TITLE OF PROJECT: Perceptual Motor Interaction

NAME OF PRINCIPAL INVESTIGATOR: Shailesh Kantak, PT, PhD

PRINCIPAL INVESTIGATOR'S PHONE: 215-663-6290

AFTER HOURS PHONE: 213-210-4465

SPONSORS: National Institutes of Health

Funding Statement

Funding to support this study is provided by the National Institutes of Health (NIH). The NIH is a public agency that promotes and funds health related research.

What is this consent form about?

We are inviting you to be in a research study. You do not have to be in this study. Your medical care will not change in any way if you say no.

Before you decide if you want to do it, you should understand what you will do in the study. You should also know all the possible risks and benefits of this study. This is called giving *Informed Consent.* Here's what that means:

- You learn all the details of the study;
- You ask questions about the study until you fully understand it;
- You read this consent form. If you decide to be in the study, you sign it and date it;
- You get a copy of your signed and dated consent form to keep;
- You can change your mind about being in the study after you say yes.

What is this research about?

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.

This study looks at the ways stroke affects arm and hand movements.

Medical Arts Building
50 Township Line Road Elkins Park, PA 19027 P: 215-663-6000 F: 215-663-6113 einstein.edu

Why you?

About 100 people will be in this study. We are inviting you to join this study because you experience hemiparesis (weakness on one side) due to a stroke, or, because you have no history of neurological problems.

Is research like medical treatment?

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 benefit you.

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 an Einstein Healthcare Network 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.

How long will the study take?

We will tell you how many times you will be asked to come in before you agree to do the study. Some people may come in for just 1 or 2 visits. Other people may attend up to 15 visits; it may be possible to complete some parts of the study by telephone or videoconference. In-person visits usually last between one and two hours.

What will you do?

If you have experienced a stroke, you will first compete some assessments . We will test your range of motion, muscle strength, reflexes, and sensation in both arms. You may also be asked to complete tests of your communication and cognitive abilities. If eligible to continue, you will be scheduled for 2 or more visits. *If you have not experienced a stroke*, you will be scheduled for 2 or more visits; your first session will include a brief test of your cognitive (thinking) skills as well as some tests to assess motor function, strength, and sensation.

During the study, you will perform a variety of everyday upper extremity movements and play computer games that require you to reach forward to make a series of arm movements. You will usually be seated when performing these tasks. For some tasks, a motion activity marker will be placed on your arm or hand. A motion capture system (sometimes called a kinematic system) uses these magnetic markers to record how you're moving on a computer. During these sessions you may be in physical contact with the researcher for brief periods of time. This may occur when your physical abilities are being evaluated and as the researcher helps you put on and remove motion trackers. Most times, you and the researcher will be in the testing room together and will be located 4 to 8 feet from each other.

You will also be interviewed about your health and medical history. Depending on your personal situation, you may be asked to take part in sessions that include neural (brain) stimulation. During this phase you may receive TMS (Transcranial Magnetic Stimulation). During TMS sessions, you will be in physical or close contact with the researcher throughout the visit. During this procedure, we will hold a coil above your head that delivers a magnetic pulse to the part of your brain that controls arm movements. Sticky electrode pads are attached in your arm and hand to measure the muscle activity caused by the TMS. You may feel a light tapping on your skull and hear loud clicking sounds. Your arm may twitch. Otherwise, the procedure is painless. TMS may be applied a few times over the course of 30-60 minutes. Each application takes only a few minutes but it can be stopped at any time if you find it to be too uncomfortable. You will be given earplugs to wear if you wish.

Most sessions will be 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.

Where will you go to do this study?

Neuroplasticity and Motor Behavior Laboratory
Moss Rehabilitation Research Institute
Medical Office Building
50 Township Line Road
Elkins Park, PA

A friend or family member can come with you.

Will it cost you anything to be in this study?

There are no charges to you or your health insurance for being in this research study.

Will we pay you to be in this study?

Yes, we pay you $20 an hour for each session you attend, with $5 paid every additional 15 minutes.

Payment will be made using a pre-paid debit card. It works like a bank debit card except you do not need to have a bank account. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit. You may use this card at any store that accepts a credit card or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

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 asked to fill out a W-9 form that also asks for your name, address, and social security number. If Einstein pays you $600 or more during a calendar year, we must report this to the Internal Revenue Service. This includes money you receive for this study and any other activities at Einstein Healthcare Network. Depending on your personal finances, you may have to pay income tax on the money you collect.

Depending on your situation and 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 is scheduled by Einstein, please understand that Einstein is not responsible for anything that may occur during that transportation, just like Einstein would not be responsible if you were to make your own transportation arrangements. If transportation costs make it impossible for you to attend study visits, we will contribute to your travel costs up to $20. Travel reimbursement will be added to the pre-paid debit card after each completed visit.

