

Subject ID:

Inclusion Criteria:	Yes	No
Age ≥ 18 years	<input type="checkbox"/>	<input type="checkbox"/>
Clinical signs of stroke	<input type="checkbox"/>	<input type="checkbox"/>
Hospital presentation within 48 hours from symptom onset	<input type="checkbox"/>	<input type="checkbox"/>
Brain CT obtained within 48 hours from symptom onset that demonstrates supratentorial ICH.	<input type="checkbox"/>	<input type="checkbox"/>

Exclusion Criteria:	Yes	No
Intracerebral hemorrhage etiology due to a tumor	<input type="checkbox"/>	<input type="checkbox"/>
Intracerebral hemorrhage etiology due to vascular malformation	<input type="checkbox"/>	<input type="checkbox"/>
Intracerebral hemorrhage etiology due to trauma	<input type="checkbox"/>	<input type="checkbox"/>
Infratentorial ICH	<input type="checkbox"/>	<input type="checkbox"/>
Primary intraventricular hemorrhage (IVH)	<input type="checkbox"/>	<input type="checkbox"/>
Planned immediate hematoma evacuation	<input type="checkbox"/>	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>	<input type="checkbox"/>
Active cancer	<input type="checkbox"/>	<input type="checkbox"/>
Immunosuppression	<input type="checkbox"/>	<input type="checkbox"/>
Anticipated death within 48 hours	<input type="checkbox"/>	<input type="checkbox"/>
Inability to tolerate MRI	<input type="checkbox"/>	<input type="checkbox"/>

Name of Investigator: _____

Signature of Investigator: _____ Date: _____

**UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM**

Protocol Title: **Blood and Brain Imaging Biomarkers of Inflammatory Neutrophils in Stroke: Intracerebral Hemorrhage (BABINSKI)**

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Sponsor American Heart Association

Research Study Summary for Potential Participants

You (or your family member) are invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to examine blood samples and brain images of patients with intracerebral hemorrhage, a bleeding type of stroke that you (or your family) has experienced. We will analyze your blood, and possibly brain fluid, to see how much inflammation is occurring after the brain bleed. We will perform a brain imaging study (magnetic resonance imaging [MRI]) to see the amount of blood and swelling surrounding the blood (edema), and possibly see additional mini strokes in other areas of the brain.

If you agree to join the study, you will be asked to complete the following research procedures: provide blood samples on the day of admission or the day after, and again approximately 3 days later, undergo a brain MRI on approximately hospital day 3, and participate in one follow up phone call approximately 90 days after the intracerebral hemorrhage. Brain fluid will be collected at the same time as blood sampling for participants who already have a drain placed for clinical purposes. Risks related to being inside an MRI scanner are overall

small as you will undergo a dedicated MRI questionnaire to check if it is safe for you to undergo MRI.

Your participation in this study will last approximately 90 days and will conclude with the follow-up phone conversation.

There are no direct benefits for you as a result of being in this study. It is hoped that this study will increase our understanding of inflammation worsening brain injury in patients with brain bleeding strokes. This knowledge may one day help us to develop new treatments for patients with brain bleeds or to use blood tests to predict which of the patients with intracerebral hemorrhage experience worsening brain injury after the brain bleed and when that worsening may occur.

The risks associated with this study are small. The most common risk of participation is loss of personal and health-related information. However, because the research team conducting this study will follow a strict protocol according to which personal health information will be collected and stored, the risk of data loss is small. The research staff will make every attempt to collect the research blood samples at the same time as routine blood draws that would be done regardless of your participation in the study. However, up to two blood draws (needle sticks) may be necessary in the context of this study depending on the timing of the routine clinical blood samples. As a result of providing the research blood and brain fluid samples your body will lose a small amount of blood or brain fluid (cerebrospinal fluid, CSF) in addition to what is necessary for routine clinical care. However, the additional amount of blood or brain fluid sampled for this study is so small that it will very likely not impact you. As part of routine clinical care, the team of doctors may have decided to place a so-called external ventricular drain into your (your family member's) brain ventricles to sample brain fluid and measure the pressure within the skull. Only if such a drain is in place, a small amount of brain fluid (on the day of drain placement and day 3) will be collected for this study as well. The amount of brain fluid used for this study (less than 15 ml) is a fraction of the amount of brain fluid that your body produces every day (~400 to 500 ml). The risk associated with the loss of such a small amount of brain fluid (15 ml) is therefore very small. Significant amount of CSF loss could lead to transient headache and shifts of brain portions within the skull. These complications are extremely unlikely with the amounts of brain fluid collected in this study.

