Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Middle Meningeal Artery Embolization for Chronic Subdural Hematoma

Principal Investigator: Joshua Osbun

Research Team Contact: Christina Moore, 314-273-0368

If you are the legally authorized representative of a person who is being invited to participate in this study, the word "you" in this document refers to the person you represent. As the legally authorized representative, you will be asked to read and sign this document to give permission for the person you represent to participate in this research study.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have been diagnosed with a chronic subdural hematoma, a blood clot on the brain. These blood clots form when there is bleeding around the brain, often from a blood vessel called the middle meningeal artery.

The purpose of this research study is to see if middle meningeal artery embolization is effective in preventing reoccurrence of the blood clot. Currently the treatment options for chronic subdural hematoma are close medical follow up to see if the clot worsens or surgery to drain the blood clot. Often patients with this condition will have the blood clot reoccur multiple times, even with treatment. This reoccurrence can cause severe symptoms and complications, especially if multiple surgeries are required for treatment. Embolization is a minimally invasive option to try to prevent this reoccurrence by injecting small particles into the blood vessel and therefore block it off and prevent more bleeding. Polyvinyl alcohol particles are approved by the U.S. Food and Drug Administration for neurovascular (brain blood vessel) embolization.

WHAT WILL HAPPEN DURING THIS STUDY?

Your physician will discuss the standard treatment options with you. This may involve monitoring you closely to make sure the blood clot and symptoms resolve or undergoing surgery to drain the blood clot.

If you agree to participate in this study, in addition to receiving the standard treatment for your condition, you will have a procedure to treat your subdural hematoma. This is called middle meningeal artery embolization with polyvinyl alcohol particles and is intended to help resolve the bleeding and prevent it from reoccurring. This procedure will likely take place 24-48 hours after signing the consent form, based on availability to schedule the embolization procedure in the interventional neuroradiology department.

Embolization is a minimally-invasive procedure used to treat disorders of the blood vessels. It is performed using fluoroscopy, which uses X-rays to make detailed pictures of the blood vessels inside your brain. A long thin plastic tube called a catheter is inserted into an artery, usually in the leg (but it can also be in the arm). A small incision in the skin might be required to insert the catheter. Guided by X-rays, the catheter is pushed all the way to the blood vessels in your neck that supply blood to your brain. This is a painless process. Once there, a dye is injected through the tube and images are captured using X-rays to show the location, size, and shape of all the blood vessels in your brain. Once the catheter is in the correct artery, the doctor will inject polyvinyl alcohol particles to block off the artery that is supplying blood to the subdural hematoma in your brain. Your doctor may decide to give you a sedative before the procedure to help you lie still on the table, or you may be put to sleep (general anesthesia). You will have your vital signs measured and be closely monitored during this procedure. The entire procedure will take approximately one to three hours to complete.

Surgical Evacuation:
If your physician believes surgical drainage of the blood clot is necessary, you will undergo a standard surgical procedure for drainage of the blood clot. This surgery is separate from the study and your surgeon's recommendation for this procedure is not based on your participation in the study. The procedure involves the use of anesthesia in an operating room. The neurosurgeon will make small holes in your skull (called burr holes) or remove a small portion of your skull (called a craniotomy) to be able to remove the clot from the surface of your brain. The surgeon may place a drain under the skull to continue to drain fluid over the next day. After recovery from this procedure but before leaving the hospital, you will have the middle meningeal artery embolization procedure in the angiography suite to try to prevent the blood clot from re-occurring.

If prior to the embolization procedure your condition worsens or becomes unstable, you will be withdrawn from the study and may need to undergo emergent surgical treatment. No additional data would be collected from your medical record should you be withdrawn.

Before to the procedure, we will collect some demographic information from your medical record, such as your birth date, gender, and race. We will record your relevant medical history and other medical conditions, as well as any other previous neurologic illnesses. We will record some information from the current admission, such as any blood-thinning medication you take, the date of admission, presenting symptoms, neuro exam results, and head CTs to determine the size and location of the subdural hematoma.

You will also have a short neurologic exam consisting of an NIH stroke scale and Modified Rankin Scale assessment. The NIH Stroke Scale checks how much your movement and neurologic function is affected by the brain blood clot. The Modified Rankin Scale measures how much assistance you need with daily activities and walking. We will use the computed tomography (CT) scan of your head from

admission to the hospital to determine the size of your subdural hematoma (blood clot) and which side of your brain it is on. A CT scan is a non-invasive test that uses a machine to take a series of x-rays to produce a picture of your brain.

If you had surgery for your bleed, we will record the date of surgery and indication, as well as if there were any complications.

After the embolization procedure, we will gather information such as the date and time of your procedure, any procedural complications, neurologic exam results, head CT results, and angiography imaging. You will again have a neurologic exam to see if there were any changes since the procedure.

30 and 90 days after your procedure you will see your physician to have a CT scan and neurologic exam to track your progress and see if the hematoma has grown or is starting to shrink. This is the normal follow up schedule of scans for your condition. If your hematoma has stayed the same size or has grown, or you are still having symptoms, your physician may discuss further treatment options with you that do not involve this research study, including surgical drainage.

	Pre-Procedure			30 Days Post Procedure	90 Days Post Procedure
Location:	Inpatient			Clinic	Clinic
Assessment:					
Head CT	x			x	x
NIH Stroke Scale	x			x	x
Modified Rankin Score	x			x	x
Adverse Events				x	x

Will you save my research information to use in future research studies?

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding chronic subdural hematomas, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We might remove identifiers from your private information and your data and then use the information and your data for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information or data.
We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the

research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately **200** people will take part in this study conducted by investigators at Washington University and undergo middle meningeal artery embolization.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 90 days.

