



**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Study Title:** StATins Use in intracerebral hemorrhage patients (SATURN)

**Sponsor/Protocol Principal Investigator:** Magdy Selim, MD, PhD; Harvard Medical School/Beth Israel Deaconess Medical Center

**Performance Site Principal Investigator:** <<Fill in the name of the PI at your site>>

**Performance Site:** <<Fill in your site name>>

Participant's Name: \_\_\_\_\_

Participant's Telephone Number: \_\_\_\_\_

If applicable,  
 Legally Authorized Representative's Name: \_\_\_\_\_

Legally Authorized Representative's Telephone Number: \_\_\_\_\_

**INTRODUCTION**

*<<If submitted consent document already contains the California Experimental Subject's Bill of Rights, make sure that text precedes the placeholders; the placeholders should follow the Bill of Rights with a page break. Add the following text to comply with CA state law or if consent document is for a single site in CA and if the study would be considered a medical experiment under CA state law:*

Before you read this consent document, you should read and sign a copy of the California Experimental Subject's Bill of Rights. Ask the study staff for a copy of this document if you have not already received one.>>

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 the research.

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

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

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 50 years old, had bleeding in the brain (brain hemorrhage), and were taking a statin drug (a drug that is used to reduce cholesterol level in the blood). Brain hemorrhage is a type of stroke that occurs when a blood vessel in part of the brain bursts open. You will not be able to participate in this study if you are a woman with a potential for becoming pregnant during the course of the study.

### **WHY IS THIS RESEARCH BEING DONE?**

This research is being done to find out if it is better to continue or discontinue statin drugs in people who had a brain hemorrhage while taking a statin drug.

Statin drugs help prevent heart disease and ischemic stroke. Ischemic strokes are caused by a clot in a blood vessel that blocks blood flow to a part of the brain.

However, statin drugs might increase the risk of having another brain hemorrhage in some people that already had a brain hemorrhage. Many physicians are not sure what to do about using statin drugs after a brain hemorrhage. They are not sure if it is better to continue or stop treatment with a statin drug after a brain hemorrhage.



Some people may have an increased likelihood of having another brain hemorrhage while taking statin drugs. This may be due to people having certain genes. Genes are made up of DNA. DNA contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child. Genes provide an instruction book for making proteins that make a person unique. This “uniqueness” includes a person’s diseases, response to drugs, or other problems.

Having certain Apolipoprotein-E genes might make some people more likely to have another brain hemorrhage while taking statin drugs. This study is also being done to see if you have one of these Apolipoprotein-E genes and to examine whether having these genes actually increases the risk of brain hemorrhage in people who take statin drugs.

### **HOW LONG WILL YOU BE IN THE RESEARCH STUDY?**

You will be in the research study for approximately 2 years.

We will contact you on the telephone (or video conference call) or by mail occasionally during these two years. In case we cannot contact you, we will ask you to give us contact information for someone else such as a family member or caregiver that we could contact.

The researcher may decide to take you off this research study at any time for failure to follow instructions, if the investigator decides that continuation could be harmful to you, or if the sponsor decides to stop the study.

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 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.

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 arising.

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

### **WHO IS CONDUCTING THE RESEARCH STUDY?**

This study is funded by National Institute of Neurological Disorders and Stroke (NINDS). This is a federal organization that conducts and supports research on brain and nervous system disorders.



This study is conducted by Magdy Selim, MD, PhD at Harvard Medical School/Beth Israel Deaconess Medical Center in Boston, Massachusetts.

Medical supervision for the study is provided by <<name of local PI>>.

### **HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?**

Approximately 1456 people with brain hemorrhage will take part in this study across more than 140 sites in the United States and Canada. A total of <<number>> people will take part at <<Fill in the name of the local performance site.>>

### **WHAT IS INVOLVED IN THE RESEARCH STUDY?**

We reviewed your medical records and test results and determined that you meet the basic criteria to be in the study. If you think you may want to be in the study, we will explain the study to you using this consent document. If you want to be in the study, you will have to sign this consent document. If you decide to be in the study, the following activities will be performed.

You have already had a brain scan (MRI or CT), which showed that you had a bleeding in your brain. We will review the results of the scan to determine if you are able to be in the study. If the scan show that you can be in the study, we will perform tests to check your consciousness and the severity and extent of your disability.

If the results of these tests show you can be in the study, you will be "randomized" into one of the following study groups. Randomization means that you are put into a group completely by chance. It is like flipping a coin.

- Group 1: You will continue taking the same statin drug and dosage that you were taking when your brain hemorrhage occurred (or restart it if it was stopped after your admission to the hospital) without any change.
- Group 2: You will stop taking your statin drug for 2 years.

