UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	A Randomized Pilot Study of the Efficacy of the OsciPulse System for the Reduction of Serum D-dimer.
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Sponsor	Trustees of the University of Pennsylvania

Research Study Summary for Potential Subjects

You are being invited to participate in a research study because you had an ischemic stroke. Your participation is voluntary, and you should only participate if you completely understand what the study requires and all of the risks of participation. 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 compare the effects of the OsciPulse system and the standard compression device to reduce the risk of blood clots forming in the veins in your legs. Having had a stroke puts you at risk of developing these blood clots, which can be a major complication that can even lead to death. The OsciPulse system is a non- invasive medical device that has been cleared by the United States Food and Drug Administration (FDA), for the reduction of blood clotting in the legs and to improve the efficacy of mechanical devices when treating this condition. This research is funded by the University of Pennsylvania, “Dream Team” Grant .

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

Screening (Day 1-Baseline): Your medical records will be reviewed to confirm that you are eligible to participate in this study. You will be asked questions about your medical history. If you are of childbearing potential, we will review standard of care pregnancy testing to ensure that you are not pregnant. If you are eligible, a blood draw will be taken to determine the d-dimer level, which measures how much clotting is occurring in your body.

Intervention Phase (Hospital Stay): You will be randomly assigned to either receive treatment with the OsciPulse device or treatment with a standard intermittent pneumatic compression (ICP) device used to help prevent blood clotting. Random assignment is similar to flipping a coin; there is an equal chance that you will be in the standard treatment group as there is a chance that you will be in the OsciPulse device group. **ONLY IF** routine labs are being drawn for your clinical care, a daily d-dimer blood test will also be included during this phase. No additional venous blood draws will occur.

End of Study (Discharge or Day 7): If you were assigned the OsciPulse device, this will be removed. One final d-dimer blood test will be drawn, and you will be asked to complete a questionnaire. If you remain in the hospital beyond Day 7, you will switch to a standard compression device. No additional follow-up will take place.

Your participation in this research study will last for the duration of your hospital stay or 7 days, whichever comes first.

It is unknown whether participation in this study may offer any benefit. The knowledge gained by participating in this study may help advance the development of a better device for preventing blood clots in the future. The most common risks of participation in this study include but are not limited to:

- Loss of privacy
- No decrease in risk of forming blood clots

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 had an ischemic stroke.

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. You will receive a copy of this consent form should you sign it and choose to participate.

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?

In this study, we will test a novel leg compression device, the OsciPulse System, to determine if it can effectively reduce d-dimer levels in stroke patients compared to usual care with a standard intermittent pneumatic compression (IPC) device. Serum D-dimer is a biomarker of blood clots forming and breaking down. These d-dimer levels can vary significantly in stroke patients. OsciPulse system was designed specifically to mimic the way your leg muscles naturally move blood out of the legs, which may reduce the risk of clots forming.

How long will I be in the study?

Your participation in this research study will be expected to last for the duration of your hospital stay or for 7 days.

What am I being asked to do?

If you choose to participate in this research study, you will be required to sign this informed consent form before any study related information is collected. You will be asked to complete the following:

Up to 8.1mL of blood will be collected throughout the study (approximately 2 teaspoons) The table below outlines which procedure or tests that are performed at each visit.

Visit	Procedures and Test Performed
Screening (Day 1-Baseline)	• Informed consent • Demographics/ Medical Record Review • Vitals • Blood Draw for D-dimer
Intervention (Hospital Stay)	• Application of OsciPulse device (Group A) or Application of IPC device (Group B) • Daily d-dimer level, only if you are already having a blood draw for usual clinical care • Adverse event Monitoring
End of Study (Day 7 or Hospital Discharge)	• All patients use routine compression devices if still hospitalized • Blood Draw for D-dimer level • Adverse event Monitoring

What are the possible risks or discomforts?

The novel compression device may not be as effective at reducing the risk of lower extremity blood clots as the standard compression device. Additionally, there are minimal risks that include mild discomfort and interference with sleep and movement.

Rare risks include skin ulcers, nerve palsy, falls and circulatory compromise. People with higher risk of these events will be excluded from the study.

