Domain A – Low NIHSS Stratum		
Inclusion Criteria:	**Yes**	**No**
Suspected diagnosis of acute ischemic stroke	☐	☐
Likely causative intracranial large or medium vessel occlusion	☐	☐
Pre-stroke modified Rankin Scale 0-2	☐	☐
Presentation to enrolling hospital within 24 hours of last known well/stroke onset	☐	☐
Able to initiate arterial puncture within 2 hours from qualifying CTA/MRA or CTP/MRP imaging *For LVO mild deficit/Low NIHSS, baseline imaging would only need to be repeated if there has been significant improvement in the NIHSS prior to randomization*	☐	☐
Mild presenting neurologic deficits - NIHSS 0-5 *If 0, must have some focal neurological deficit attributable to the target occlusion*	☐	☐
Complete occlusion of the intracranial ICA or M1 MCA	☐	☐
Exclusion Criteria:	**Yes**	**No**
Proven contraindication to endovascular thrombectomy	☐	☐
Prisoner or incarcerated	☐	☐
Presumed septic embolus; suspicion of bacterial endocarditis	☐	☐
Seizure at stroke onset or between onset and enrollment	☐	☐
Known anaphylactic reaction to contrast material that precludes endovascular reperfusion therapy	☐	☐
Intracranial occlusion suspected to be chronic, based on history and/or imaging	☐	☐
Intracranial dissection, based on history and/or imaging	☐	☐
Cerebral vasculitis, based on history and/or imaging	☐	☐
Known pregnancy	☐	☐
Known pre-existing medical, neurological, or psychiatric disease that would confound the neurological or functional evaluations	☐	☐
Known serious, advanced, or terminal illness or life expectancy less than 6 months in the investigator judgment	☐	☐
Known or high suspicion for underlying intracranial atherosclerotic disease (ICAD)	☐	☐
Known platelet count less than 100,000/uL	☐	☐
CT ASPECT score less than 6 or MRI ASPECT score less than 7	☐	☐
Unfavorable vascular anatomy that limits access to the occluded artery precluding endovascular reperfusion therapy	☐	☐
Acute occlusions in multiple vascular territories *E.g., bilateral anterior circulation, or anterior/posterior circulation*	☐	☐
Tandem occlusions	☐	☐
Significant mass effect with midline shift *Greater than 5mm*	☐	☐
Evidence of intraaxial tumor *Except small meningioma*	☐	☐
Evidence of acute intracranial hemorrhage	☐	☐

Name of Enrolling Investigator: _____

Signature of Investigator: _____ Date: _____

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: STEP Platform Domain A EVT Indication Expansion
LVO Mild Deficit/Low NIH Stroke Scale Score Strata

Protocol Principal Investigator: Eva A. Mistry, MBBS, MSCI-University of Cincinnati

Performance Site Primary Principal Investigator: Brett Cucchiara, MD

Performance Site Secondary Principal Investigator: Jan-Karl Burkhardt, MD

Performance Site: The Hospital of the University of Pennsylvania

Participant Name: _____

Telephone Number: _____

If applicable,
Legally Authorized Representative Name: _____

Telephone Number: _____

KEY INFORMATION

Purpose of the Study:	Participation in this research study is voluntary. This study is being done to learn whether adding an immediate clot removal procedure, along with standard medical treatment, is better for stroke patients that have a blockage of a *large* sized blood vessel (artery) in the brain, but with mild stroke symptoms. Immediate clot removal treatment is used for some stroke patients; however, it is not standard treatment for the type of stroke you are experiencing.
Length of the Study:	It will take you about 3 months to complete this study. You will have three visits, 2 in the hospital (24 hrs. and hospital discharge) and 1 around 3 months after you leave the hospital (in-person or by video or telephone).

Risks:	The most common risk associated with a clot removal procedure is bleeding. Bleeding complications can range from minor to severe and may require additional medical intervention to manage. See section titled "What are the Risks and Discomforts of the Research Study?" for additional risks related to the study.
Benefits of the Study:	Because the purpose of the study is to determine if adding an immediate clot removal procedure is better than standard medical treatment alone, it is not known whether you will benefit from being in this study. We hope the information learned from this research study will benefit other patients with stroke in the future.
Alternative procedures:	The alternative to participating in this study is not to participate in the study. If you choose not to participate in the research study, you will receive standard medical treatment for your stroke.

INTRODUCTION

The study doctor wants to know if you would like to be part of a research study. This informed consent document contains important information about 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 participant's wishes cannot be determined, what the representative thinks is in the person's best interest. If possible, an attempt should be made to obtain permission from the individual. Some persons may resist participating in a research protocol that has been approved by their representatives. Under no circumstances may individuals be forced to participate.

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

You are being asked to take part in this research study because you are at least 18 years of age and you have been diagnosed with a stroke, which is a blockage of blood flow to part of your brain.

WHY IS THIS RESEARCH BEING DONE?

Currently, it is not known whether patients who are having a stroke due to a blockage of a *large* sized blood vessel (artery) in the brain, *but with mild stroke symptoms*, have better outcomes with or without an immediate clot removal procedure.

