CONSENT TO PARTICIPATE IN A RESEARCH STUDY
and
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

(Stroke Participants)

Sponsor / Study Title:	**National Institute of Health (NIH) / "Validation of Early Prognostic Data for Recovery Outcome after Stroke for Future, Higher Yield Trials (VERIFY)"**
Principal Investigator: (Study Doctor)	**Kelly Sloane, MD**
Telephone:	**(215) 349-8651** **(215) 349-5990 (24 Hours)**
Address:	**Pennsylvania Hospital** **800 Spruce Street** **Philadelphia, PA 19107**

KEY INFORMATION

Purpose of the Study:

The purpose of this research study is to understand how well we can predict your arm recovery by using tests done early after stroke.

Why would we want to predict your arm recovery? During the months after a stroke, some people recover all the way, some people don't recover at all, and many people have a partial recovery. If we can predict how you will do in the coming months, we can choose the right rehabilitation therapies more quickly and more accurately.

Previous research studies have found several tests that could help your doctors and therapists predict your arm recovery. This study will see whether these tests are useful predictors in a larger group of people.

Validating these predictors will mean they can be used to guide rehabilitation therapy for people with stroke. This research is also important to future patients with stroke, as this knowledge will also help doctors do a better job of finding new treatments to help people recover from stroke.

Length of the Study:	You will be in the research study starting within 2 to 7 days of when your stroke started and lasting until around 90 days after your stroke started. The study doctor may decide to take you off this research study at any time, for example, if you are unable to take part in the tests that are part of this study or if those tests are unable to be analyzed. You may withdraw from the study at any time. If you decide to stop being in the study, we encourage you to talk to the study doctor and your regular doctor first so that stopping can be done safely. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.
Risks:	The magnetic resonance imaging (MRI) scans is a procedure much like a CT scan. The major risks are feeling confined by the equipment and uneasiness with loud banging noises during the procedure. Transcranial magnetic stimulation (TMS) can cause a mild headache that does not last long. TMS might increase the risk of seizure but this is very rare. See section titled “What are the Risks and Discomforts of the Research Study?” for additional risks related to the study.
Benefits of the Study:	You will not receive any personal benefits from being in this study. We hope the information learned from this research study will benefit other patients with stroke in the future.
Alternative procedures:	The study doesn’t offer any additional treatment. You will receive standard medical treatment and rehabilitation during this study. The alternative to participating in this study is to not participate in the study. If you choose not to participate in the research study, you will receive standard medical care.

INTRODUCTION

The study doctor wants to know if you would like to be part of a research study. This informed consent document contains important information about the research.

If you have any questions about or do not understand something in this document, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are 18 years or older and you have been diagnosed with a stroke with arm weakness.

A stroke means that part of your brain was injured because the blood flow got interrupted. A stroke happens when a blood vessel becomes blocked (called an *ischemic stroke*) or when a blood vessel cracks open (called an *intracerebral hemorrhage*).

A stroke injures the brain, and when this happens, a person can have many different kinds of symptoms. This study targets people with one specific symptom, arm weakness.

The purpose of this research study is to understand how well we can predict your arm recovery by using tests done early after stroke. The tests being used in this study include magnetic resonance imaging (MRI) scans and Transcranial magnetic stimulation (TMS). The use of these tests to predict arm recovery is investigational which means they are not approved by the Food and Drug Administration (FDA) for this purpose.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is funded by the National Institutes of Health (also known as “NIH”). Medical supervision for the study is provided by the study doctor listed on page 1 of this form.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 657 people will take part in this study at up to 45 sites in the U.S.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

If you agree to be part of this study and sign and date this form, there will be 7 study visits.

Visits 1 through 4

- Take place while you are still in the hospital.
- Study visits 1 – 3 can sometimes be performed on the same day.
- Involve tests as described below.

Visit 5

- Can occur over the phone or in-person about 30 days after your stroke.
- This call will probably take less than 20 minutes.