Roughly half of the participants will be randomly assigned to each group. Participants in both study groups will receive the same standard medical care as anyone else with a brain hemorrhage who is not participating in this study. This care includes close monitoring and treatment of high blood pressure.

The study team will monitor you closely for any serious side effects during the rest of your hospital stay. When you are in the hospital, you may have other brain scans, and tests that we routinely carry out for patients with a brain hemorrhage. We will collect information from your hospital chart regarding these scans, test results, and medications.



On the day of discharge from the hospital, we will review your medications; repeat a neurological examination to check your consciousness and the severity and extent of your disability; and ask you a few questions about how you are functioning.

A member of the study team at Beth Israel Deaconess Medical Center (BIDMC) in Boston will contact you (or the person you identified as another contact) by telephone or mail once a month for the first 3 months, then at 6, 9, 12, 18, and 24 months. The study team at BIDMC can also use a secure video conferencing call if you prefer a video call instead of telephone. None of these calls/videos will be recorded. However, you or your caregiver must have a smartphone, tablet, or computer with internet connectivity, and an e-mail address in order to be able to use video conferencing. We will send you a link to join the video call prior to the scheduled follow-up visit.

They will ask you questions about the medications that you are taking; any hospitalizations, medical procedures, or bad side effects that you may have had since your brain hemorrhage; how your memory is working; and how you are able to perform your daily activities to determine how you are functioning.

Each of these calls will take approximately 15 to 30 minutes. When telephoning, the study staff will ask if it is a convenient time and will call back if it is not. These follow-up telephone calls are very important. Information from these calls will help study doctors to know if continuing or discontinuing statin drugs is helpful long term. If we are unable to reach you by phone, we will send you these questions by mail. We will ask you to call back or return the answers in a self-addressed, stamped, envelope that we will provide to you.

Your name and contact information will be provided to the study team at BIDMC. BIDMC is the main coordinating clinical center for this study. This information will be kept strictly confidential and be used solely for purposes related to your participation in this study.

You may have to sign a separate consent document before you have some of the tests that are routinely carried out for patients with a brain hemorrhage.

## **OTHER STUDY PROCEDURES**

### **Cholesterol level**

If your cholesterol level was not checked, we will take a blood sample (1 tablespoon or 10 ml) to check your cholesterol level. We will attempt to do this whenever blood is drawn for your routine clinical care, if possible. If not, a needle stick may be required.



### **Apolipoprotein-E gene Testing**

We will take a blood sample, approximately 2 tablespoons (or 20 milliliters). We will attempt to do this whenever blood is drawn for your routine clinical care, if possible. If not, a needle stick may be required.

We will label your blood sample with a unique “code” number to protect your privacy. We will not label the sample with your name or any other identifying personal information. We will send the sample to the Center for Human Genetic Research at the Massachusetts General Hospital (MGH) and the BROAD Institute in Boston, Massachusetts. The researchers there will collect your DNA from the blood sample. They will test your DNA to see if you have certain Apolipoprotein-E genes. We do not plan to tell you or your doctor the results of these tests.

### **Future Studies with your DNA**

Your DNA may be stored forever and used in other future testing at the Center for Human Genetic Research at the MGH and the BROAD Institute. Your sample will be used to learn more about brain hemorrhage, its treatment and complications. It may also be used to identify new genes that may influence the effects of statins in patients like you. We do not plan to tell you or your doctor the results of these tests.

We may use some of your blood cells to make a cell line in the laboratory. A cell line is able to grow forever in the laboratory. This means that we will be able to obtain more of your DNA for future genetic testing without your participation. You will not be notified at the time the cell line research begins. We will not obtain your consent for this additional research. We do not plan to tell you or your doctor the results of these tests.

The researchers at the Center for Human Genetic Research at the MGH and the BROAD Institute will not see any personal information such as your name, date of birth, or medical record number. Only employees with ID badges can enter the Center for Human Genetic Research at the MGH and the BROAD Institute.

The genetic information, derived from your DNA, will be deposited in the US NIH genomic database (dbGAP) and used for future research.

### **PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include:

- Following the instructions of the Principal Investigator and study staff.
- Answering/returning the follow-up telephone calls from the study staff. If it is necessary to miss a scheduled telephone call, please contact the Principal Investigator or research study staff to reschedule as soon as you know you will miss the call.



