NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Anticoagulation in Intracerebral Hemorrhage (ICH) Survivors for Stroke Prevention and Recovery (ASPIRE)

ASPIRE Sponsor/Primary Principal Investigator
Kevin N. Sheth, MD – Yale School of Medicine, New Haven

Performance Site Principal Investigator: Daniel Woo, MD

Performance Site: University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC offices and clinics, UC Health West Chester Hospital

Participant Name: _____

Telephone Number: _____

If applicable,

Legally Authorized Representative Name: _____

Telephone Number: _____

KEY INFORMATION

Purpose of the Study:	Compare the effects of apixaban (also known as Eliquis®) with aspirin in patients with atrial fibrillation and a recent brain hemorrhage to see which is better in preventing strokes and death.
Length of the Study:	You will be in the research study for up to 3 years (minimum of 1 year). After your first visit, routine follow-up visits will occur every 3 months for a maximum of 3 years.
Risks:	The main risk of this study is bleeding. Both apixaban and aspirin can cause bleeding which can be serious and rarely may lead to permanent disability or even death. See section titled “What are the Risks and Discomforts of the Research Study?” for additional risks related to the study.

Benefits of the Study:	The researcher and sponsor of this study do not promise that you will receive any benefits from this study.
Alternative procedures:	The alternative to participating in this research trial would be to receive standard of care medical treatment based on your physician's discretion. Your doctor may choose to prescribe a blood thinner such as apixaban or a blood thinner such as aspirin, or no blood thinner at all.

INTRODUCTION

The study doctor wants to know if you would like to be part of a research study. This informed consent document contains important information about your participation in a research study for which you are eligible.

If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should also feel free to discuss your participation with anyone you choose in order to better understand this study and your options.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

If you are acting as a representative to give consent for another person to participate in this study, "you" throughout this consent document refers to that individual. The obligation of a representative is to try to determine what the individual would do if competent, or if the subject's wishes cannot be determined, what the representative thinks is in the person's best interest. If possible, an attempt should be made to obtain permission from the individual. Some persons may resist participating in a research protocol that has been approved by their representatives. Under no circumstances may individuals be forced to participate.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are at least 18 years old and you have recently been diagnosed with a brain hemorrhage. You have also been diagnosed with an irregular heart rate which is a condition known as atrial fibrillation.

WHY IS THIS RESEARCH BEING DONE?

Survivors of intracerebral hemorrhage (ICH) who have atrial fibrillation (AF) are at high risk for subsequent ischemic stroke.

An “ischemic” stroke is an injury to the brain caused by a blocked blood vessel supplying the brain. Atrial fibrillation is a common cause of ischemic stroke. In people with atrial fibrillation, blood clots can form in the heart. These clots can break free, travel to the brain, block a blood vessel, and cause a stroke.

Blood thinners are the best way to decrease the risk of ischemic stroke in patients with atrial fibrillation. Apixaban (also known as Eliquis®) and aspirin are two types of blood thinner medications.

Most patients with atrial fibrillation are treated with a blood thinner such as apixaban because this type of medicine (called an anticoagulant) has been shown in clinical trials to decrease the risk of ischemic stroke better than aspirin. In general, aspirin is less effective at preventing ischemic stroke than apixaban or similar drugs like apixaban. But these trials did not include patients who have had a brain hemorrhage. Having had one brain hemorrhage increases the risk of another brain hemorrhage, and this risk may be increased even more with blood thinners.

Nearly all doctors agree that patients like you with atrial fibrillation who have had a brain hemorrhage should be treated with some kind of blood thinner. But doctors are currently unsure which type of blood thinner should be used. Because of this uncertainty, some patients like you receive aspirin and some patients like you receive apixaban or another drug like apixaban.

The purpose of this research study is to compare the effects (good and bad) of apixaban with the effects (good and bad) of aspirin in patients with atrial fibrillation and a recent brain hemorrhage to see which is better at preventing future strokes and death.

Apixaban is approved by the U.S. Food and Drug Administration (FDA) for stroke prevention in patients with atrial fibrillation. The FDA does not address the use of apixaban in your condition because apixaban has not been studied in patients like you.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for up to 3 years (minimum of 1 year).

