UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Serial Physiologic MRI in Minor Stroke with Large Vessel Occlusion
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Sponsor	not applicable

Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

This research study is being conducted to use MRI to measure blood flow and brain metabolism over time in patients suffering minor stroke symptoms. This will help better understand why some patients experience worsening of stroke symptoms, and may help identify patients for a more aggressive course of treatment. This study will not directly impact your clinical treatment.

If you agree to join the study, you will be asked to undergo several research procedures:

1. First, the research team will collect (from the medical record) basic information about you, including your age, race/ethnicity, medical history, and current stroke symptoms.
2. Three study MRI's will measure blood flow and metabolism in your brain. All MRIs will be performed in a MRI scanner located in the middle of the neuroscience unit (10th floor).
    a. MRI 1: Will take place shortly after you agree to participate. This MRI will require an estimated 45 minutes to complete.
    b. MRI 2: Will take place 2 hours after MRI 1, and will require an estimated 45 minutes to complete.
    c. MRI 3: Will take place 3 days after MRI 1, and will require an estimated 25 minutes to complete.
3. Additional clinical data will be abstracted from the medical record when you are discharged from the hospital (stroke severity measures).
4. You will receive a brief phone call 90-days post-stroke to assess your level of function.

You not expected to directly benefit from this study, although by participating you are contributing to the advancement of knowledge, which has the potential to benefit society and may result in improved clinical care for stroke patients in the future. MRI scanning is very safe, but some subjects may feel closed in and not be able to tolerate the study. If that occurs, you may elect to stop the scan immediately.

Please note that more detailed information about the study procedures is available below. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You (or your family member) are invited to participate in a research study since you (or your family member) has experienced an acute stroke due to a blockage in a large artery in the brain, but fortunately the stroke symptoms are relatively minor. Patients with minor symptoms may be treated with medications, rather than surgery, but there is a chance that stroke symptoms may worsen. Thus study is designed to measure blood flow and brain metabolism in order to better understand why some patients remain stable while some patients may experience worsening symptoms. Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in the study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will explain the study in plain language. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research any questions. A signed copy of this consent will be provided for your records.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

This research study is being conducted to test whether MRI scans can predict who will remain stable and who will experience worsening of the stroke symptoms. If imaging can predict symptom worsening, in future work, this strategy may help identify high-risk patients in whom a more aggressive course of treatment could be considered.

How many other people will be in the study and how long will I be in the study?

Each subject will be in the study for 90 days. Study MRIs and data collection will take place during your stroke hospitalization, and at 90-days, a study team member will call you to assess your level of function. We will enroll 24 patients. We expect to complete the study in 2 years.

What am I being asked to do?

If you agree to join the study, you will be asked to undergo several research procedures. First, study personnel will collect basic information about you, including your age, race/ethnicity, medical history, and stroke symptoms from your medical record. Then you will undergo a study MRI shortly after agreeing to participate in this study, which will take an estimated 30 minutes. You will undergo a second study MRI 2 hours later which will also take an estimated 30 minutes. You will undergo a third, and final, study MRI 3 days later which will take an estimated 25 minutes. None of these MRIs will require a contrast agent. Additional clinical information

about your stroke severity will be collected from your medical record when you are discharged from the hospital. And 90-days later you will receive a brief phone call from a study team member to assess your level of function.

An MRI (Magnetic Resonance Imaging) is a type of scan that uses radio waves to take detailed pictures. You will be asked to lie on an MRI table where the technologist will place a coil over your head. You will be provided a blanket for comfort and earplugs since the MRI makes loud banging noises. You will still be able to hear some sound to ensure you can communicate with the technologist and can follow any direction given throughout the MRI scan. The technologist will slowly slide you into the MRI magnet where radio waves will be transmitted into you. Your body will give off radio waves which will be picked up by the coils and made into detailed pictures.

What are the possible risks or discomforts?

The overall risks of participating in this study are very low.

Loss of confidentiality. Risks of loss of confidentiality are low, but are nonetheless possible. As detailed below, we will make efforts to minimize this risk including minimizing the amount of identifying information collected, restricting access to identifying information, using anonymous patient identifiers, maintaining data in secure, password protected files and databases, and ensuring all research staff are training in HIPAA, human subjects ethics and compliance.