The study involves the embolization procedure and four follow up visits, some of which may take place while you're in the hospital and some of which require returning to the clinic for follow up. The visits involve a head CT and neurologic exam to track your recovery and see if the blood clot has grown. The study specific assessments may add 5 to 10 minutes to your regular follow up visits. These visits will occur 30 days, and 90 days after your procedure. Your participation in the study and all data collection will end after 90 days.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Risks of middle meningeal artery embolization:

Likely / Common

Life Threatening

- None

Serious

- Catheter insertion site hematoma

Mild

- Temporary Blurred Vision
- Skin Rash from Contrast Dye
- Bruising at the catheter insertion site
- Mild pain at the catheter insertion site

Less Likely / Less Common

Life Threatening

- Stroke
- Carotid Artery Dissection (separation of the layers of the wall of the carotid artery, which can lead to stroke)

Serious

- Blindness
- Cranial Nerve Palsy (Facial Weakness, Hearing Loss, Swallowing Difficulty)
- Anaphylactic Reaction (a severe allergic reaction to the contrast dye that can cause low blood pressure and swelling of the windpipe and airways)

Mild

- Temporary neurologic deficit (weakness or numbness)

Rare

Life Threatening

- Brain Hemorrhage (bleeding in the brain, which can cause a stroke)

Serious

- Radial Artery Occlusion (clot in the blood vessel of the wrist, which can result in severe lack of blood flow to the hand and loss of the hand)
- Arterial perforation (hole in the blood vessel at the catheter insertion site or in the brain that can cause bleeding)
- Reaccumulation of subdural hematoma

Mild

- Infection

Risks of Sedation:

Your physician may use conscious sedation or general anesthesia for the embolization procedure. All

types of anesthesia involve some risk, though complications are rare.

Conscious sedation is a combination of medications used to help you relax and to block pain during a medical procedure. This type of sedation lets you stay mostly awake and recover quickly. You will receive this medication through an intravenous line. You may receive extra oxygen through a mask or IV fluids through the intravenous catheter into a vein. After the sedation, you may feel drowsy and not remember much about your procedure. You will be monitored closely and have your vital signs measured throughout the procedure and in recovery. Some side effects of sedation include drowsiness, low blood pressure, slow breathing, headaches, and nausea. The IV site may cause pain, bruising, swelling, or tenderness.

If you receive general anesthesia, the anesthesiologist or anesthetist will see you and take a medical history before the procedure to make sure anesthesia is appropriate. They will monitor you closely during the procedure and in recovery, including continuously monitoring your vital signs. The anesthesia provider will give you medications through an intravenous line to make you temporarily go to sleep during the procedure. They will place a breathing tube to help you breathe properly during the procedure until the medication wears off. The most common side effects of general anesthesia include sore throat from the breathing tube, nausea, vomiting, and dizziness. You may experience temporary high or low blood pressure. You may in rare cases have an allergic reaction to the medication. Other rare complications include respiratory failure, seizure, stroke, or heart attack. The IV site may cause pain, bruising, swelling, or tenderness.

Questionnaires
If you feel upset about the questions please talk about it to your study doctor or study coordinator. You are free to skip questions you would prefer not to answer.

Radiation Exposure in Women Capable of Becoming Pregnant
You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before exposing you to research-related radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

Computed Tomography (CT) Scan
Rare: Malfunction of worn or implanted electronic medical devices.

If you have electronic medical devices implanted such as a pacemaker or a drug pump, please make sure you tell your study doctors and research staff. The CT scan may cause a malfunction of electronic medical devices.

Radiation Risk
This study may expose you to radiation from cerebral angiography and standard of care computed tomography (CT) scans if you undergo middle meningeal artery embolization. The amount of radiation from this, when averaged over your entire body, is 25% of the amount a person who works with radiation is allowed to have in one year. The risk from the radiation exposure in this study is too small to be measured. It is not a big risk when compared with other risks you take every day. If you want to know more about radiation exposure, please see the "Radiation Fact Sheet" at http://hrpo.wustl.edu or

ask the study staff for a copy.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because it will help us to learn more about the best ways to treat patients with this condition.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could undergo surgical treatment by burr hole drainage or craniotomy. Your condition may be medically managed, where you are closely monitored without any intervention. If your condition worsens or becomes unstable, you will not be eligible for the study or will be withdrawn and may need emergent treatment.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.

If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact Joshua Osbun, MD at **314-747-6141** and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, the information you give us will be given a code number (also called an 'anonymous ID'). A master list linking the code number and your identity will be kept separate from the research data. Only the PI and people helping him/her will be able to see the list. This secure list is maintained on a password protected computer in a locked office. Clinical information like your surgery outcomes and other medical conditions will be linked to this anonymous ID in a secure online database. Only research team members will have access to this database. We will protect your information, but there is a chance somebody might see it.

A description of this clinical trial will be available on http://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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.

- You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify. If you choose not to participate, you will receive standard treatment for your condition, including medical management or surgical treatment.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Leaving the study early may cause you to experience the following harms or discomforts: Higher risk of complications from your treatment due to insufficient follow up.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue, because your condition has become worse, or because you are or became pregnant.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Christina Moore, 314-273-0368. If you experience a research-related injury, please contact: Joshua Osbun, 314-747-6141.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 07/15/20.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Legally Authorized Representative's Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: 07/15/20.

_____
(Participant's name – printed)

_____ _____
(Signature of Legally Authorized Representative) (Date)

_____ _____
(Name of Legally Authorized Representative - printed) (Relationship to Participant – printed)

Who should sign as the Legally Authorized Representative (LAR)?
If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.

If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.

(1) Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
(2) Adult child;
(3) Parent;
(4) Brother or sister;
(5) Relative by blood or marriage.

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)