The purpose of this study is to determine if adding the clot removal procedure to standard medical treatment, immediately after presentation to the hospital, will be better for you than standard medical treatment alone.

Immediate clot removal treatment is used for some stroke patients; however, it is not standard treatment for the type of stroke you are experiencing, because your symptoms are mild. If you are assigned to the standard medical treatment group and your stroke symptoms worsen, your clinical care team may offer clot removal treatment at that time.

This study is part of a larger trial that includes several studies like this one being presented to you. This will be explained to you in a separate Participant Information Sheet.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately 90 days (3 months).

The researcher may decide to take you off this research study at any time for things such as loss of funding or new information that could affect the risks or benefits.

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 to discuss what follow-up care could be most helpful to you.

If you withdraw, the data collected to the point of withdrawal will remain part of the study data and may not be removed. You may be asked whether you wish to provide further data collection from your routine medical care.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is funded by the National Institutes of Health (NIH), National Institute of Neurological Disorders and Stroke (NINDS).

The sponsor of the study is the Medical University of South Carolina (MUSC).

This study is conducted by StrokeNet at the University of Cincinnati.

Medical supervision for the study is provided by Dr. Brett Cucchiara.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 1000 people will take part in this part of the study at up to 50 sites across the United States and up to 10 sites in Canada. The Hospital of the University of Pennsylvania plans to enroll approximately 25 people in this part of the study.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

We will use information from your medical records and your hospital tests from this admission to help us determine whether you are able to take part in this study.

Some of the procedures, like laboratory tests (including a pregnancy test for women of child-bearing age) and brain imaging (i.e. CT/MRI scan), would be done as part of your regular care even if you were not in the study. We will use the results of these standard of care tests and procedures for the research study.

If you choose to take part in this study, we will ask you to sign and date this consent form before we do any study procedures.

Assignment to a Study Group
You will be put into one of the study groups described below by chance. Neither you nor your study doctor can choose which group you are placed into. The group will be decided by a process called “randomization” which is like flipping a coin. You will have a 50/50 chance of being placed in either group.

- Group 1: Standard Medical Treatment plus the immediate clot removal procedure.
- Group 2: Standard Medical Treatment only.

Standard Medical Treatment may include medications that dissolve blood clots, prevent, or reduce brain swelling, thin the blood, control cholesterol, control blood pressure, and

control blood sugar. Your doctor will decide which of these medications are the best for you. You will receive Standard Medical Treatment regardless of the group you are assigned to.

Clot removal is a procedure in which a small tube/catheter is inserted into an artery, usually in your leg or arm, and moved toward the blocked brain vessel (artery). A device is then used to remove or break-up the clot in the blocked blood vessel to restore blood flow to that part of the brain. This treatment is used for some stroke patients; however, it is not standard treatment for the type of stroke you are experiencing, because your symptoms are mild.

You may have to sign a separate consent document before you have some of the procedures listed above.

Follow-up Visits

Follow-up visits will be performed on all participants participating in the STEP study.

24-hours after enrollment:
The clinical team will routinely perform a physical exam called the National Institutes of Health Stroke Scale (NIHSS) at 24 hours after stroke for all patients as standard care. The NIHSS measures specific skills, which are used to determine how severe your stroke symptoms are.

Hospital discharge:
At this visit, we will ask you a series of questions to assess how you are doing with your daily activities.

90-days after your stroke:
This visit can be in-person, by video, or by telephone. We will ask you a series of questions to assess how you are doing with your daily activities and about how you are feeling. We will also ask you questions about whether you have experienced any illnesses/injuries/surgeries since your stroke.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Principal Investigator and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Principal Investigator or research study staff to reschedule as soon as you know you will miss the appointment.

- Tell the Principal Investigator or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Ask questions as you think of them.
- Tell the Principal Investigator or research staff if you change your mind about staying in the study.

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

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this document. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Participation in this research involves the following risks:

If you are placed in the standard medical treatment plus immediate clot removal group, the clot removal procedure has some risks. Your study doctor will monitor your care closely to identify any of these potential risks and then treat you appropriately to minimize any negative effects on your health. During the clot removal procedure these risks include the following:

- You may have another stroke from the procedure. A blood clot can form on the tubes used for the procedure or break free from the blood vessel wall and block an artery in the brain. This could cause your stroke to be worse or cause another stroke.
- You may feel dizzy, faint, have chest pain or low or high blood pressure.
- When the needle goes into the artery in your arm or leg, you might feel pain, get a bruise, or see some bleeding. There is also a small chance of infection, muscle cramps, or swelling. Very rarely, problems could happen like air entering the blood vessel, a hole in the vessel that needs surgery, bleeding that may require a blood transfusion, a blocked artery, or damage to the tissue, including a nerve. You might have trouble using your arm or leg, feel extra cold, or in extremely rare cases, lose the function in the arm or leg.
- Removal of the blockage in the brain artery may also cause bleeding in the brain. This can be fatal but is unlikely.
- During the clot removal procedure, if it is considered necessary by your doctor for your safety and comfort, you may be given a sedative and /or anesthesia with

placement of a breathing tube in your throat. The risk of anesthetics and sedative agents include, but are not limited to, difficulty breathing, lowering of your blood pressure, allergic reactions (such as a rash; swelling around the mouth, throat, or eyes; a fast pulse; sweating), and rarely even life-threatening events or death.