Magnetic Resonance Imaging (MRI). The known risks associated with MRI are minimal. However, there is a potential risk of MRI for anyone with medical implants or other metal objects inside the body. Anyone undergoing MRI scanning must complete a screening in advance of the study for the presence of medical implants or other foreign bodies that could pose an injury. Every effort will be made to ensure that disclosed implants or foreign bodies do not pose a risk to subjects. In cases where there is insufficient information to evaluate the risks associated with an implant or foreign body, the MRI study will not be allowed to proceed. We require that all people involved with the study remove all magnetic metal from their clothing and all magnetic metal objects from their pockets. No magnetic metal objects are allowed to be brought into the magnet room at any time except by approved personnel. In addition, once you are in the magnet, the door to the room will be closed so that no one inadvertently walks into the room.

There is no known health risk associated with exposure to magnetic fields during an MRI. Some of the MRI pulse sequences and equipment components used in this scan are not FDA-approved, but they are considered to pose no more than minimal risk. There are minimal risks from the loud noise associated with the MRI scanner and from the discomfort of lying on a hard surface. We will provide you with protective earplugs and make every attempt to ensure your comfort with blankets during your time in the scanner. Additionally, it is possible that you may feel too closed in when inside the MRI scanner and experience discomfort as a result. If this occurs, the scan will be stopped immediately upon your request.

Although there are no known risks related to MRI on a pregnant woman or a fetus, there is a possibility of yet undiscovered pregnancy related risks. Since there is no possible benefit from participating in this protocol for a pregnant woman, we will exclude pregnant women. In order to confirm non-pregnant status prior to the start of the MRI scan, female subjects of child-bearing potential will be required to have a negative pregnancy test prior to enrollment (pregnancy test in women of child bearing potential will undergo urine pregnancy test as part of routine clinical stroke care).

The study MRIs are not routine clinical scan (they are research scans), but some components of the scan will be made available to your clinical team. If during the course of the research study, the research team notices an unexpected finding(s), the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to experience a direct benefit from this study; although, by participating you are contributing to the advancement of knowledge, which has a societal benefit.

What other choices do I have if I do not participate?

You may choose not to participate in this research study.

Will I be paid for being in this study?

You will not be compensated for participation

Will I have to pay for anything?

You will not have to pay to participate in this research. The study MRIs will not be billed to you or your insurance company.

Will I receive the results of research testing?

The tests done in this research study are only for research, but some components of your MRI may have clinically relevant information for your treating clinicians. Therefore, the MRI scans will be made available to your treating team to use as they see fit. In general, research results will not impact your clinical care, and some aspects of your MRI scans will require additional time for processing, so these components will not be available to your clinical team. Results from your MRI scans will not be returned to you in any formal capacity. However, it is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary.

What happens if I am injured from being in the study?

If at any time you believe you have sustained an injury as a result of participating in this study, please contact the Principal Investigator using the contact information listed on this form. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

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.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. For this study, most study activities are completed during your hospitalization, but you will also receive a brief phone call 90-days later. After the phone call, your involvement in the study is complete. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. Your information will be coded by a study-specific identification number to protect your confidentiality. Study documentation will be kept and archived securely. Your identity will be kept confidential when the results of this study are published.

However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

What may happen to my information collected on this study?

Your information will be de-identified. De-identified means that all identifiers have been removed. The information will then be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the de-identified information collected during this study.

Electronic Medical Record and Release of Study Related Information

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.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing 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).

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. Not sharing or delaying certain research information within your EMR may be necessary to protect the integrity of the trial results or for other reasons.

Reports from the MRIs will be placed in your chart and available to view on MPM.

What information about me may be collected, used or shared with others?

- Name, telephone number, and medical record number
- Personal and family medical history
- Results from physical examinations, tests or procedures

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, 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

Who, outside of the School of Medicine, might receive my information?

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by expressing your desire to end the study to the research staff during a study visit, or by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study. In the event that you withdraw your permission to collect or use your health information, the investigator, by regulation, retains the ability to use all information collected up to that point.

What if I decide not to give permission to use and give out my health information?

You will not be able to be in this research study if you do not give permission to use and give out your health information.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

A copy of this consent form will be given to you.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

_____	_____	_____
Name of Subject (Please Print)	Signature of Subject	Date
_____	_____	_____
Name of Person Obtaining Consent (Please Print)	Signature	Date

(if applicable)
For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

_____	_____	_____
Name of Authorized Representative (Please Print)	Signature	Date

Provide a brief description of the above person authority to serve as the subject's authorized representative