Please note, that this study will not involve any surgical procedures and that brain fluid will only be collected if the external ventricular drain is necessary for your (family member's) clinical care.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Who is conducting the research study?

This study is a local study being conducted at the Hospital of the University of Pennsylvania and Penn Presbyterian Medical Center and funded by the American Heart Association. The Principal Investigator of the study is Jens Witsch, MD, in the Department of Neurology at Penn Medicine.

Why am I being asked to volunteer?

An intracerebral hemorrhage (ICH) is an injury to the brain caused by a ruptured blood vessel. ICH is one of the most severe stroke types, and stroke is among the leading causes of disability worldwide. You are being invited to participate in this research study because you have had a ruptured blood vessel that led to an ICH.

While we have therapies to help treat strokes due to blocked blood vessels, there are limited measures we can take to help patients with stroke due to ruptured blood vessels such as an ICH. It is therefore useful to find out more about how brain injury occurs in patients with ICH in order to eventually be able to prevent and treat this injury.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

This is a study in patients with ICH that tries to assess whether results of blood and brain fluid tests indicating inflammation in the blood or brain fluid can predict the extent of swelling (edema) around the brain bleed/ICH on brain MRI and whether these blood or brain fluid tests can predict additional mini strokes in the brain MRI. This study will not include any investigational drugs or devices. There will be no needle sticks or surgical procedures done for this study that would otherwise not be done in the context of regular clinical care.

How long will I (your family member) be in the study?

Your participation will last for approximately 90 days (the duration of the study will vary between 83 days to 97 days after the brain bleed depending on when we can have the telephone conversation with you or your family member that concludes study participation). A total of 40 patients with brain bleed/ICH will be enrolled in this study at Penn Medicine. There will be one blood sampling on admission, one blood sampling on day 3, and one telephone survey approximately 90 days after the brain bleed/ICH. If an external ventricular drain is in place, there will be two additional brain fluid (cerebrospinal fluid, CSF) samples on the day of the placement of the drain, and on hospital day 3.

What am I being asked to do?

After you agree to be in the research study, study personnel will collect information from your medical record, including your past medical history and results of diagnostic testing done for routine clinical purposes. If eligible based on these available data, the following tests will be performed:

- For your (or your family member's) clinical care (outside of this study), each day of your hospital stay blood will be collected through a vein of your arm and analyzed in the laboratory. On admission day and 3 days later, this study will collect a small additional amount of this blood from the vein of your arm (~1-2 tablespoon (~15-25 ml), filled into two separate small tubes) and put them aside into a research freezer and then analyze them in the research laboratory. Blood samples will preferably collected from regular clinical blood draws, but it is possible that up to two needle sticks may become necessary for the research study (one needle stick on admission, and one needle stick 3 days later).
- You (or your family member) may have an external ventricular drain in place, or your team of doctors may decide that it is clinically necessary to place such a drain. This type of drain goes through the skull into the fluid-filled space (called ventricles) within the brain, and enables your doctors to collect and analyze some of the brain fluid which helps determine if there are infections or blood in the brain fluid. If such a drain is in place, the study will use a small amount of the brain fluid called cerebrospinal fluid, and analyze the brain fluid samples just like the blood samples (stored in a freezer, and then analyzed in the research laboratory). Brain fluid sampling will occur on the day of placement of the drain (usually on the day of admission, but placement can happen later during the hospital stay) and on day 3, ideally at the same time the second set of blood samples are collected. The amount of collected brain fluid is small (total [admission and subsequent CSF collection] of less than ~ 1 tablespoon (15 ml)). If an external ventricular drain is not in place as part of regular clinical care, this study will not collect any brain fluid (CSF).
- For the purpose of this study, you will be asked to undergo an MRI (Magnetic Resonance Imaging) scan of the brain. MRI is a type of scan that uses radio waves to take detailed pictures of the body. You (your family member) are eligible regardless of whether a clinical MRI brain scan is planned by your doctor team or not. If an MRI brain scan was planned by your clinical team and you (your family member) are included in this study, it is at the discretion of the clinical team whether an additional clinical MRI is necessary or whether the research MRI scan is sufficient. The research MRI images can be reviewed through the clinical EMR. If no MRI brain scan was planned by the clinical team, you (your family member) are in principle still eligible for study inclusion. The costs for the research MRI will not be billed to you (your family member) or your (family member's) insurance regardless of whether the research MRI is the sole MRI done during this admission or whether the research MRI is also used to inform clinical care.

