participants who do not have any impairment nor a neurological condition. The purpose of this work is to learn identify optional locations for placement of brain-computer interface sensors.

Screening procedures include: a medical record review for individuals with ALS or SCI, a MRI safety screening interview to ensure there are no unsafe metals in your body, and a pregnancy test if you are a female of child-bearing potential.

Research procedures include: questionnaires, a functional assessment of your abilities to move and feel, a practice session to review the movement videos and assess muscle activity with electromyography (EMG) sensors, and a functional MRI while you lay very still, watch videos, and think about specific movements.

Risks include: the MRI machine's large magnet attracting metal, falls while transferring onto and off of the MRI bed, or breach of confidentiality if your records become misplaced. We have procedures in place to minimize the potential of all of these risks.

There is no direct benefit for your participation in this study.

You will be provided with financial compensation and parking validation.

BACKGROUND:

Individuals with paralysis due to conditions such as amyotrophic lateral sclerosis (ALS) or spinal cord injury (SCI) often have intact brain function but are unable to move or feel. Brain-computer interfaces (BCIs) can restore some of this lost function using sensors to obtain brain signals to control external devices such as a computer or prosthetic arm. We have shown that a person with paralysis can use a BCI to achieve up to almost normal movement of a robotic arm and that brain microstimulation can create sensations that feel like they are coming from one's individual fingers.

BCIs require the precise placement of sensors in the areas of the brain that control specific movements and feel specific feelings helpful for movement control. Precise sensor placement is crucial to the success of a BCI for restoring function.

PURPOSE OF STUDY:

The purpose of this research study is to improve our knowledge of motor function in the brain in people with impaired hand function. The information learned in this study will identify areas that have a higher likelihood of being successful areas for BCI control.

We are inviting you to consider participating in this research if you are age 18 or older, you have normal or corrected to normal vision, you have arm and hand impairment as a result of a cervical level spinal cord injury (SCI) that occurred at least one year ago, or as a result of amyotrophic lateral sclerosis (ALS). We are also inviting individuals who have no impairment nor neurological conditions, in order to provide comparison data. **You cannot participate in this study** if you have any metal in your body that would be unsafe for MRI, if you have an implanted electronic device, if you have difficulty breathing while lying down, if you are pregnant, or if you weigh over 300 lbs.

STUDY PROCEDURES:

As part of this study, you will complete the following procedures that will be conducted during one or two visits up to approximately 4 hours. We will work with you to determine a testing schedule.

Screening Procedures:
Procedures to determine if you are eligible to take part in a research study are

called "screening procedures." For this research study, the screening procedures include:

- **Medical record review:** If you have any implanted metal or electrical devices, we will ask for your written permission to access your medical records in order to learn the exact make, model, and part numbers of your implanted devices. Then we will work with the manufacturer and experts in neuroimaging to provide details that will ensure your safety while scanning. We will also review your medical record to verify your eligibility for this study.
- **Pregnancy test:** Women of child bearing potential will be given a urine pregnancy test prior to undergoing the MRI. A positive result will exclude further participation.
- **MR safety screening:** Prior to the MRI, you will meet with an MR technologist for safety screening.
- **Cognitive assessment:** You will complete a short questionnaire that tests your ability to remember information and follow directions.

Experimental Procedures:
If you qualify to take part in this research study, you will undergo the experimental procedures listed below. These procedures may occur on one or multiple days and will be scheduled based on your preference and the testing facility schedule.

- **Questionnaires:** You will provide basic information related to the following.
    1) Demographic (age, gender, race, ethnicity, height, weight) information
    2) Handedness (left, right, both) Inventory
    3) Pain questionnaire (hand, wrist, elbow, shoulder, other)
    4) KVIQ Kinesthetic and Visual Imagery Questionnaire which asks you to *imagine* certain movements and sensations.

  The questionnaires will take approximately 20 minutes to complete.

- **Motor and sensory function assessment:** We will test your residual movement and ability to feel in your hand and arm using the American Spinal Injury Association (ASIA) International Standards for Neurological Classification of SCI (ISNCSCI) exam, Manual Muscle Testing (MMT), and/or the ALS Functional Rating Scale. This will take approximately 30 minutes.

- **Functional magnetic resonance imaging (fMRI):** You will have an fMRI scan at the Magnetic Resonance Research Center located at UPMC Presbyterian Hospital. The MRI uses a large magnet to take pictures of the blood flow in your brain while you watch videos of hand, arm, mouth, foot, and leg movements and do simple tasks such as imagining or attempting to move your hand, or imagining having your hand touched. We may also use small vibratory devices to produce feeling in your hand, shoulder, or foot. We can adjust the level of intensity based on your preference. The fMRI helps us identify the area of your brain that responds to imagined or attempted movement or sensation. We will be in communication with you throughout the MRI, and if at any point, you feel anxious or discomfort, we will stop the scan. You will have a chance to practice

these tasks prior to entering the scanner and we may record your muscle activity while you practice.

The fMRI is expected to take approximately 2 hours.

- **Electromyography (EMG):** We may place EMG sensors on your arms to track muscle activity during a practice session while you practice/attempt tasks.
- **Sensory Stimulation:** We may place vibrotactors on your fingers, hand, wrist, and/or collar bone to create a mild vibrating sensation during the MRI.
- **Communication with study team:** We will communicate with you about future study visits by phone or text message, whichever you prefer.

Follow-up Procedures:
There are no follow-up procedures for this research study.

RISKS:

There are a number of possible risks, side effects, and discomforts associated with participation in this research study. As with any investigational study, there may be risks of adverse events or side effects that are currently unknown and it is possible that certain unknown risks could be serious, permanent, severe or life threatening.