- The clot removal procedure requires X-Ray Dye. Mild allergic reactions to x-ray dye may also occur in up to 2-4 out of 100 participants. Severe reactions to x-ray dye occur in 1 person in 1000. There is also a risk of kidney problems or kidney failure after receiving x-ray dye.
- The clot removal procedure involves exposure to radiation given off by x-rays. X-rays are used to watch the placement of the tubes/catheter in the blood vessels.
    - Exposure to radiation can increase your risk of developing cancer during your lifetime. The risk from the amount of radiation used in this procedure is considered low by radiation safety experts. The exact amount of radiation you will be exposed to depends on how long the procedure takes. Typical radiation exposure from this type of procedure is about 400 millirem. A millirem is how we measure radiation dose. This amount of radiation is about the same as 1-2 years of exposure to natural background radiation in the environment.
    - Your risk of developing cancer from radiation exposure may increase if you are also exposed to radiation from medical tests like CT scans or x-rays, or from other research studies.
- Possible physical effects of radiation exposure include hair loss, skin damage ranging from redness and irritation to severe burns or ulcers, and the development of cataracts

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

WHAT ARE THE REPRODUCTION RISKS?

There is a potential risk of injury to a developing fetus by the x-rays used for the clot removal procedure. Because of this, you cannot participate in this study if you are pregnant. If you are a woman of child-bearing age, you will have a pregnancy test to confirm you are not pregnant before enrolling into the study.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

Because the purpose of the study is to determine if adding an immediate clot removal procedure is better than standard medical treatment alone, it is not known whether you will benefit from being in this study. We hope the information learned from this research study will benefit other patients with stroke in the future.

WHAT OTHER CHOICES FOR CARE ARE THERE?

You do not have to take part in this study to be treated for your stroke.

If you choose not to participate in this research trial, you would receive standard medical care, which is similar to the treatment provided to all trial participants, and may include the clot removal procedure used in this study in some situations.

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. 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.

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

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 do 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.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

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

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

AVAILABILITY OF INFORMATION

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

Any results from research related tests or assessments will not be used in your clinical care.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

All routine laboratory tests, imaging studies and clinical care, including the clot removal procedure, for those who are assigned to that group, will be part of your hospital bill. You and/or your health insurance will be billed for those services, supplies, procedures, and care that you require during this study for routine medical care. Clot removal devices may be used off-label (for a new use not cleared for marketing by the FDA) in this study which make the devices investigational for the purposes of the study and the type of stroke you are experiencing. Your healthcare insurer may not pay for investigational devices and procedures in which investigational devices are used. You will be responsible for any co-payments and/or deductibles as required by your insurance. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. The study site and the sponsor will not pay for these costs. The study will pay for the services and care associated with this study, which are not a part of your routine medical care.

Before you agree to be in this study, you should contact your health-care payer/insurer to see if your plan will cover the costs required as part of your participation. You can ask the study doctor or study staff to find out more about costs.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will not be paid for taking part in this study.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form The Hospital of the University of Pennsylvania 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 The Hospital of the University of Pennsylvania but in this case, you will be identified by a unique code number. This information will be kept in a secure location and access limited to research study personnel. The results of this research study may be presented at scientific or medical meetings or published in scientific journals; however, your identity will not be disclosed.

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

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

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

If you sign this informed consent 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.

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

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 in the U.S. Department of Health and Human Services.
- The funder of this research, National Institutes 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 Coordinating Center at the University of Cincinnati.
- 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).
-

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 investigator for the study 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

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 Subject 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.

Future Use

Information that could identify you will be removed from the study data. After removal, the study data could be used for future research studies. The study data could also be given to another researcher for future research studies. This may be done without getting additional permission from you.

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).

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study. Please initial your selection below.

____I **want** the researcher to inform my primary care physician/specialist of my participation in this study.
____I **do not want** the researcher to inform my primary care physician/specialist of my participation in this study.
____I do not have a primary care physician/specialist.
____The researcher is my primary care physician/specialist.

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: Brett Cucchiara, MD at 215-349-5990.

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:

The Hospital of the University of Pennsylvania	
Local Site Name	
Brett Cucchiara, MD	215-349-5990
Local Principal Investigator Name	Telephone Number 24-hour Emergency Contact

CONSENT:

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)	Telephone Number
_____	_____
Signature of Participant (18 or older with capacity to Consent	Date

OR

_____	_____
Name of Legally Authorized Representative (PRINT)	Telephone Number
_____	_____
Signature of Legally Authorized Representative	Date
_____	
Relationship or Authority of Legally Authorized Representative to Participant	

PERSON OBTAINING CONSENT:

I attest that the requirements for informed consent for the medical research project described in this document 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.

_____
Name of Person Obtaining Consent (PRINT)

_____ _____
Signature of Person Obtaining Consent Date

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