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first so that stopping the study medication can be done safely. Another reason to tell your doctor

that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is funded by the National Institute of Neurological Disorders and Stroke. This study is directed by Kevin N. Sheth, MD and Hooman Kamel, MD, at Yale and Cornell University, respectively.

The local investigator for the study at University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC offices and clinics, UC Health West Chester Hospital is Daniel Woo, MD.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 700 people will take part in this study at approximately 125 sites throughout the United States. About five people will take part at our site, University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC offices and clinics, UC Health West Chester Hospital.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

You will have the following tests and procedures:

Baseline Visit: This visit may take up to 60 minutes. It can occur as soon as 14 days after your brain hemorrhage. Activities at this visit include:

- Assessing your blood pressure;
  - If your blood pressure is higher than guidelines suggest, we will discuss this information with your doctor.
- Obtaining your weight and height;
- Assessing your mental and physical health;
- Asking you questions about your medical and personal history;
- Recording the medications you take;
- Randomization to one of the two study treatment groups described below.

Randomization means that you are put into one of the two study treatment groups by chance. Half of the participants will be in group 1 and half will be in group 2.

Your study treatment will depend on which group you are assigned to:

Group 1: Aspirin 81 milligrams once per day, plus a placebo (inactive) pill twice per day that looks identical to the apixaban pills of Group 2

OR

Group 2: Apixaban 5 milligrams twice per day (or 2.5 milligrams twice per day depending on your age, weight, and kidney function), plus a placebo (inactive) pill once per day that looks identical to the aspirin pill of Group 1.

Neither you nor the researchers conducting this study will choose or know what group you will be in. However, in the event of an emergency, the researcher and your other physicians will be able to find out which treatment you are receiving.

- We will notify your physician, if you have one, about your participation in this study, so they will understand that you are taking one of two possible blood thinner medications, and so they can contact the study research team with any questions.

After being randomized, you will be given a 100-day supply of medications. You need to take the first doses of study medications within 48 hours of randomization.

Routine Follow-Up visits will occur every 3 months for a maximum of 3 years: These visits will take 15-30 minutes. If in-person visits are not possible, these contacts may be completed by telephone or other HIPAA-compliant telehealth technology. Activities at routine follow-up visits include:

- Assessing for any strokes or adverse events since your last visit;
- Assessing how well you are taking your study medications;
- Assessing your mental, emotional and physical health;
- Assessing what other medications you are taking;
- Assessing your blood pressure;
  - If your blood pressure is higher than guidelines suggest, we will discuss this information with your doctor.
- Obtaining your current weight;
- Providing you with a re-supply of the study medications;
  - If a follow-up visit is not done in-person for any reason, your new supply may be mailed to your home from the site pharmacy. The study staff will still need to collect all unused study medication, so please save all bottles and unused medication until they can be returned.

In case you are not available for a follow-up visit, the study team may contact people that you designate so that we can find out about your health since your last visit.

Unscheduled visits may occur if the study doctor feels it is necessary to re-assess your health status.

Some of the procedures in this study are standard of care procedures that you should undergo even if you were not in the study. Some of the procedures are done only for research purposes. Your regular doctors will perform or provide the standard tests and study doctors will oversee the study research procedures. The procedures done for research purposes will not be used for your clinical care, with the exception described above that your blood pressure may be discussed with your doctor if it is higher than it should be.

WHAT HAPPENS AT THE END OF THE STUDY?

At the end of your participation in the study, the study team will work with your regular doctors to advise you on what blood thinner to continue. The researchers may contact you after participation in ASPIRE has ended to ask if you are interested in future studies.

OTHER INFORMATION ABOUT STUDY PROCEDURES

Brain imaging studies performed during the hospitalization for your brain hemorrhage will be centrally stored by the researchers for future study.

Guidance on Discontinuing Study Medications

There are times when you may need to stop your study medication, either for a short time or permanently. In general, you should call the study team who can work with your regular doctors to make the best and safest plan. Do not stop taking the medications unless your doctor tells you to. Stopping suddenly can increase your risk of blood clot or stroke. If you have a medical emergency, including possibly bleeding, your treating doctors may need to know which of the study medications you are taking. Your treating doctors can call the study team and immediately find out which study medication you are taking.