- Tell the Principal Investigator or research study staff about any side effects, doctor visits, or hospitalizations that you may have. Tell them if you have a new stroke or brain hemorrhage, a heart attack, or circulatory problems with your blood vessels requiring medical treatment or surgery.
- Tell the research study staff if your doctor decides to stop or re-start a statin medication or make changes to your current statin medication or dosage in the future.
- We also urge you to check your blood pressure on a regular basis at home and to record the readings. Ideally, your blood pressure goal should be 130/80 or less to decrease the risk of having another brain hemorrhage.
- Ask questions as you think of them.
- Tell the Principal Investigator or research staff if you change your mind about staying in the study.
- If you are a female, you must tell the Principal Investigator or research study staff if you have the potential for becoming pregnant during the study.

### **WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?**

You are at risk for side effects listed in this section. You should discuss these with the investigators and with your regular doctor. It is important that you consider all of the options before you decide to participate in this research study.

Participation in this research involves the following risks:

The effects of discontinuation of statin therapy may be ischemic stroke, heart attacks, or requiring procedures to treat blocked blood vessels in the brain or heart. The risk may be higher in people with a history of these occurring. These complications can cause long-term disability and even death.

The effects of continuations of statin therapy may be increased risk of recurrent brain hemorrhage.

Individuals that have a brain hemorrhage are at high risk for having additional complications

These complications may include;

- another brain hemorrhage
- ischemic stroke caused by a clot
- increased bleeding into the brain
- infections (such as pneumonia)
- brain swelling
- seizures



All of these complications can cause long-term disability and even death.

Side Effects of Statin Therapy:

You have been already taking a statin drug. Therefore, it is unlikely that you will develop new side effects from statin therapy during your participation in the study if you have been taking it for a while. Reported side effects of statin drugs are muscle pains, joint pains, muscle weakness, and elevation of muscle or liver enzymes.

Muscle weakness occurs in about 1 out of 1000 patients treated with statins. It could lead to a rapid breakdown of muscle cells and release of their breakdown products into the blood stream (rhabdomyolysis). This could lead to kidney failure if untreated.

Elevation of liver enzymes occurs in approximately 1 out of 100 patients treated with statin drugs. Elevated liver enzymes may indicate inflammation or damage to cells in the liver. It often causes no symptoms and improves with discontinuation of the drug.

Blood Sample Risks:

There are some minor risks and discomforts associated with obtaining blood drawing from a vein. These include: the possibility of pain or bruising at the site of the blood draw; occasional feelings of lightheadedness or fainting; and, rarely, infection at the site of the blood draw.

Whenever possible, blood samples for this research study will be drawn at the same time as samples for other laboratory tests ordered by your treating physician. If not, an additional needle stick may be required.

Risk of Loss of Confidentiality:

Privacy and re-identification risks:

Through all stages of sample and data collection, storage, sharing, and analysis, your privacy and confidentiality will be protected. Exception: the research team is required to report child abuse and neglect, or substantial risk of harm to self or others to state or local authorities.

While neither the public nor the restricted-access databases developed for this project will have information such as your name, address, telephone number, or social security number, it may be possible to identify you based on the information in these databases and other public information (including information you tell people or post about yourself). The risk of this happening is currently very low.

Although your genomic information is unique to you, you do share some genomic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genomic information from them could be used to





help identify you. Similarly, it may be possible that genomic information from you could be used to help identify them.

It is possible also that someone could get unauthorized access or break into the system that stores information about you. Every precaution will be taken to minimize this risk.

If your genomic information is linked back to you, someone might use this information to learn something about your health.

There also may be other privacy risks that we have not foreseen.

Protections against misuse of genetic information:

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.

Additional privacy protections:

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.

There may be unknown or unforeseen risks associated with study participation.

**ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?**

If you agree to take part in this research study, there may not be a direct benefit to you. We hope the information learned from this research study will benefit other patients with a brain hemorrhage 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, similar to that which will be received by all subjects in the trial.

**WHAT IS THE CLINICAL TRIALS REGISTRY?**

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. ClinicalTrials.gov is a registry and results 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 still receive care for your brain hemorrhage and 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 your willingness to continue participation in this study.

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

**AVAILABILITY OF INFORMATION**

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

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.

**WHAT ARE YOUR COSTS TO BE IN THIS STUDY?**

All routine (not for study) laboratory tests, imaging studies and costs related to the treatment of your brain hemorrhage will be part of your hospital bill. Participation in this study is not a substitute for health insurance. You and/or your health insurance must



pay for those services, supplies, procedures, and care that you require during this study for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance.

The study will pay for the services and care associated with this study, which are not a part of your routine medical care, for example you will not be charged for the genetic blood tests that are part of this research study.

### **WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?**

You will not be paid for taking part in this study. However, you will be mailed a kit of appreciation items after the completion of your 3-month visit. An example of the appreciation items may include a study-branded mug, T-shirt, or baseball hat, and a \$15 gift card (GrubHub, Door Dash, Amazon, or other similar services). The actual items selected will be based on price and availability at the time of purchase. << If your site decides to provide reimbursement, compensation, tokens of appreciation, or incentives to the participants, you will need to describe: what will be provided, when it will be provided, how it will be provided. You will also need to add: "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.