You will be asked to lie on an MRI table where the technologist will place a receiver on the part of your body to be studied. You will be provided a blanket for comfort and earplugs since the MRI makes noises while it is scanning. You will still be able to hear some sound to ensure you can communicate with the technologist and can follow any direction given throughout the MRI scan. The technologist will slowly slide you into the MRI magnet where radio waves will be transmitted into you.

- Screening for MRI: You must complete a screening evaluation form in advance of the MRI exam for the presence of medical implants or other foreign bodies that could pose an injury when undergoing MRI. The screening is only as effective as the provided medical history. In cases where there is insufficient information to evaluate the risks associated with an implant or foreign body, the MRI study will not be allowed to proceed.
- The MRI study will occur approximately 3 days after your (or your family member's) hospital admission. The MRI study collects detailed images of the brain that helps the researchers to measure how much bleeding occurred in the brain, and how much swelling there is surrounding the bleed. In addition, small clotting strokes (ischemic strokes) can sometimes be identified in remote areas of the brain and will also be looked at. To make the research MRI scan happen, on day 3 of the hospital stay, your nurse and the research team will transport you to the MRI scanner located on the same floor as the hospital ward or intensive care unit where you are being treated. The duration of the MRI study will be approximately 45 minutes. Most of the MRI images obtained are routine clinical sequences that will be collected in the majority of patients with ICH even outside of the research study (regular clinical care). In addition to the regular clinical MRI images, a research sequence will also be obtained that is more detailed than routine clinical sequences. Throughout the time in the MRI scanner, a trained team of nurses and doctors are nearby and available to assess and treat you if you feel unwell. When the study is done, the brain MRI images will be transferred to a password protected computer, imaging measurements will be conducted by trained research physicians, and the results will be compared to the results of blood and brain fluid testing that are being analyzed separately in research laboratories.

Other Study-Related Procedures:

- Up to two blood draws through a vein in your arm
- Clinical intracerebral hemorrhage severity scores will be calculated from data collected during routine clinical care. These include the so-called Intracerebral Hemorrhage Score and other scores frequently used to determine disease severity
- Modified Rankin Scale (mRS), measures the degree of disability or dependence in the daily activities of people who have suffered an intracerebral hemorrhage.
- Adverse event review
- Review of medication adherence
- Review of any medications you (or your family member) take(s)

Standard-Of-Care Procedures:

- Brain imaging: CT or MRI (as detailed above)
- Blood draw through a vein in your arm (routine blood draws are the preferred way to collect the blood samples)
- CSF collection through an external ventricular drain inserted into your skull (if placed out of clinical care necessity)
- Pregnancy test, if applicable

What are the possible risks or discomforts?

- Known risks of blood sampling include excessive blood loss. The amount of sampled blood is very low and will be no more than ~2-4 tablespoons (~50 ml) of blood (~15-25 ml on admission and ~15-25 ml 3 days later).
- Risks associated with the needle stick (venipuncture) itself are redness of the skin around the needle stick, skin infection, excessive bleeding, skin bruising, and pain from the needle stick.
- Known risks of cerebrospinal fluid sampling are very low. Your (or your family member's) body constantly produces new cerebrospinal fluid. Thus, the risk associated with loss of the sampled amount in this study (2 x 1 tablespoon, ~ 2 x 15 ml) is very low.
- If you (or your family member) is injured, you should inform the treating physician that you are in a research study.
- Descriptions of MRI risks:
 - *Flying objects* The greatest risk of MRI is a magnetic object flying through the air toward the magnet and hitting you. To reduce this risk, we require that all people involved with the study remove all magnetic metal from their clothing and all magnetic metal objects from their pockets. No magnetic metal objects are allowed to be brought into the magnet room at any time except by approved personnel. In addition, once you are in the magnet, the door to the room will be closed so that no one inadvertently walks into the room.
 - *Medical implants and foreign bodies.* There is a potential risk of MRI for subjects with medical implants or other metallic objects in their body. All subjects undergoing MRI scanning must complete a screening evaluation risk in advance of the study for the presence of medical implants or other foreign bodies that could pose an injury. Every effort will be made to insure that disclosed implants or foreign bodies do not pose a risk to subjects. In cases where there is insufficient information to evaluate the risks associated with an implant or foreign body, the MRI study will not be allowed to proceed.
 - *Possible side effects* related to the MRI scan include:
 - *Possible:*
Anxiety/stress, claustrophobia, discomfort, nausea/vomiting
 - *Rare, but serious:*
Injury related to the presence of metallic or surgical implants or metal pieces in the body and the MR magnet. This also includes: wearable sensors, medicinal patches, certain types of tattoos, and hair weaves containing metallic threads. It is important that you let the MRI team know about whether you have these before the MRI procedure.
 - *Incidental findings clause.* The MRI performed under this protocol is not for medical purposes, and the images are not planned to be interpreted by a clinical Radiologist. It is possible that during the course of the research study, the investigator may notice an unexpected finding(s). What happens in the even of an incidental finding is explained in the paragraph "incidental findings" on page 9 of this document.
 - *Research risk clause:* Some of the pulse sequences and/or RF coils are not FDA approved but are considered to pose no more than minimal risk.

