# UNIVERSITY OF PENNSYLVANIA
# RESEARCH PARTICIPANT
# INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

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| **Protocol Title:** | **Networks of Arousal in Stroke Recovery (NEST)** |
| **Principal Investigator:** | **Aaron Rothstein, MD**<br>**3400 Spruce Street, 3 West Gates Bldg.**<br>**Philadelphia, PA 19104**<br>**(215) 662-3339** |
| **Emergency Contact:** | **Neurology On-Call**<br>**(215) 662-4000** |
| **Sponsor** | **American Heart Association** |

## Research Study Summary for Potential Participants

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.

The research study is being conducted to determine how strokes in certain areas of the brain on MRI affect fatigue, cognition, attention, and stroke recovery. The MRI of your brain has either already been performed as part of standard clinical care or, if it has not been performed, you will be asked to get one as part of the research study.. The study, if you agree to join, will involve non-invasive data collection in order to learn more about stroke location and stroke recovery.

Your participation in the study will last for 3 months because clinical data will be collected by the study team during this time.

The risks of participating in this study are very low as you will only undergo some standardized tests and questionnaires about how you are functioning and how you feel after your stroke. If you have not had an MRI as part of your clinical care, you will undergo a research MRI. 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. 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.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. 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 ischemic stroke.Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. You do not have to participate in any research study offered by your doctor.

In this research study, we plan to use the brain MRI obtained as part of your clinical care (or, if that is not the case, obtain a research MRI) and assess how the stroke location affects your recovery after stroke. Your participation is voluntary, which means you can choose whether or not you want to participate. Being in a research study is different from being a patient. 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. 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.
If you decide to participate, you will be asked to sign this form. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team any questions. A signed copy of this consent will be provided for your records.

## What is the purpose of this research study?

The purpose of the study is to determine if certain stroke locations on MRI affect your overall stroke recovery and your degree of fatigue, cognitive impairment, and attention impairment after stroke. This study will use the brain MRI already obtained as part of your clinical care--or if you have not gotten one as part of your care we will obtain a research MRI free of charge-- and will ask you questions about your fatigue and overall sense of recovery after stroke as well as give you cognitive and attention tests at different time points over the next three months. We will compare how strokes that do or do not affect certain brain locations affect your performance on these tests.

## How long will I be in the study?

You will be in the study for 3 months. There will be 150 patients enrolled in this study. We anticipate that it will take approximately 36 months to enroll the necessary subjects.

## What am I being asked to do?

After you agree to be in the research study, study personnel will collect information from your medical record, including your past medical history and results of diagnostic testing done for routine clinical purposes. And if you have not gotten an MRI brain as part of your clinical care, we will obtain one free of charge to you. If eligible based on this available data, the testing sessions will take place after you consent to be in the study and at approximately 3 days, 30 days, and 90 days thereafter. Each testing session will last approximately 20-30 minutes and can be done either virtually (by phone or video) or in person. They will consist of tests of cognition, attention, and stroke severity as well as questionnaires on fatigue and overall stroke recovery.

Participation in this study will not result in the withholding of standard treatments and will not result in any additional blood sampling or imaging than what you would normally receive as standard of care.

If you require a research MRI you will be transported to the MRI machine in this hospital to have one done. 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?

Because there is no drug involved in this study the risks are very low. There may be some discomfort in taking the cognitive and attention tests as they will challenge you. But you are free to leave the study at any time if this is too much of an inconvenience. If you have not gotten an MRI brain as part of your clinical care we will obtain one as part of the study. The risks are also low and are laid out below.

The greatest risk of MRI is a magnetic object flying through the air toward the magnet and hitting you. To reduce this risk, 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 a potential risk of MRI for participants with medical implants or other metallic objects in their body. All participants undergoing MRI scanning must complete a screening evaluation 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 participants. 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.

Possible Side Effects Possible side effects related to the MRI scan include:

Possible:
• Anxiety/stress
• Claustrophobia
• Discomfort
• Nausea/vomiting
• Tingling in arms

Rare, but serious: • Injury related to the presence of metallic or surgical implants or metal pieces in the body and the MR magnet. This also includes: wearable sensors, medicinal patches, certain types of tattoos, and hair weaves containing metallic threads. It is important that you let the MRI team know about whether you have these before the MRI procedure.

This MRI is not a clinical scan. It is possible that during the course of the research study, the Investigator 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 the finding requires any further 3 action on your part. 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.

Although there are no known risks related to MRI on pregnant participants 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 participant, we will exclude participants who are pregnant.

This MRI is not a clinical scan. It is possible that during the course of the research study, the Investigator 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 the finding requires any further 3 action on your part. 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.
There is always a very small risk of protected data being breached. However, all data from this study will be recorded and kept on file in a secure and HIPAA compliant fashion. Moreover, the files will not contain your name.

## 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?

One possible direct benefit of being in this study is that you may become more aware of certain symptoms after your stroke through taking the required tests and filling out the required questionnaires. In this case you will be able to speak with your treatment team

about these symptoms and how to deal with them. However, you may not get any benefit from being in this research study.