If you are having a non-urgent medical procedure, the study medications may need to be stopped around the time of the procedure. Your procedure doctor and the study team will work together to make a safe plan to stop the study medications. The study medications should then be restarted after the procedure, as soon as it is safe.

If during the study you have another brain hemorrhage, or you develop a clear need for a blood thinner like apixaban, you will be taken off the study medication and given the appropriate medication. Even if you have to stop the study medication, the research team would still like to follow you in the study.

At the end of the study, or at any time if you withdraw from the study or have to stop study medications, the study team will work with your regular doctors to choose a blood thinner medication.

You are not expected to need any time to recover from participating in this study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Principal Investigator and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Principal Investigator or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Principal Investigator or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Ask questions as you think of them.
- Tell the Principal Investigator or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Principal Investigator of each study. This is to protect you from possible injury.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Both study medicines (apixaban and aspirin) have risks.

Most Common Risks

	Risk	
Complication	**Apixaban**	**Aspirin**
Major bleeding (see additional information below)	Occurs in 4 out of 100 people per year	Occurs in 3 out of 100 people per year
Abnormal liver function tests (indicates possible liver damage)	Occurs in 1-2 out of 100 people per year	Occurs in 1-2 out of 100 people per year
Asthma worsening	Not reported	Occurs in 5-10 out of 100 people with asthma
Allergic reaction (skin rash or swelling)	Less than 1 out of 100 people per year	Less than 1 out of 100 people per year

Both apixaban and aspirin can cause bleeding which can be serious and rarely may lead to permanent disability or even death. This is because both are blood thinner medicines that reduce blood clotting. Apixaban is a stronger blood thinner than aspirin and may have a higher risk of bleeding than aspirin. The risk of bleeding is increased by

chronic use of other nonsteroidal anti-inflammatory drugs (NSAID) such as ibuprofen, Advil, Motrin, or Aleve. Some supplements (such as St. John's wort), antibiotics, and foods (grapefruit) can also increase the risk of bleeding. Do not start taking any supplements or new drugs without informing the study doctors. Talk to the study doctors about eating grapefruit or drinking grapefruit juice while on the study. We will provide a list of medications that you should avoid while you are on study treatment.

If bleeding occurs, various measures will be taken to try to stop the bleeding. If the bleeding is life-threatening or uncontrolled, a drug called andexanet may be used to try to stop the bleeding. Andexanet blocks the activity of apixaban. This drug may not be available at all hospitals; however, this medication may be available in your community. Your current hospital may evaluate your condition and direct your care to another hospital if needed. Some side effects of andexanet may be serious and life-threatening. These include strokes, heart attacks, and sudden death. You or your insurance company would have to cover the cost of andexanet.

If you have active, uncontrolled bleeding, your health care provider should immediately call the study team and rapidly find out which study medication you are taking. You will be provided with a wallet card that lists the contact numbers for the study team which you should carry with you.

While taking study medication:

- You may bruise more easily.
- It may take longer than usual for any bleeding to stop.

Apixaban can cause a very serious blood clot around your spinal cord if you undergo a spinal tap or receive spinal anesthesia (epidural), especially if you have a genetic spinal defect, if you have a spinal catheter in place, if you have a history of spinal surgery or repeated spinal taps, or if you are also using other drugs that can affect blood clotting. This type of blood clot can lead to long-term or permanent paralysis. Therefore, you would need to stop your study drug if you need to have one of these procedures.

Co-administration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding.

Call your doctor or get medical help right away if you have any of these signs or symptoms when taking study medications:

- Unexpected bleeding, or bleeding that lasts a long time, such as:
  - Unusual bleeding from the gums.
  - Nosebleeds that happen often.
  - Menstrual bleeding or vaginal bleeding that is heavier than normal.
  - Bleeding that is severe or you cannot control.
  - Red, pink, or brown urine.

- Red or black stools (looks like tar).
- Cough up blood or blood clots.
- Vomit blood or your vomit looks like coffee grounds.

- Headaches or feeling dizzy or weak.
- Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing.
- Chest tightness, wheezing.
- Severe stomach pain.

Participants who have to stop study drug for invasive procedures may face an elevated risk of bleeding if the study drug is not held for long enough. Stopping the study drug may also increase the risk of a stroke or heart attack.

Also, unknown or unforeseen risks may be associated with study participation.