- **MRI and fMRI scanning is associated with several risks.** There is the potential risk related to the machine itself attracting metal. Therefore, if you have metal within your body (e.g. shrapnel, plate, wire, aneurysm clip, pacemaker, etc.) that is not compatible with MRI, you will be excluded from this study. Participants with dental fillings can be studied without risk. The magnet will make intermittent, loud, knocking noises that could cause ear discomfort in some people. Also, the rapidly switched magnetic fields used during imaging may cause nerve stimulation (e.g., an uncontrolled twitch or tickle near the waist). Because you must lie with your head and neck inside the narrow scanner tube, you may become anxious and frightened in the enclosed space. Some subjects will have suffered this reaction, called claustrophobia, in other situations. If you develop anxious feelings during the study or for any reason feel that you cannot remain in the scanner, the fMRI can be stopped and you will be able to exit the scanner. You will be in constant communication with the staff during the MRI. The scans also require you to remain still for a long period of time and so there is a risk of developing a pressure sore, particularly for those with decreased sensation. Padding will be used and rest breaks can be incorporated to allow for pressure relief to be performed.
- **EMG testing**, which would allow us to record muscle activity while you practice the study tasks, may involve mild discomfort from cleaning the area where we place the sensors or possible irritation from the tape or adhesives.
- **Sensory stimulation**, which provides vibration during the tasks, involves medical tape for placement of vibrotactors. If you have sensitive skin, you can recommend a specific type of medical tape. The level of vibration can be adjusted to help you "feel" the vibration without causing discomfort.

- **There is a risk of falling during transfers that are required as part of this study.** Some of the research activities, including the MRI, may require you to move onto a bed or seat. If you have difficulty walking, our staff will be available to assist you as needed and may spot you to ensure your safety.
- **Since personal information is collected, there is a risk of breach of confidentiality.** We will take the necessary steps to protect your personal information to the best of our ability. Research data will be collected using a coded ID to protect your private information. Contact information and other identifiable information will be stored separately from your research data. Your name will be provided to schedule your MRI. Personal information will be collected from you during the MRI safety screening visit just prior to the MRI. This information will be securely stored at the MRI center, in electronic or paper form. Your coded data may be shared in an online data repository, or database, that would be accessible by other researchers or individuals for research purposes. An example of a database that we will use is called "DABI: Data Archive BRAIN Initiative" and you can learn more about it here: https://dabi.loni.usc.edu/home.
- **Women who are pregnant are excluded due to potential risks to the unborn fetus or themselves.** There are no known risks associated with undergoing an MRI scan while pregnant and the risks of MRI to the fetus are felt to be very small, but are, nevertheless, also not known.
- **Completion of questionnaires:** Questionnaires will be completed in a private setting. You may become bored or frustrated while completing study questionnaires. We will go at a comfortable pace and take breaks, if needed.
- **Text messaging:** By using a cell phone to communicate, there is a risk of inadvertently sending/receiving incorrect messages.

BENEFITS:

You will not receive any direct benefit from taking part in this research study. However, this study will be useful for studying brain function in people with motor or sensory impairments and, in particular, will be used to guide brain-computer interface electrode placement for individuals in the future.

COST AND PAYMENTS:

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study (i.e., the Screening Procedures, Experimental Procedures described above).

You will be compensated for participating in this research study. Complete participation may take place in one or multiple visits.

	One complete visit including all parts	$150
OR		
	Two study visits compensated at $75/visit	$150

Compensation may exceed this amount if we need to repeat any procedure.

You will be required to travel to UPMC Presbyterian Hospital, and possibly the University of Pittsburgh, for these study procedures. You will be provided with validated parking tickets for UPMC parking garages for all study visits.

If you withdraw from the study, you will be compensated for the completed study visits at the rates described above. Please contact a research team member if you have questions about payment.

COMPENSATION FOR INJURY:

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

CONFIDENTIALITY:

Any information about you obtained from this research will be kept as confidential (private) as possible. All paper records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a coded ID rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. Imaging studies (fMRI) will be stored electronically using your case number on our password-protected server. Paper hard copies will be stored in a locked file cabinet with the rest of the research data. All electronic records will be stored on a password-protected server.

This research study will <u>not</u> result in identifiable information that will be placed into your medical records at UPMC Presbyterian. The MRRC is physically located within UPMC Presbyterian Hospital, **however**, it is <u>not</u> a UPMC medical facility. None of the fMRI or EMG data will appear in your medical records.

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable information for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

We may share your de-identified information with our collaborators at the University of Chicago, other researchers interested in this topic at the University of Pittsburgh, Carnegie Mellon University, and other centers. Coded data may be uploaded to data repositories as required by the

National Institutes of Health.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

Your information will be maintained by the investigators after your participation is completed. The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of seven years after final reporting or publication of a project.

You may access information that results from participation in this study. Contact a research team member on the first page of this form.

RIGHT TO PARTICIPATE or WITHDRAW FROM PARTICIPATION:

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. Any identifiable research information resulting from your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If the investigators feel that you cannot complete the study requirements safely, they may withdraw you from the study.

VOLUNTARY CONSENT:

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Participant's Signature	Printed Name of Participant	Date

VERBAL CONSENT:

If the participant is unable to sign this form, above, an impartial witness must be present for consent and sign below.

Participant's Name (Print)

This participant provided verbal consent because they are unable to sign. I have witnessed this participant's verbal consent.

Witness's Signature	Printed Name of Witness	Date

CERTIFICATION of INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent	Role in Research Study
Signature of Person Obtaining Consent	Date