RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: **Silent Brain Infarcts in Spontaneous Intracerebral Hemorrhage as a Prognostic Biomarker for Vascular contributions to Cognitive Impairment and Dementia (VCID)**

Sponsor(s): **National Institutes of Health (NIH)**

Name of Participant: _____

Note: If you are a parent, guardian or legal representative of a person who is not able to consent (give permission) for themselves, the terms "you" or "your" refer to the research participant.

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent (permission) form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

Previous research has suggested that patients who are diagnosed with spontaneous intracerebral hemorrhage (sICH) are at high risk for decline (a drop) in cognitive abilities, such as thinking, learning, memory, and problem solving.

The purpose of this study is to see if silent brain infarcts (SBI)s, or stroke-like symptoms detectable during brain imaging, are a possible contributor to cognitive decline for patients diagnosed with spontaneous intracerebral hemorrhage (sICH), or blood clot in the brain.

If you agree to participate in this study, your participation may last up to 12-months, and you will be asked to complete a 3-month, 6-month, and 12-month follow-up study visit.

At your hospitalization and 12-month visits, you will be asked to complete a blood draw, Magnetic Resonance Imaging (MRI), and cognitive assessment. At your 3-month and 6-month visits, ablood draw and cognitive assessment will be completed. For a detailed description of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There are risks to you for participating in this study. In this study, there is a risk of your study information or identity may be seen or used by someone other than the investigators working on this study, but we will do our best to prevent that from happening. There are also risks associated with cognitive assessment, MRI imaging, and blood draw, which include but are not limited to discomfort and possible infection. For a detailed description of risks you should know about, please see the "*What are the risks and discomforts of participating in this study?*" section of this consent form.

You may benefit from taking part in this study. MRI of the brain can uncover pathology (disease or injuries) not detectable by head Computed Tomography (CT) scan. Unexpected findings may lead to early interventions (approaches to treatment) that may benefit your health.

You have the option to not participate in this study.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you have been diagnosed with an intracerebral hemorrhage and are over the age of 18.

How many participants will take part in this study?

About 118 participants are expected to take part in this study at Rush University Medical Center.

What are the activities you will be doing if you participate in this study?

As part of this study, data will be collected from your electronic medical records. This may include demographic information (i.e., age, sex, ethnicity), information and medical history relating to your hospitalization and diagnosis such as medical examinations, complications, imaging, lab results, and cognitive assessments. You will not be asked to complete any study questionnaires.

Table 2: Participant Follow-Up Timeline

	Hospitalization	3 Month	6 Month	12 Month
Aim #1: Cognitive Testing	X	X	X	X
Aim #2: MRI of the Brain	X			X
Aim #3: suPAR sampling	X	X	X	X

At your hospitalization and 12-month follow up visit, a standard blood draw of no more than 30 ml (2 tablespoons) per visit will be performed to test for a biomarker called soluble urokinase-type plasminogen activator receptor Biomarkers are substances in your body such as proteins that can be used to indicate disease processes or responses to therapy. You will also receive MRI imaging and a cognitive assessment. During the cognitive assessment, a certified (a person who has met the necessary training and qualifications) interviewer may ask you questions about your thoughts, memory, and reasoning as well as other simple questions.

At your 3-month and 6-month follow-up study visits, a standard blood draw to test for a biomarker called soluble urokinase-type plasminogen activator receptor will be completed. A Cognitive assessment will also be conducted.

What do you need to know regarding the collection of biospecimens?
Biospecimens are materials that come from your body that may include blood, tissue, urine, bone marrow, saliva, cells, etc. This study will be collecting blood.

Your blood samples will be stored in Dr. Eunsil Hahm's laboratory located in the Cohn Research Building at 1735 W Harrison Street Chicago IL 60612 for 5 years before being destroyed using accepted laboratory standards.

Most biospecimens contain DNA. We will not use biospecimens collected as a part of this study for whole genome sequencing, which involves mapping (identifying the location of genes and the distance between them) of all of your DNA.

Will your information or biospecimens be used for research in the future?
Information or biospecimens collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information or biospecimens is shared. Since identifying information will be removed, you will not be asked for additional consent.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?
Cognitive Assessment
Cognitive testing may lead to emotional distress if you notice that you are not performing cognitively as you expected or are used to. The study physician and other clinical staff will be present to offer support and resources if you are distressed following cognitive testing.
MRI Imaging

During the MRI scan, you may hear a loud noise while the pictures are being taken, but this can be reduced with ear plugs that can be provided by the MRI technicians. The imaging chamber is also narrow, which may cause some feelings of discomfort. Technologists will be available to make sure that you are as comfortable as possible. No gadolinium contrast dye (the MRI contrast dye) will be given for this study.

Blood Draw

The study blood draws may lead to local pain, bruising, bleeding, swelling, or infection where the needle enters the skin. Blood draws will be completed by qualified/certified individuals who follow standard blood draw protocols.

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?

Generally, activities performed for research purposes are not meant to provide clinical information. We may learn things about you from this study which could be important to your health or treatment. If this happens, this information will be shared with you. If there are findings on the MRI imaging, your treating physician will share these results with you. After the study is completed and the data has been analyzed, all of the participants will be invited to learn about the results of the study and its future implications.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold (keep back) or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study.

By signing this document, you voluntarily authorize (give permission to) Dr. Rajeev Garg, his study team, and other Rush personnel involved with the conduct and review of this study (which

may include off-site personnel) to use or disclose (release) health information (the personal information we collect about you) that identifies you for the study described in this document.

During the study, Dr. Rajeev Garg and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Demographic information, information and medical history pertaining to your hospitalization and diagnosis such as medical examinations, complications, imaging, lab results, and cognitive assessments.

Dr. Rajeev Garg and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The people who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used by or disclosed to:

- Monitoring agencies such as the Food and Drug Administration (FDA) or the National Institutes of Health (NIH).

While you participate in the study you will have access to your medical record, but] Dr. Rajeev Garg, is not required to release study information to you that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Rajeev Garg at 1520 W Harrison St 7th Floor Chicago IL 60607. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety (the entire time) of this research study. It will expire when the study is completed or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Your study data will be assigned a unique study identifier. Any identifying information such as your name or birthday will be removed from your study data and associated with your study identifier.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

What are the costs to participate in this study?
All costs for the required study procedures including MRI imaging, blood draw, and cognitive assessment will be paid by the study sponsor.

Will you be paid for your participation in this study?
You will be paid a $50 Amazon gift card for each completed study follow-up visit for a total of $150 in Amazon gift cards if you complete the 3-month, 6-month, and 12-month follow-up visits. If you do not finish this study, you will be paid for the study visits you have completed. You will be paid at your follow-up visit or within 30 days of your completed follow-up visit.

You will not be paid for your hospitalization visit.

You will also receive a $25 Visa gift card to cover food and transportation costs related to your follow-up clinic visits. This will be paid to you at your follow-up visit or within 30 days of your follow-up visit.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Rajeev Garg at telephone number 312-942-4500.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call the study coordinator at 312.94**2.0593** or email her at Amanda_C_Sremac@rush.edu

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Rajeev Garg in writing at the address on the first page. Dr. Rajeev Garg may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT OR THE PARTICIPANT'S LEGAL REPRESENTATIVE:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

Name of Legal Representative

Signature of Legal Representative	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant or the participant's legally authorized representative. I further attest that all questions asked by the participant or the participant's legal representative were answered to the best of my knowledge.

_____
Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:
I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant or the participant's legally authorized representative and the person signing the form has done so voluntarily.

_____
_____
Name of Witness/Interpreter

_____ _____
Signature of Witness/Interpreter Date of Signature