WHAT ARE THE REPRODUCTION RISKS?

If you are pregnant, planning on becoming pregnant, or unwilling to practice effective contraception while of childbearing age, you cannot participate in this research study. Because apixaban may affect an unborn baby, you should not become pregnant while in this research study. You should discuss birth control options with your researcher. You must notify the researcher immediately if you become pregnant.

If you become pregnant, the treatment used in this research study might involve unknown risks to the embryo or fetus, so you will be asked to stop the study drug. Also, the study doctor will wish to follow the outcome of any pregnancy and condition of any newborn and report this to the study sponsor.

If you are a man and your female partner becomes pregnant during the course of this study, then we will ask to follow the outcome of the pregnancy. In order for the investigators to collect this information, your female partner will be asked to sign an informed consent form for disclosure of this information.

You should not nurse a baby while on this research study.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may or may not be a direct benefit to you. We hope the information learned from this research study will benefit other patients with brain hemorrhage and atrial fibrillation in the future.

WHAT OTHER CHOICES FOR CARE ARE THERE?

The alternative to participating in this research trial would be to receive standard of care medical treatment based on your physician's discretion. Your doctor may choose to prescribe a blood thinner such as apixaban or a blood thinner such as aspirin, or no blood thinner at all.

WHAT IS THE CLINICAL TRIALS REGISTRY?

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. ClinicalTrials.gov is a database of publicly and privately supported clinical studies of human participants conducted around the world.

This Web site 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 ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide not to participate, you will not lose any benefits to which you would otherwise be entitled. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You will be told of any important new information that is learned during the course of this research study which might affect your health, welfare, or willingness to continue participation in this study.

Nothing in this consent form waives any legal rights you may have nor does this consent form release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Study center/sponsor employees and their family members do not have to be in this study. No one should influence or pressure you to be in this study. An employee's or his/her family member's decision to be in the study, or to leave the study early, will not affect the employee's job or job benefits.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal,

administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

At the end of the trial, overall results will be published in a scientific journal and will be available to the public. A summary of the results will also be posted on the clinicaltrials.gov website mentioned above.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

There are no extra costs for you to participate in this study. Blood tests, physical exams and all study visits performed as part of the study will not cost you anything. The study will pay for your study medications. The study will not pay for the standard medical care that you receive during the course of the study. If you receive the drug andexanet, you or your insurance company would have to cover the cost.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

No, you will not be paid to participate in this research study. However, the study will pay for transportation that is required for study visits. Study payments will be made using a reloadable debit card. The debit card will be assigned to you at the first paid study visit and used to load payments at the end of each individual paid study visit throughout your participation in this research study. You will be paid $50 for each visit you complete starting at the baseline visit. There are a total of 13 visits you will be paid for (baseline & 12 quarterly follow-up visits). You may receive a total of up to $650 for study participation. Payment will be loaded onto your debit card within two days of your visit. The study will not pay for the standard medical care that you receive during the course of the study.

If you receive payments for being a part of this research study, you may be asked to complete an Internal Revenue Service (IRS) form. The amount you receive may count as income and may affect your income taxes. Your social security number will be required to complete the IRS form.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator. Your hospital or physician's office will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance. If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs.

You do not waive any liability rights for personal injury by signing this form.

University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC offices and clinics, UC Health West Chester Hospital has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier outside of NIH StrokeNet. Your research records may be disclosed outside of University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC offices and clinics, UC Health West Chester Hospital but in this case, you will be identified by a unique code number. This information will be kept in a secure location and access limited to research study personnel. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION
Authorization to Use Your Health Information for Research Purposes

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you.

If you sign this informed consent form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form. However, if you do not sign this form, you will not be able to participate in the study.

Who Will Use and Disclose My Health Information? The study doctor and research staff (the study team) may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication without your permission.

What Health Information will be Used and Disclosed? The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms. The study team will send the study data to the study sponsor. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

Who Will Receive My Health Information? Your study information or medical records (as described above) or both may be shared with the following people or groups:

- The Office for Human Research Protections and agencies (including the FDA) in the U.S. Department of Health and Human Services.
- The funder of this research, National Institutes of Health (NIH).
- Representatives of companies/institutions working on the study on behalf of the sponsor (Yale University) may have access to, inspect and review your information during and after the study for verification of clinical and scientific research procedures and/or data.