Visit 6

- Can occur over the phone, text message, in-person, or through e-mail or a mail notice about 60 days after your stroke.
- This call will probably take less than 5 minutes.

Visit 7

- Takes place in the clinic or in your home about 90 days after your stroke.
- It involves an assessment of any ongoing effects of your stroke.
- This visit will probably take around 2 hours.

OTHER INFORMATION ABOUT STUDY PROCEDURES

You will have the following tests at the study visits.

If there are any issues with data collection (e.g. equipment malfunction), it is possible that you may be asked to repeat individual tests as long as it would still be possible to obtain quality data without increasing risk.

Visit 1 includes the following procedures:

- Signed and dated informed consent

Visit 2.A includes the following procedures:

- Evaluation of your arm and hand strength.
- Collection of demographic information (for example, age, date of birth, etc.) and your medical history
- Pregnancy test
- This will take about 20 minutes.

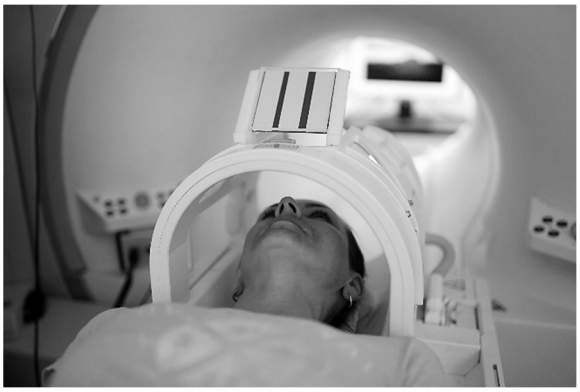
Visit 2.B includes the following procedures:

- Behavioral testing - This is like the physical exam your regular doctor and your therapist perform.
- Perform an additional neurological exam- the same exam they performed when you first arrived at the hospital

Visit 3.A includes the following procedures:

An MRI scan

- We will also do an MRI (also known as “magnetic resonance imaging”) scan of your brain.
- An MRI scan gives us pictures of your brain and shows which parts of the brain were injured by the stroke and how badly.
- For an MRI scan, you will be asked to lie flat and hold still.
- A checklist will be used to make sure that MRI is safe for you.
- Your study doctors are going to try to do this MRI scan as part of your regular hospital care, plus they will ask to keep you in the MRI scanner for about 5 extra minutes.

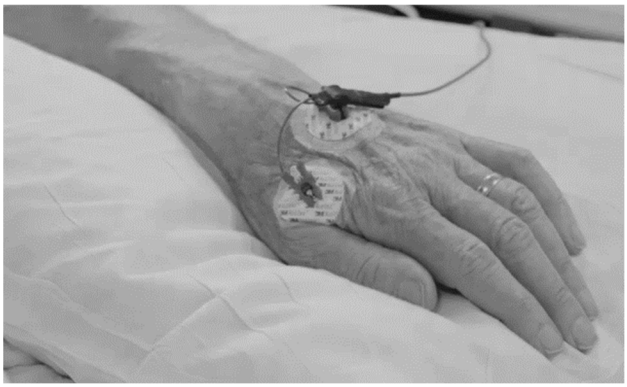


Visit 3.B includes the following procedures:

- You will be asked what kind of treatments you’ve been getting
- You will be asked how you are feeling and if you experienced any side effects

Transcranial magnetic stimulation

- This is also known as “TMS”.
- TMS is very safe. TMS has been done safely with thousands of people, and certain types of TMS have even been approved to treat different diseases.
- The study doctor or study staff will complete a checklist with you, to make sure that TMS is safe for you.
- The TMS is about the size of a plate and makes a click sound when activated.
- TMS creates a very small and brief magnetic field that can activate nerve cells.
- The study doctor or study staff will hold the TMS device gently on your head, to activate the brain area that controls your weaker arm.
- We will put sensors on your skin to see if the nerve cells send a message from your brain to the muscles of your weaker arm. The sensor system is called a surface Electromyography (EMG).
- The study staff will send several dozen magnetic signals to see how well messages from your brain reach the muscles of your weaker arm.
- This will take up to 1 hour.