Demographics/ Medical Record Review: Collection of demographics and medical records leads to a risk of loss of privacy. People who wouldn't normally have access to your medical record will have access to reviewing and collecting information from it. Study data will be recorded on paper and in password protected computer databases. As with any use of paper and electronic data storage, there is a risk of breach of data security.

Blood Draw: Collection of blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. This is no different than the risk associated with a routine blood draw.

There may be unknown or unforeseen risks associated with your study participation.

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?

There is no known benefit for participating in this study. An indirect benefit will be that the knowledge gained by participating in this study may help advance the development of a better device for patients at risk of lower extremity blood clots in the future.

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

You do not have to be in this study. It is completely voluntary. Your study doctor can inform you about how we usually work to prevent blood clots in the legs in stroke patients. As part of that discussion, your study doctor may discuss treatment with the study device even if you do not participate in this study. If you choose not to be in this study, you and your doctor should discuss your treatment options available at your hospital.

Participation in this research study is voluntary. You have the right to choose not to take part in this study. Your decision will not affect your routine treatment, or your relationship with those treating you or your relationship with your hospital. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

Will I be paid for being in this study?

You will not receive payment for participation in this study.

Will I have to pay for anything?

Participation in this study visit will not require any additional cost. 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.

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

This study will not pay for medical care for research-related injury.

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. 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.

If you decide to leave the research, contact the investigator so that the investigator can stop any upcoming data analysis. Any analysis performed prior to the point of withdrawal may not be removed.

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 study doctor and hospital will keep your private information confidential. The study sponsor will keep your information confidential and will not release your information without your permission except as required by law. Participating in this study may involve risk of loss of privacy and the potential for a breach in confidentiality. Study data will be recorded on paper and in computer databases. As with any use of paper and electronic data storage, there is a risk of breach of data security.

If you decide to participate in this study, you will be assigned an identification number that will be used instead of your name and other personal identifying information for the entire study to keep your identity confidential.

Your identity will not be revealed at any time or in any report when the results of the study is analyzed. The study team, authorized personnel form the hospital, the study sponsor, independent data review committees, Institutional Review Boards, and regulatory agencies such as the Food and Drug Administrative (FDA) and other country regulatory agencies, may have access to identifiable information, study data and your medical records to monitor the conduct of the study.

Publications and/or presentations that result from or relate to this study will not identify you by name. The study records and any recordings retained by sponsor will not contain identifiable information about you. Those records or recordings that do not contain identifiable information about you may be used by sponsor for any lawful purpose and will be retained by the study sponsor as needed for the life of the manufacture of the products in this study and future generations of these products.

Will information about this study be available to the public?

A 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 web site will include a summary of the results. You can search this web site at any time.

What may happen to my information and samples collected on this study?

If you decide to participate in this study, you will be assigned an identification number that will be used instead of your name and other personal identifying information for the entire study to keep your identity confidential. In other words, the information collected and stored will be coded.

Your name and personal health information will be kept on a password protected database, and will be linked only with a study identification number for this research.

Collection of Identifiable Specimens

Your specimens will not be used for commercial profit and will not include whole genome sequencing.

Future Use of Data

Your information will be de-identified. 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.

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.

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. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

What information about me may be collected, used or shared with others?
All assessments done for the study will be done in accordance with routine care at the hospital, at minimum the following data will be collected.

- Your demographics
- Your collected vital signs
- Your personal and family medical history
- The results from any physical examinations, tests or procedures
- Results of the National Institute of Health Stroke Scale or NIHSS (a way of assessing the severity of your stroke)
- Other medical events or symptoms that occur while participating in the study
- The location that you are discharged to and the date of discharge
- Other relevant medical information

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
- 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

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

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

- The Principal Investigator or designee
- OsciFlex LLC

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)
- The Institution's Privacy and Security Officers or other internal oversight staff
- Safety Monitoring Boards
- The Institutional Review Board
- The Department of Health and Human Services (HHS)
- The Food and Drug Administration (FDA)
- Center for Device and Radiologic Health (CDRH)
- The Office of Human Research Protections (OHRP).

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 Penn Medicine 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.

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 Subject 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 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.

Financial Interest Disclosure

The University of Pennsylvania has significant financial interest in the OsciPulse technology being evaluated as part of this research protocol. If the study product proves to be effective, the University of Pennsylvania will likely receive significant financial benefit.

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.

IRB Approval From: 05/28/2025 To: 05/27/2026