Will being in this study help you in any way?

You should not expect to get better just from being in this study. The information we get may help people with stroke in the future.

Is there any way being in this study could be uncomfortable?

- You may become tired or frustrated when completing the research tasks and you may have slight muscle soreness in your muscles from repeatedly moving your arms. 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 feel any pain, we will immediately stop the task.
- You may experience minor, temporary skin irritation from the tape used to place motion markers for the kinematic system. This should disappear within 1-2 days. Rubbing the area with lotion will help with any discomfort.
- You may get a headache or feel uncomfortable sensations over your scalp during or immediately after the neural (brain) stimulation. Permanent side effects have never been reported. TMS also makes a loud clicking noise which may bother some people.

Are there risks related to this study?

There is an extremely small risk of brain stimulation causing a seizure. However, no seizures have occurred with the exact type of stimulation being used in this study for either people with healthy brains or for people with stroke. We minimize any risk by asking you a series of questions each time you are about to receive TMS. You will be excluded from the related procedures if you do not pass this screen. You will be monitored visually and electronically whenever stimulation is applied for signs of the activity spreading beyond the stimulation area. Your participation in the study will be discontinued if any signs occur.

Although no serious risks or discomforts are expected, there is a possibility that you may experience unexpected complications or consequences from participating in this project. If you experience any complications, please let us know immediately.

What are your rights?

- **Do you have to sign this consent form?**
  No. If you do not want to be in the study, do not sign. Your medical benefits will not change. You can still see your doctors and have therapy at Einstein Healthcare Network
- **Do you have to sign this consent form to be in the study?**
  Yes. Please take as much time as you need to make your choice.
- **What happens if you say yes now, and change your mind later?**
  This is voluntary. You can stop being in the study at any time. You do not have to worry about hurting anyone's feelings or hurting the results of the study. If you change your mind, please tell the researcher.

- **Can someone else decide that you cannot be in the study after you start?**
  Yes. Dr. Kantak and the research team members may decide you should stop being in the study if they feel:
    - It is too hard for you.
    - It is too easy for you.
    - It is not right for you for some other reason.
- **Can you have any guarantees about the results of the study**?
  No. We cannot promise anything about the results of the study, or that you will be able to finish it.

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 yourself or your part in this research if you wish.

When you sign this form, you agree to be in the study. You also must "authorize" (allow) us to use and share some of your personal information.

A 1996 federal law called the Health Insurance Portability and Accountability Act (HIPAA) requires that we ask you if it is okay to use and share information that members of the study team collect about you during this study. When you give your okay by signing, it is called an "authorization". You should understand what you are allowing us to do.

What will be collected?

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, audio/video recordings of you 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.

NOTE*: We will not collect or use special health information about genetic testing, treatment for AIDS/HIV, psychiatric care and treatment, or treatment for drug and alcohol abuse.*

Who will share this information?

If you sign this form, you are authorizing (allowing) the study's team members to identify you and share general, health and research information with certain people *only.* This list says who these people are. *We will not share your general, health, or research information with anyone who is not on this list unless you authorize (allow) it in writing separately.*

- All members of the research team: They help us understand the results and get the information ready so we can write papers describing what we found.
- 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.
- Other Research Sites: Researchers we work with from the University of Pennsylvania help us understand the information we get from you during the study. They also help us plan future studies.
- Regulatory Agencies: The Institutional Review Board at Einstein Healthcare Network looks over the results of this study every year to make sure all the rules are being followed. The Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are government agencies that provide research oversight and sometimes audit studies. Regulatory agencies may look at and photocopy records that have your name listed.
- Study Sponsor: The National Institutes of Health (NIH) pays for this research to be conducted and may ask to look at our study records.
- 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 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, so you can hear of other studies. We will also send them results from some of our research surveys and tests.
- The 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, we may share information 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 and will be for one or both of the following specific purposes: (1) to assist the project team in interpreting your research information; or (2) to assist the project team in planning future studies.

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 this study. But, we will not use your name, and there will be no way to identify you.

What else should you know about confidentiality?