Visit 4 includes the following procedures:

- You will be asked what kind of treatments you've been getting
- You will be asked to record treatments in a paper diary
- You will be asked how you are feeling and if you experienced any side effects
- Any contact information- so that we can easily follow-up with you later
- You will be discharged from the hospital

Visit 5 includes the following procedures:

- Happens over the phone or in-person about 30 days after your stroke.
- We will ask you some questions about what kinds of treatments you've been getting and your recorded treatments from your paper diary
- We will ask about how your overall health has been since leaving the hospital.
- This will take about 20 minutes.

Visit 6 includes the following procedures:

- Can occur over the phone, text message, in-person, or through e-mail or a mail notice about 60 days after your stroke.
- This is just to provide a check-in to see how you are doing and if there is anything we can do for you.
- We will also ensure that the day-90 in-person visit has been scheduled.
- This call will probably take less than 5 minutes.

Visit 7 includes the following procedures:

- Takes place about 90 days after your stroke. We expect this visit to take place in the research clinic, but if you need this visit to occur in your home, we can do this as a home visit.
- We will ask you questions about your health and any treatments you received including recorded treatments from your paper diary. This will include questions about your mood and how well you are functioning.
- We will also do an exam, with a focus on arm strength and walking.
- This will take approximately two hours.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the study doctor and study staff.
- Keep your study appointments. If you need to miss an appointment, please contact the study doctor or study staff to reschedule as soon as you know you can.
- Tell the study doctor or study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Ask questions as you think of them.

Tell the study doctor or study staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the study doctor of each study. This is to help protect you from injury arising from involvement with two different research studies at the same time. You should not participate in another clinical trial involving an experimental stroke treatment (acute or rehabilitation) after completing baseline activities for this study.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

MRI

- Magnetic Resonance Imaging (MRI) scans create images of the body using a magnet and radio waves. While the procedure is much like a CT scan, there is no radiation involved in an MRI exam.
- MRI scans are safe for most people and are commonly obtained in persons with a stroke.
- No known ill effects have been directly attributed to exposure to the radio waves or the strong magnetic field used in MRI, but it is not safe to scan people with certain kinds of metal in their bodies (such as a metal heart valve, brain aneurysm clip, ear implants, spinal nerve stimulator).
- The person organizing your scan will ask you questions to make sure it is safe for you to have an MRI scan. It is very important that you answer these questions accurately and thoroughly.
- The MRI machine is open at both ends, but you may still feel confined (claustrophobic). If this bothers you, please tell the study staff.
- The MRI machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRI exam. You will be able to hear the study staff and they will be able to see and hear you.
- The study staff will put a safety button in your stronger hand so that you can alert study staff if you need their attention.

TMS

- TMS is safe for most people, but some people cannot have TMS because they have metal in their body, such as a cochlear implant.
- The person organizing your TMS exam will ask you questions to make sure it is safe for you to have TMS.
- The TMS device makes a click sound each time it is activated. This can be loud, and we will offer you ear plugs.
- Some people feel a light muscle twitch in the forehead or arm, but this is not expected to be painful.
- Some people experience a mild headache after TMS but it does not last long.
- About 1 in 20 people have a seizure within the first two weeks after their stroke. This is more common when the stroke is caused by bleeding in the brain than when it's caused by a blocked artery. In theory, TMS might increase the risk of seizure after stroke, but this has not been observed.
- People who are anxious about medical procedures may feel faint, although this is rare.
- We will watch carefully for these possibilities and other unforeseeable risks in this larger study.

