UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title:	The Neuralert Stroke Monitor Pilot Trial
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Research Study Summary for Potential Participants

You are being invited to participate in a research study because you are planning on having surgery which may have a small risk of stroke or you are admitted to the hospital with a stroke or TIA and are at risk of another stroke. 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 is being done to test a non-invasive device that may be able to detect stroke before it would otherwise be found by the clinical team.

If you agree to join the study, you will be asked to complete the following research procedures:

-If you are having surgery, the Neuralert devices will be placed on both of your wrists after the procedure.

-If you are admitted with a stroke or TIA, the Neuralert devices will be placed on both of your wrists once the consenting process is complete

- You will wear the devices for about 5 days and then take them off.

Please note: the study doctor performing the research procedures may or may not be your treating physician.

A potential benefit of this study is that the device may identify stroke symptoms faster than hospital staff would otherwise, which may allow for earlier treatment than would have occurred without the device. This study may also benefit other patients, including possibly you in the future, as it has the potential to support the device's use in various healthcare settings. As the device is currently being evaluated, there is no guarantee that you will benefit from participating in this study.

There are no meaningful known risks associated with wearing the devices used in this study though staff may potentially check on you more frequently throughout your hospital stay.

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 are being invited to participate in a research study because you are currently or plan to be admitted to the hospital and will be at increased risk of stroke. This may include undergoing surgery which has a risk of stroke or having had a recent stroke or TIA which puts you at risk of another stroke. Stroke is treatable but every minute counts; faster treatment is associated with better outcomes. We are testing a non-invasive device that may be able to detect stroke before it would otherwise be found by your clinical team. Your participation is voluntary, which means you can choose whether 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 this 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 give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about this form. If you decide to participate, you will be asked to sign this form. 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. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

This consent form is written from the point of view of a research participant. If a legally authorized representative will be providing consent, the words "you" and "your" should be read as "the research participant".

What is the purpose of this research study?

The purpose of this study is to test the Neuralert Monitoring System's ability to integrate into clinical care and monitor for stroke symptoms in patients in the hospital who are at risk of stroke. The earlier we can identify a stroke, the more likely we are to be able to help patients. Stroke very frequently presents with weakness on one side of your body and the Neuralert devices continuously monitor for asymmetric arm movements, which may be indicative of a stroke. Our goal is to demonstrate that the Neuralert Monitoring System will detect strokes before they would be identified by current standard of care.

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

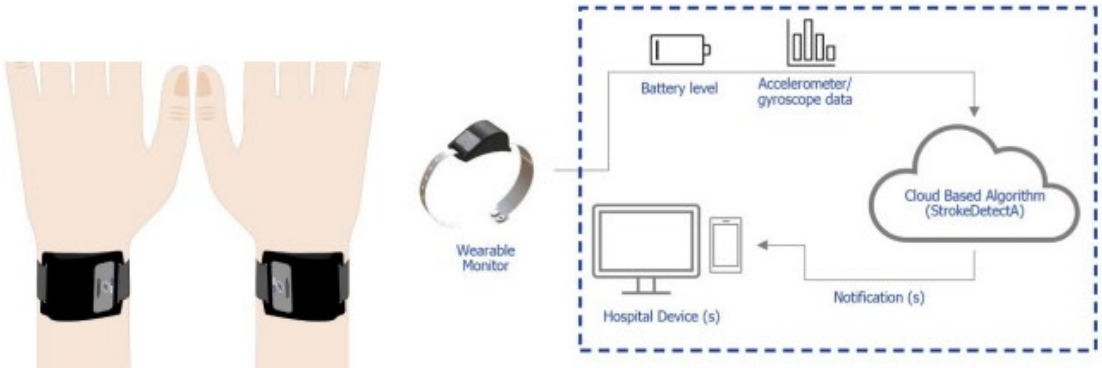
You will wear the devices for approximately 5 days, or less if you are medically cleared for discharge before 5 days. We hope to enroll at least 50 subjects in the study.

What am I being asked to do?

Sign informed consent with the research team prior to wearing the devices.

If you are admitted with a stroke or TIA, the Neuralert devices will be placed on both of your wrists after you are done with the consent process. If you are planning on having surgery, they will be placed on your wrists when you are done with the procedure. You will wear the devices for about 5 days and then take them off. They can be temporarily removed if needed for clinical care. If the devices are bothering you, you can also feel free to ask your nurse to remove them for you at any time. If you are ready for discharge before 5 days are completed, you will take off the devices before you leave the hospital.

The Neuralert devices are similar to wearing a portable monitoring device like an iWatch or Fitbit (see picture below). Each device includes a lithium battery. The wristband is similar to the wristbands commonly used in hospitals for identification purposes, and the electrical and electronic components of the device are fully encased and do not come into direct contact with you.