<<Enter the name of the performance site here>> 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 <<insert name of local performance site>>, 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.

We will handle your blood sample(s) and any data generated from your DNA in a secure manner.

The blood samples and DNA will be de-identified. Your name and social security number, phone number, address (or any other information uniquely identifying you) will not be written on or associated with the sample(s).

We may submit your health and DNA information to a data repository, such as The US National Institute of Health genomic database called dbGAP. Information from many research studies is stored in the database. The information in the repository is used for research. We do not know what types of research will be done with your information that is sent to the database. There may be further risks to your privacy and confidentiality by sharing your information with the database. However, all of your personal identifiable information will be removed from your information. This includes your name, address, and phone number. The information is only identified with a unique code. The code consists of numbers and letters [for example: [1A462BS]].

We may send samples of your DNA to other researchers. We will remove all of your personal identifiable information from the DNA samples. These researchers may use your samples for scientific research, product testing, or commercial development. There are no plans to provide you with any payments if a commercial product is developed from this research.

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.

Some information that identifies you (name, phone number, and address) will be given to the investigators at Beth Israel Deaconess Medical Center (BIDMC) in Boston. They will use this information to conduct the follow-up assessments by telephone or mail.



The investigators at BIDMC will also contact your own doctor or another doctor that takes care of you while you are in the study. They will ask the doctors about your overall health status. They will also ask if you have had any medical issues related to your participation in this study.

By signing this consent document, you are allowing the investigators at BIDMC to contact your doctors. In some cases, we may request medical information or records about you from your doctor(s) or hospital(s) in which you receive future treatment.

For this reason, we ask you to sign an authorization for release of medical record/information form (attached) to allow your doctors and medical facilities to release your records to the investigators at Beth Israel Deaconess Medical Center in Boston (if needed). Again, the investigators at Beth Israel Deaconess Medical Center are obliged to protect your privacy and confidentiality.

## USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

### Authorization to Use Your Health Information for Research Purposes

<< This section may replace the stand-alone HIPAA authorization document. This section or a standalone HIPAA authorization is required for all research being performed at a Covered Entity allowing Protected Health Information (PHI) to be shared for purposes specified in the Authorization. [Site specific language may be entered here.](#)>>

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 document, 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 document. However, if you do not sign this document, 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 completed study forms 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 (including the FDA) in the U.S. Department of Health and Human Services.
- The funder of this research, National Institute of Health.
- The representative of companies/Institutions working on the study on behalf of the Sponsor 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.
- Data and Safety Monitoring Boards 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. Your name and other identifying information will not be disclosed.
- Department of Health and Human Services (DHHS) agencies.
- 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?** <<Insert site name of local performance site/covered entity is/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 drugs, 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, its business partners, 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 document. 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 decision 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: <<Fill in the PI name and 24 hour contact number at your site>>.

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:**

Magdy Selim, MD, PhD	
Principal Investigator Name <span style="color: blue; font-style: italic;">&lt;&lt;Fill in the local site name&gt;&gt;</span>	
Local Site Name	<span style="color: blue; font-style: italic;">&lt;&lt;Fill in the local PI name&gt;&gt;</span> <span style="color: blue; font-style: italic;">&lt;&lt;Fill in the 24 hour contact phone number&gt;&gt;</span>
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 document 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.

_____	
Name of Participant (PRINT)	
_____	_____
Signature of Participant (18 or older with capacity to consent)	Date



OR

<p>_____</p> <p>Name of Legally Authorized Representative (PRINT)</p>	
<p>_____</p> <p>Signature of Legally Authorized Representative</p>	<p>_____</p> <p>Date</p>
<p>_____</p> <p>Relationship or Authority of Legally Authorized Representative to Participant</p>	

<p><b>Person Obtaining Consent</b></p> <p>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 document, 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.</p>	
<p>_____</p> <p>Name of Person Obtaining Consent (PRINT)</p>	
<p>_____</p> <p>Signature of Person Obtaining Consent</p>	<p>_____</p> <p>Date</p>



**WITNESS STATEMENT:**

The participant or LAR is unable to read or sign this consent form because of the following reason(s):

- 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 form. 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 named above was read the information in the consent document and that the participant has agreed to take part in the research study.

\_\_\_\_\_  
 Name of Impartial Witness (PRINT)  
*(may be interpreter if participant/LAR is non-English speaking)*

\_\_\_\_\_  
 Signature of Impartial Witness

\_\_\_\_\_  
 Date