- A Data and Safety Monitoring Board and others authorized to monitor the conduct of the study.
- Other collaborating institutions.
- The results of imaging studies may be disclosed to outside institutions, not directly involved in this research study, as part of a collaborative imaging project.
- The StrokeNet Central Institutional Review Board and any other committees responsible for overseeing the research.
- StrokeNet Central Institutional Review Board Human Research Protection Program staff.
- The StrokeNet National Data Management Center (NDMC), housed in the Data Coordination Unit (DCU) in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC).

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others? University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC offices and clinics, UC Health West Chester Hospital are required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about medications, devices or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, or companies it hires to provide research-related services.

What Happens if I Leave the Study Early? If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will My Authorization Ever Expire? This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

May I Take Back My Authorization? You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose

information is listed on the front of this form. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

May I Look At My Study Information? You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make medical or billing decisions about you (e.g., if included in your official medical record).

Who Can Answer Your Questions?
If you have questions, concerns, complaints and or suggestions about this research study or to report a research-related injury, please contact the Principal Investigator: Daniel Woo, MD 513-584-8282.

You can also call the StrokeNet CIRB at 513-558-5259, Monday-Friday 8AM--5PM EST if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research, cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

Investigator Information:

Kevin N. Sheth, MD
Principal Investigator Name

University of Cincinnati Medical Center, UC Gardner Neuroscience Institute, UC Health, LLC and UC Physicians Company, LLC offices and clinics, UC Health West Chester Hospital
Local Site Name

Daniel Woo, MD 513-584-8282
Local Principal Investigator Name Telephone Number 24 hr Emergency Contact

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.

_____
Signature of Participant Date

_____
Print Name

Or

_____
Signature of Legally Authorized Representative Date

_____ _____
Print Name Relationship to Participant

Person Obtaining Consent
I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent from, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____

Signature of Person Obtaining Consent Date

_____

Print Name

WITNESS STATEMENT:

The participant or LAR was unable to read or sign this consent document because of the following reason:

___ The participant or LAR is non-English speaking
___ The participant or LAR is illiterate
___ The participant or LAR is visually impaired
___ The participant or LAR is physically unable to sign the consent document
Please describe: _____
___ Other
Please specify: _____

_____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant or LAR named above was read the information in the consent document and that the participant or LAR has agreed to take part in the research study.

_____

Signature of Witness Date

_____

Print Name

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

ASPIRE BIOBANK

INTRODUCTION

We are inviting you to take part in the ASPIRE Biobank. Your participation is voluntary. Before you decide whether or not to participate and sign this consent form, please read this form carefully. If there is any information or words that you do not understand, please ask for more information. It is important that you fully comprehend what participation in this project entails.

WHAT IS A BIOBANK?

A Biobank is a collection of human samples donated by volunteers which is combined with information such as age, sex, race, health information and medical images (X-rays, CT scans, MRIs and others). A Biobank allows doctors and researchers to learn more about your disease efficiently since human samples, medical images and health information from many different people will be available in one place. Doctors and researchers use the Biobank like a library — when they want to study something, they can use Biobank samples and information.

WHAT IS THE PURPOSE OF THIS BIOBANK PROJECT?

The research team is trying to learn more not just about the best treatment, but also causes and outcomes of brain disease like yours. Some of this research is done using human samples (like blood) and health information. Through these studies, doctors and researchers hope to find new ways to detect, treat, prevent or cure health problems.

We are asking you to let us store some of your blood and collect demographic and health information in the ASPIRE Biobank. Your participation in this project involves you giving broad consent to utilize the samples and information collected in the Biobank for future research. This means that you allow your demographic information, health information and samples to be used for a variety of future medical research approved by an ethics committee, but which cannot be specified at the present time. If you agree to participate, your samples may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you are your legally authorized representative. These samples will be ‘de-identified’, meaning that there will be no link between the sample and your name or other identifying information.

WHAT IS INVOLVED IN PARTICIPATION IN THE BIOBANK?

We will draw approximately two teaspoons of blood for storage in the ASPIRE Biobank.

The Biobank will be located at the Neurocritical Care and Stroke Research Center at Yale University School of Medicine in New Haven, CT, under the direction of Dr. Sheth and Dr. Kamel.