Reproductive risks

If you (or your family member) are/is currently pregnant, it is important that you inform the investigator because you (or your family member) will not be able to participate in the study. Although there are no known risks related to MRI on pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy-related risks. Since there is no possible benefit from participating in this protocol for a pregnant woman, we will exclude women who are pregnant.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you (or your family member). This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to get any benefit from being in this research study.

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

You may choose not to participate in this study. Your decision to participate or not will not affect your regular medical care in any way.

Will I be paid for being in this study?

You will not be paid for participation in this study.

Will I have to pay for anything?

You (or your family member) will not have to pay for participation in this study. You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance. The costs of the research MRI will be covered by the study and will not be billed to you or your insurance.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. Study duration is anticipated to be approximately 3 years. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

The confidentiality of your information will be protected in the following way during the study:

To protect against potential breach of confidentiality, data will be collected in a case report form on Penn's RedCap software installation and backed up daily to ensure we do not lose data. The data will be de-identified and transferred to the RedCap password-protected database. Only the consent form will contain your (your family member's) name. The consent will be kept in a locked file-cabinet in a locked office. All other data will be de-identified and stored on a password protected server.

Will information about this study be available to the public?

Information about this study will not be available to the public.

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

Collection of Identifiable Specimens

1. Your samples will be shipped to the University of Utah where a study collaborator (Dr. Robert Campbell, PhD) will conduct part of the laboratory testing in the blood and brain fluid samples. Before your samples are shipped, they will be marked with a number (de-identification) so that only the sample and the number will be shipped. Your personal information (name, date of birth etc.) will not be shared with the collaborator at the University of Utah. In the unlikely case that the shipment and your samples get lost and then found by an unauthorized third party, it will be nearly impossible for them to determine that the samples belong to you.
2. Whole genome sequencing (WGS) will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.
3. Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Future Use of Data and/or Specimens

Your information and samples will be de-identified prior to storage for future use. The information and samples will be stored and shared for future research in this de-identified fashion. The information and samples may be shared with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected on this study.

Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a participant, have access to research related information within the EMR?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Most of the MRI sequences collected by the research MRI scan, are standard clinical sequences and will be entered in the EMR. Images obtained using pulse sequences and/or RF coils are not FDA approved and will not be entered into the EMR. The blood and CSF test results generated in this study will not be entered in the EMR..

Will I receive the results of research testing that may be relevant to my health?

Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare. Some of the data recorded for this study, (e.g. the clinical severity score ICH score) are also collected as part of your clinical care, will become part of the EMR, and will thus be available to you.

Incidental Findings

It is possible that during the course of the research study, the research staff may notice an unexpected finding(s) or information related to your health. Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety. You may need to meet with professionals who have the expertise to help you learn more about these results. You can decide whether you want this information to be provided to you. The study team/study will not cover the costs of any follow-up consultations or actions.

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

Information to be used and/or disclosed for the research project includes personal information, laboratory information, imaging information, and other information. This may include, for example, information in the medical record, results of physical examinations, medical history, lab tests, or PHI identifiers such as name, dates, or address.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right

- to evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator for the study, Dr. Jens Witsch, and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

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

- Those working under the direction of the investigator for the study, (e.g. under subcontracts).
- The funding sponsor, the American Heart Association, and organizations supporting the sponsor

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission

- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Participant HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Participant **[print]**

Signature of Participant

Date

Name of Person Obtaining
Consent **[print]**

Signature

Date

For use with Non-English Speaking participants / LARs utilizing a short-form process:

_____ Name of Witness (Please Print)	_____ Signature of Witness	_____ Date
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_____ Name of Interpreter (Please Print) (When available)	_____ Signature of Interpreter	_____ Date
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For participants unable to give authorization, the authorization is given by the following authorized participant representative:

_____ Authorized participant representative [print]	_____ Authorized participant representative Signature	_____ Date
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Provide a brief description of above person authority to serve as the participant's authorized representative.