It is hoped that this study will increase our understanding of how stroke location affects recovery after stroke. This knowledge may one day help us to develop new treatments for stroke or to individualize post-stroke care for patients in the future using brain MRI.

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

You may choose not to participate in this study. Your decision to participate or not will not affect your regular medical care in any way.

## Will I be paid for being in this study?

You will not be paid for participation in this study.

Will I have to pay for anything?

There is no additional cost for participating in this study.

You and/or your health insurance will be billed for the costs of medical care associated with your stroke as these expenses would have happened even if you were not in the study. You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

## Will I receive the results of research testing?

If you end up needing a research MRI to take part in this study, the MRI done in this research study is 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?

We will offer you the care needed to treat injuries directly resulting from taking part in this research, though the likelihood of any injury from this study is extremely low. 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. 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 the participants have completed all visits, and all information has been collected. It is expected to take 36 months to complete the study. This study may also be stopped at any time by your physician, the Food and Drug Administration (FDA), or the University of Pennsylvania Institutional Review Board (IRB, the committee charged with overseeing research on human subjects) 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 study Principal Investigator, the IRB or the FDA has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. 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. 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.

The confidentiality of your information will be protected in the following way during the study: Any information will be coded by a study-specific identification number to protect your confidentiality. Study documentation will be kept and securely archived in private offices under lock and key available only to the research personnel. Your identity will be kept confidential when the results of this study are published.

## Will information about this study be available to the public? Who, outside of Penn Medicine, might receive my information?

As part of the study, the Principal Investigator, study team, University of Pennsylvania Institutional Review Board, Office of Regulatory Affairs or Office of Human Research may disclose your personal health information, including results of the research study tests and procedures to the following:

Government agency and/or their representatives:

1. The FDA is the governing agency that regulates clinical research in the United States.
2. Oversight organizations: The U. S. Office of Human Research Protections (OHRP)

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 Penn Medicine procedures developed to protect your privacy. Once information is disclosed to others outside the University of Pennsylvania Health System and School of Medicine the information may no longer be covered by federal privacy protection regulations.

The American Heart Association (AHA) is the funding agency for this study at the University of Pennsylvania and will receive reports regarding the function of the study as well as summary of data results but they will not receive identified personal health information of the subjects in this study.

In all disclosures outside of the University of Pennsylvania Health System and School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

## What may happen to my information and imaging collected in this study?

**Future Use of Data and/or Specimens**

The storage of imaging studies and study results is a required element of participation.

Your coded or identifiable information and MRI will be stored for future research purposes. Future researchers may receive information that could identify you. 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 information collected on this study. The following identifiers will be retained with your information: your unique study ID number. Your information may be stored and used for future research purposes for an indefinite amount of time.

There are no plans to tell you about any of the specific research that will be done. Possible future research may include: further analysis of imaging in relation to the scores on the tests that you completed. We may share your identifiable information with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies.

We will not follow up with you to tell you about the specific research that will be done. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by ensuring that the data is coded behind a study ID, thus it will be linked through the study ID. We will keep that study ID secure with a password protected file that will be stored on HIPAA compliant servers within the Penn system.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information and MRI study or have changed your mind, you can contact Aaron Rothstein at 215 662 3339. If you change your mind and withdraw from the study, we will permanently delete any data tied to your subject ID only after this study for which you are consenting is completed.

## 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 participant, 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 results or for other reasons. Imaging results that relate to this study, however, will be immediately available to you since they will be studies done for the purposes of clinical care. No other research results will be entered into the EMR.

If you end up needing a research MRI to partake in this study, reports from the MRIs will be placed in your chart and available to view on MPM.

## Will I receive the results of research testing that may be relevant to my health?

Many of tests done in research studies are only for research and have no clear impact on your healthcare. However, results from the research questionnaires that you fill out and tests that you take that may be relevant to your healthcare may be released to you. Those that are deemed relevant by the research team will be immediately released to you as soon as you complete the questionnaires. You will know how you did on the tests and they will be discussed with you individually. These tests will not be included in the Penn EMR as they are not a part of your clinical care.

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

The following personal health information will be collected and used for research:

- Name
- Address
- Telephone number
- Email address
- All elements of dates, including the dates from your study participation and date of birth
- Medical record number

- Medical history
- Information from the tests and procedures described earlier in this document
- MRI scan of your brain obtained for clinical purposes

## 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.

## Where may my information be stored?

Information related to your participation in clinical research will be contained in a HIPAA-compliant online database under the auspices of Penn known as RedCap. 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 RedCap your information will be accessible to authorized research personnel involved in this study.

## 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 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

## How long may Penn Medicine use or disclose my personal health information?

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

However, Penn 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 sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

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

Then you will not be able to be in this research study.

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

By signing this document, you are permitting Penn 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 participant?

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 participant, 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.

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 protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

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

| _____ | _____ | _____ |
|---|---|---|
| Name of Participant **[print]** | Signature of Participant | Date |
| _____ | _____ | _____ |
| Name of Person Obtaining Consent **[print]** | Signature | Date |

*For participants unable to give authorization, the authorization is given by the following authorized participant representative:*

| _____ | _____ | _____ |
|---|---|---|
| Authorized participant representative **[print]** | Authorized participant representative Signature | Date |

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

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