Any use of the sample and information in the ASPIRE Biobank must be approved by the ASPIRE research team. Because the information and samples you provide are an invaluable contribution to science, their use in any research study will be carefully monitored.

Your blood contains DNA, which has all of your genetic information. Researchers are especially interested in studying genetic information and these studies may involve whole genome sequencing, a technique that generates a complete reading of all the genetic information contained in an individual's DNA. The process of obtaining genetic information from blood is often funded by research funds provided by the US government. In this instance, the law mandates that a de-identified version of this genetic information is deposited in repository of genetic data that can be accessed by the research community after a strict application process.

Samples obtained from you in this research may be used for producing immortalized cells, which can live and divide indefinitely in culture outside the body. The generation of immortalized cell lines will provide an unlimited supply of cells without needing to take additional samples from you. If cell lines were generated from your samples they would never be used to clone (known as "reproductive cloning") or to otherwise create an entire human being.

Findings from the research could also be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, universities, and researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information. All research that uses your blood must comply with all applicable laws and policies. You will not be able to retrieve your donated samples from the researchers for personal use.

In the future, we may occasionally ask you to provide additional information. Each time this happens, you can decide if you wish to provide this information. Biobank staff will not contact you more than twice every year (and generally much less), and such contact does not mean that anything has been learned about your health. We may also ask you to provide an additional blood sample in order to study changes in your blood over time, or because we used up the first sample you provided. If we ask you for another sample, you can always say no.

WHAT ARE THE POSSIBLE RISKS?

The risks of drawing blood include pain, bruising, or infection at the site of the needle stick. These are the same risks you face any time you have a blood test.

We will make every effort to keep your data confidential; however, there is a risk that someone could get access to these data, including genetic information obtained from your blood samples, and attempt to trace these data back to you. Since some genetic variations can help to predict future health problems for you and your relatives, this information might be of interest to health care providers, life insurance companies, and others. However, Federal and State laws provide some protections against discrimination based on genetic information. For example, the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not prevent companies that sell life insurance, disability insurance, or long-term care insurance from using genetic information as a reason to deny coverage or set premiums. This risk may grow in the future if people come up with new ways of tracing information. We believe the chance these things will happen is very small, but we cannot make guarantees.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?
Your privacy is very important to us and we will make every effort to protect it. Here are just a few of the steps we will take:

- The ASPIRE Biobank will be located in a secure building that requires multiple forms of identification to be accessed.

- In the ASPIRE Biobank, to protect your privacy, your information is identified by a unique number that does not link your name or other identifying information directly to you.

- Only a few of the Biobank staff will have access to the list of unique identification numbers and they sign an agreement to keep your identity a secret.

- Researchers who study your sample and information will not know who you are.

- We will not give information that identifies you to anyone, except if required by law.

WHAT ARE THE POSSIBLE BENEFITS?
You will not get a direct benefit from taking part in the ASPIRE Biobank. The main reason you may want to take part is to help researchers make discoveries that might help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?
There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WILL I FIND OUT THE RESULTS OF THE RESEARCH?
You should not expect to get individual results from research done using your Biobank sample. We will offer to tell you something we discover only if it is about a disease that is likely to cause early death if not treated.

HOW LONG WILL MY SAMPLE AND INFORMATION BE KEPT IN THE BIOBANK?
The Biobank is a resource meant to serve doctors and researchers working to cure diseases for years, and there are no plans for it to end. You can withdraw your consent for research on your stored sample at any time you want. If you withdraw consent, the sample will be discarded but investigators may keep using information already obtained from your sample and your personal medical information.

WHAT ARE MY OPTIONS?
You can take part in this Biobank or not. This above information is meant to help you decide. Be sure to ask us as many questions as you want. No matter what you decide, now or in the future, it will not affect your medical care or your participation in the ASPIRE trial. Storage of blood samples is not a requirement for the ASPIRE trial.

____Yes, I agree to participate in ASPIRE Biobank. ____No, I do not agree.

_____
Signature of Participant/Legally Authorized Representative Date

_____
Print Name

_____
Signature of Person Obtaining Consent Date

_____
Print Name

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

_____

Signature of Witness Date

_____

Print Name