General

- You might experience fatigue during any of the tests described above. If this happens you should let the study staff know and you will be given some time for a break.
- Your normal medical care that you receive will not change as a result of your participation in this study.
- This study should not involve any physical risk to you, but we will monitor closely for any risks not previously known.
- There is a low risk of loss of confidentiality of your information. You will read more about the protection of your information later in this document. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Surface EMG

This is a very low risk procedure from which no complications are expected.

Discomfort with questionnaires

Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

Unforeseen risks

There may be other risks that are unknown.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You can choose whether or not to take part in this research study. Deciding not to take part will not affect your treatment in any way. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You will be told of any important new information that is learned during the course of this research study, which might affect your health, welfare, or your willingness to continue participation in this study.

Nothing in this consent document waives any legal rights you may have nor does it release the study doctor, the sponsor, the institution, or its agents from liability for negligence.

WHAT IS THE CLINICAL TRIALS REGISTRY?

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. ClinicalTrials.gov is a database of publicly and privately supported clinical studies of human participants conducted around the world.

This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, a Certificate of Confidentiality is automatically provided by the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the study doctor learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent document.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

There are no costs to you or your insurer for participating in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be compensated $150 for your time, and up to $40 for travel-related costs, to take part in this study. This will be provided after completing the in-person 90-day visit via a Greenphire Clincard. Coverage of additional transportation expenses, such as medical transportation, may be provided on a case-by-case basis with the approval of the VERIFY National study team.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that total $600 or more in a calendar year.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

If you think you have suffered a research-related injury, you should promptly notify the study doctor. Your hospital or physician's office will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for a mistake.

WHAT IS AN ELECTRONIC MEDICAL RECORD?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a subject, have access to research related information within the EMR/?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier outside of NIH StrokeNet. Your research records may be disclosed outside of the study site, but in this case, you will be identified by a participant identification number. This information will be kept in a secure location and access limited to research study personnel. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Participant information may be provided to the Sponsor, Advarra IRB, and Federal and/or other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

FUTURE RESEARCH STUDIES

Identifiers might be removed from your identifiable private information collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

CLINICALLY RELEVANT RESULTS

Results of research testing will not be disclosed to you.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participant. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail: Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00054139.

CONSENT

- I have read and understand the information in this informed consent document.
- I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.
- I voluntarily agree to participate in this study until I decide otherwise.
- I do not give up any of my legal rights by signing and dating this consent document.
- I will receive a copy of this signed and dated consent document.

_____

Signature of Participant Date

_____

Print Name

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent from, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____

Signature of Person Obtaining Consent Date

_____

Print Name

WITNESS STATEMENT:

The participant was unable to read or sign this consent document because of the following reason:

___ The participant is non-English speaking
___ The participant is illiterate
___ The participant is physically unable to sign the consent document
Please describe: _____
___ Other
Please specify: _____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____
Signature of Witness Date

_____
Print Name

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your study doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of University of Cincinnati
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- Representatives of NIH StrokeNet National Coordinating Center (NCC).
- The NIH StrokeNet National Data Management Center (NDMC), housed in the Data Coordination Unit (DCU) in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.

- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Your health data will be used to conduct and oversee the research, including for instance:

- For other research activities related to the study

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Signature of Participant Date

_____

Print Name

Person Obtaining Authorization

I attest that that I have discussed the authorization with the participant and explained to him or her in non-technical terms all of the information contained in this authorization from. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____

Signature of Person Obtaining Authorization Date

_____

Print Name

WITNESS STATEMENT:

The participant was unable to read or sign this authorization document because of the following reason:

___ The participant is non-English speaking
___ The participant is illiterate
___ The participant is physically unable to sign the authorization document

Please describe:

_____

___ Other

Please specify:

_____

I confirm that I was present as a witness for the authorization process. I confirm that the participant named above was read the information in the authorization document and that the participant has agreed to allow study staff to collect, use and share his/her health data as specified in this form.

_____

Signature of Witness Date

_____

Print Name