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

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| **Protocol Title:** | **Cerebral Hemodynamics or Intra-arterial Vasodilator Therapy for Vasospasm** |
| **Principal Investigators:** | Christopher Favilla, MD<br>3400 Spruce St, 3 West Gates<br>Philadelphia, PA 19104<br>215-615-3727<br>Christopher.favilla@pennmedicine.upenn.edu |
| **Emergency Contact:** | Neurology On-Call<br>215-662-4000 |
| **Sponsor** | N/A (supported by stroke team philanthropic funds) |

## Research Study Summary for Potential Subjects

You (or your family member) are 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 is being conducted to study how standard clinical treatment for vasospasm impacts blood flow in your brain. You are eligible for this study because you (or your family member) are experiencing vasospasm after a subarachnoid hemorrhage. Your treatment doctors will be treating the vasospasm by administering a medication intro the arteries in the brain. If you choose to participate in this study, the study team will use an ultrasound to measure blood flow in the brain during this treatment. The study will not affect the treatment or timing of treatment. All monitoring sessions will be closely supervised by study personnel, and either you or a study team member can stop the protocol at any time.

You are not expected to experience direct benefit from this study, although by participating you are contributing to the advancement of knowledge, which has the potential to benefit society and could impact future care delivered to patients suffering from vasospasm. There is no significant risk associated with study participation. More details are provided on subsequent sections of this document.

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) have been invited to participate in this research study because you have experienced cerebral vasospasm after subarachnoid hemorrhage, and your treating doctors plan to administer a medication into the arteries in the brain (to treat the vasospasm). The research study is being conducted to non-invasively measure blood flow in the brain during that treatment.

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 determine the effect of vasospasm treatment on brain blood flow. The treatment is designed to increase blood flow, but blood flow is not measured during routine clinical care. Instead, success is determined by measuring the size of the blood vessel. In this study, blood flow in the brain is measured non-invasively to provide important information about your treatment.

## 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 the duration of the hospitalization. We will enroll 20 patients with vasospasm after subarachnoid hemorrhage. We expect to complete the study within 2 years.

## What am I being asked to do?

If you agree to join the study, you will be asked to undergo a single research visit which will take place during your vasospasm treatment. The study visit will consist of an estimated 30-minutes of monitoring, described below in more detail. The visit will take place in the interventional neuroradiology suite at the Hospital of the University of Pennsylvania.

<u>The monitoring session is described here in detail</u>:

You will be placed on the angiography table per routine clinical care. After the diagnostic angiogram is performed, ultrasound probes will be placed on both your right and left temple. The ultrasound probes will be held in place with a padded plastic headframe. The ultrasound monitor blood flow in major arteries in your brain. Monitoring will continue while your treating doctors deliver your planned medication to the arteries in your brain. After your treatment is complete, the ultrasound probes will be removed from your head before you leave the interventional neuroradiology suite (operating room).

## 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 above, 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.

*Risks of Ultrasound Monitoring:* There is no known risk of the use of the ultrasound (transcranial Doppler, TCD) equipment used in this study. This is a commonly used clinical tool. In fact, patients with subarachnoid hemorrhage, like yourself, undergo daily TCD studies per routine clinical care. A member of the study team will be present at all times and will assist in the placement of the TCD probes and the collection of the data. Over time, the pressure of the TCD probes can cause mild discomfort. If you feel uncomfortable at any time, study personnel will reposition the probes to maximize comfort. If you choose to stop, the probes will be removed.

## 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 participating in this study

## Will I have to pay for anything?

You will not have to pay to participate in this research. You are still responsible for any deductibles or applicable co-pays associated with your routine clinical care. However, you will not be billed for any monitoring sessions or testing performed as a part of this research study.

## Will I receive the results of research testing?

Tests done in this research study are only for research. Research results from this study will not be returned to you because they would not be relevant to your immediate health care.

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

The risk of injury from this study is very low. 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. 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 securely archived. 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.

## 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.

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

- Name, medical record number, and date of birth
- Personal medical history

## 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 study investigators 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 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 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.

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 |

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

| _____ | _____ | _____ |
|---|---|---|
| Name of Authorized Subject Representative (Please Print) | Signature of Authorized Subject Representative | Date |

_____
Provide a brief description of this person's authority (i.e. relationship)

**(if applicable)**
Telephone consent may be performed if an authorized surrogate is required to complete the consent process, and if that surrogate is not available for face-to-face consent.

| _____ | _____ | _____ |
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| Name of Person Witnessing Telephone Consent (Please Print) | Signature of Person Witnessing Telephone Consent | Date |