- **Where will we keep your information?**
  In locked file cabinets, in a locked office or on password-locked computers.
- **How long will we keep your information with your authorization?**
  Until we no longer need it or 6 years after the study ends, whichever is longer.
- **If we share your information with others, can we guarantee that it will stay private?**
  No. The Albert Einstein Healthcare Network follows the rules of the federal law (HIPAA) and all other related laws that protect your privacy. Even though we are very careful, there is a chance that if we share your information with someone else, that information could then be used or shared in a way that will no longer be protected like we protect it here. Our Notice of Privacy Practices (a separate document) explains how we protect your information. A copy of the Notice will be given to you.
- **Do you have to agree to allow us to collect and use your information to be in the study?**
  Yes. If you say no, we will not be able to add your information to the study, so you will not be able to be in it.
- **What happens if you say yes now, but change your mind later about allowing us to collect and use your information?**
  You can change your mind and cancel your authorization at any time, but you will no longer be able to be in the study. The team leader and the research team may continue to use information about you that we collected *before* you cancelled your authorization. However, no new information will be collected about you after you cancel your authorization.
  To cancel your authorization, *write a letter* to:

  Shailesh Kantak, PT, PhD
  Moss Rehabilitation Research Institute
  Medical Arts Building 50 Township Line Road Elkins Park, PA 19027

Compensation For Injury Statement

If you are injured, or become ill, while in this study, the Einstein Healthcare Network will give you all the appropriate medical care it can provide. However, Einstein Healthcare Network cannot promise that the medical care and treatment will be given free of charge. Costs may need to be covered by your own health insurance, and/or by you.

Whom do you contact if you have questions?

- If you have any questions about the study,
- If you have questions about your rights if you are in the study,
- If you want to stop being in the study,
- If you want to cancel the "authorization" for us to collect and use information about you,
- If you feel that you have been injured in any way

Please contact: **Dr. Shailesh Kantak**
Moss Rehabilitation Research Institute
Medical Arts Building 50 Township Line Road Elkins Park, PA 19027
(215) 663-6290 or kantaksh@einstein.edu

- If you feel that we haven't given you enough information about your rights to have your general, health, and research information protected, or if you feel your health information was not well protected,
  Please contact: The Einstein Healthcare Network Privacy Office
  215-456-3517 or privacy@einstein.edu

- If you have questions about your rights as a research participant,
  Please contact: The Institutional Review Board
  Albert Einstein Healthcare Network
  (215) 456-7217 or LynchBet@einstein.edu

Audio and Video Recording

Video recording (with sound) is a required part of this research project. Study staff will watch and listen to these recordings in order to analyze your response.

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 recording 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 the Einstein Healthcare Network. 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.

Optional Neurocognitive Assessment

Participants in this study are invited to complete the Penn Computerized Neurocognitive Battery (CNB). This battery is designed to measure a range of thinking skills. It is administered on a computer in our offices. There is no direct benefit to you for taking this test.

Completing the CNB is optional. You can still take part in the main study even if you say "no".

There is no charge to you or your health insurance company for this test. You will be paid in the same way described earlier in this consent form.

If you choose to participate, the results of this test will become of part of you research record. However, you will not receive a report of your scores. We will use the results from battery to learn more about the relationship between thinking skills and motor abilities and how this may relate to recovery from stroke.

The CNB has several parts. These parts can be completed during one testing session or at separate times. Testing may take place on the same days as your regularly scheduled research visits, or we can add a visit for your convenience. In all, the CNB takes about two hours to complete.

Please indicate below whether or not you would like to participate in the optional testing:

____ Yes. I am interested in taking part in the optional neurocognitive testing.
(initial) I understand that I can change my mind about taking the CNB at any time.

____ No. I am not interested in taking part in the optional neurocognitive testing.
(initial)

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

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

_____ (initial) YES, I may be contacted by email.

My email address is _____

_____ (initial) NO, I do not want to be contacted by email.

Understanding of Participation:

The information in this consent form has been explained to me and all of my current questions have been answered. I have been encouraged to ask questions about any aspect of this research study at any time. Whenever I ask questions, the questions will be answered by a qualified member of the research staff or by the investigator(s) listed on the first page of this consent form.

By signing this form, I agree to participate in this research study and give authorization to use the information collected for this research as explained in this consent form. A copy of this consent form will be given to me.

_____
Printed Name of Subject

_____ _____

Subject Signature Date

_____ _____ _____

Printed Name of Person Holding Consent Discussion Signature Date

WITNESS STATEMENT (witness to consent when applicable)

Your signature indicates that you were present during the informed consent discussion of this research for the above named participant, that the information in the consent form and any other written information was verbally discussed with the participant (or legally authorized representative) in a language that he/she could understand, that he/she was given the chance to ask and receive answers to his/her questions, that the decision to take part in the research was freely made by the participant (or legally authorized representative) who indicated his/her consent and authorization to take part in this research by:

- ☐ Signing his/her name
- ☐ By making his/her mark
- ☐ Other means: _____
  (explain)

Printed Name of Witness: _____

WITNESS SIGNATURE: _____ DATE:_____ TIME:_____

Albert Einstein Healthcare Network
Institutional Review BoardApproval Date:
11/17/22