The device transfers the monitoring data to a cloud-based program that detects asymmetric arm movements, which may be indicative of stroke. If asymmetric movement is detected, an alert is sent to your care team via a smartphone app.

The nurse will then perform a routine patient assessment when able. If a stroke is suspected based upon this evaluation, the covering physician and the Stroke Team will be alerted and additional testing will be performed as part of standard of care which may include a head CT and possibly a CT angiogram and CT perfusion study, in order to confirm or refute whether you are having a stroke. If you are eligible, treatment for the stroke will be given as quickly as possible. All of these exams, scans, and treatments occur in routine practice. The device will merely facilitate the nurse performing an assessment earlier than would otherwise occur during your routine patient care. As noted above, earlier treatment of stroke, is strongly associated with better outcomes.

What are the possible risks or discomforts?

There are no meaningful risks associated with wearing the devices used in this study though staff may potentially check on you more frequently throughout your hospital stay. The study team will take every possible step to maintain your privacy, including using password protected files and minimizing the use of identifying information on study documentation, but whenever private health information is collected there is always a small risk that a breach of confidentiality could occur (e.g., someone outside of your care team may see your identifying information).

If you find the device or wrist straps uncomfortable, you can stop the monitoring at any time although we will try to make it as tolerable as possible so you can continue.

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?

A potential benefit of this study is that the device may identify stroke symptoms faster than hospital staff would typically, which may allow for earlier treatment and better outcome than would have occurred without the device. This study may also benefit other patients, including possibly you in the future, as it has the potential to support the device's use in various healthcare or home settings. As the device is currently being evaluated, there is no guarantee that you will benefit from being in this study.

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 to participate in this study.

Will I have to pay for anything?

You will not have to pay for any study related activities involving the Neuralert device. You and/or your health insurance will be billed for the costs of medical care associated with your hospitalization as these expenses would have happened even if you were not in the study. Medical care costs associated with your hospitalization include any additional clinical examinations and testing such as a head CT with possible CT angiogram and CT perfusion, in order to identify a potential stroke and provide treatment quickly. There is no additional cost for participating in this study.

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

This study is expected to end after all participants have completed their monitoring sessions, and all information has been collected. Your participation in the study should last about 5 days after your surgery, or earlier if you are discharged from the hospital in less than 5 days. 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 anytime. Withdrawal will not interfere with your future care. You may do this by contacting the Principal Investigator noted on page one of this form or telling your post-surgical care team.

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. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

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. At most, the website will include a summary of the results. You can search this website at any time.

What may happen to my information collected on this study?

Your information will be de-identified prior to storage for future use. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. 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 information collected on this study. If you change your mind, we will not be able to destroy or withdraw your information that were shared because all identifiers would have already been removed.

Your privacy and the protection of your health information are important to us. We will take every measure to protect your privacy and confidentiality. Study documentation will be kept and securely archived. Your identity will be kept confidential when the results of this study are published.

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.

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).

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

Participation in this study may lead to additional clinical examinations and testing, in order to identify a potential stroke and provide treatment quickly. All clinical assessments and tests will be maintained in your electronic health record and would be available to you.

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

- Date of birth
- Personal medical history
- Results from any physical examinations, tests or procedures

There are no plans to tell you about any of the specific research that will be done. Possible future research may include identifying treatments in acute stroke.

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 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.

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
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office which monitors research studies)
- Authorized members of the Penn Medicine workforce who may need access to your information in the performance of their duties, for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.

Who, outside of Penn Medicine, might receive my information?

As part of the study, the Principal Investigator, study team may disclose your personal health information, including results of the research study tests and procedures to the following:

- Government agencies and/or their representatives: the FDA is the governing agency that provides regulatory supervision for medical devices in the United States. The National Institutes of Health (NIH) provides funding for some clinical research at the University of Pennsylvania and may receive summary of the results for this clinical trial. Finally, the U. S. Office of Human Research Protections (OHRP) is a division of the federal Department of Health and Human Service and may review the trial data as well.
- The Neuralert Company and cloud system that has the stroke based algorithm

Once your personal health information is disclosed to others outside Penn 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 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. This information may be maintained in a research repository (database). However, Penn Medicine may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless:

- You have given written permission for the Principal Investigator to do so
- The University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects
- Use 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 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 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.

Disclosure of Researcher and University of Pennsylvania Interests

Dr. Steven Messé, who is one of the investigators for this trial, invented the algorithm that is being evaluated through this research. This research study is designed to test a product made by Neuralert Technologies. Dr. Steven Messé, who is one of the investigators for this trial, has an investment in Neuralert Technologies, as does the University of Pennsylvania. The amount of money these investments are worth might be affected by the results of this study. Therefore, Dr. Steven Messé and the University of Pennsylvania could benefit financially from the results of this research study. If you would like more information, please ask the researchers or the study coordinator.

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.

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

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

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

_____	_____	
Authorized subject representative **[print]**	Authorized subject representative Signature	Date

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

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