BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK, LLC
KINGS COUNTY HOSPITAL CENTER

SUBJECT INFORMATION, CONSENT, AND AUTHORIZATION FORM

Title: Platelet-Oriented Inhibition in New TIA and Minor Stroke

Protocol: POINT

Sponsor: National Institute of Neurological Disorders and Stroke (NINDS)

Principal Investigator Name: Pia Chatterjee, MD

Institution Address: Kings County Hospital Center
451 Clarkson Avenue
Brooklyn, NY 11203

Telephone Number: 718-245-4790

HHC#: _____

We are asking if you want to be in a research study. This study is for people who just had a TIA or a minor stroke. A TIA seems like a stroke with sudden weakness on one side of the body or trouble speaking, but gets better faster.

What you should know about research studies:

- This consent form gives you information about the study. It tells you about the purposes, risks, and benefits of this research study.
- ***Regular care*** is based on the best-known treatment. The main goal of regular care is to help the individual patient. The main goal of ***research studies*** is to learn more so that we can help future patients. You might benefit from being in the study, but we cannot promise this.
- There may be risk to participating in this study.
- Your participation is voluntary. You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor's attitude toward you will not change.
- Please read this consent form carefully. Ask any questions you have before you make a decision. The study doctor will answer your questions. You may consult with your family or friends.

1) Why is this research being done?

Patients who have had a TIA (minor stroke) can have a stroke in a few days. Treating a TIA as soon as possible may prevent a stroke. Medicines that prevent blood clots from

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forming are often used to help prevent another stroke in patients with blockage of one of the arteries in the brain. Two commonly used drugs are being used in this study.

- Clopidogrel stops platelets from sticking together. This helps blood flow more easily, and may prevent a future heart attack or stroke. These drugs are also known as blood thinners. Clopidogrel is approved for preventing stroke or TIA, and is taken once per day.
- Aspirin also may prevent a stroke or TIA

This study will see if low-dose aspirin and clopidogrel either alone or together taken within 12 hours of time last known free of new ischemic symptoms lowers the risk of a stroke, or heart attack after a TIA. This study compares the risks of the combination with the risks from aspirin alone. Both aspirin and clopidogrel are approved by the FDA. A single trial in China studying patients with stroke and TIA suggested that the combination of clopidogrel and aspirin was safe and effective. However, there are differences in the treatment of patients, the types of stroke, and the design of the trial, so it is not clear whether these results would apply to you.

2) Who is doing the study?

- Pia Chatterjee, MD, Richard Sinert, DO, - Department of Emergency Medicine
- Steven Levine, MD, Helen Valsamis, MD – Department of Neurology
- About 250 people will be entered at this site with 5,840 people participating in about 350 hospitals in USA
- This study is sponsored by the National Institutes of Health and the National Institute of Neurological Disorders and Stroke

3) Will it cost me money to be in this study?

You and/or your insurance company will be responsible for payment of all medical costs that are not related to the study (co-payments or deductibles required under your insurance for any tests and procedures, and for routine follow-up imaging and clinical examinations).

The study drug (clopidogrel and placebo) and all follow-up visits to the study doctors will be paid for by the study. The brain scans, EKG and blood tests performed at baseline and if you have another TIA or stroke are considered part of the standard evaluation for patients with a diagnosis of TIA or stroke. Their cost is not covered by the study.

4) Will I be compensated to participate in this study?

You will not be compensated for participating in this study.

5) You cannot be in this study if:

- Are on Clopidogrel and cannot stop taking it.

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- You need Warfarin, dipyridamole or NSAIDS (ibuprofen, naprosyn, COX-2 inhibitor, etc) treatment.

6) Pregnancy:

These drugs can harm a baby. If you are a woman of childbearing age, you must not be pregnant and/or currently nursing a child. You must use an acceptable method of birth control to avoid pregnancy while on this study. Acceptable methods of birth control include hormonal contraceptives, intrauterine device, abstinence or spermacide and barrier. If you should become pregnant while on the study, you should notify your study doctor immediately.

7) What will happen to you if you decide to be in this study?

Before you begin the study...

If you agree to take part in this study and sign this consent, you will be assessed to see if you meet the entry criteria for the study. A study physician will check whether or not you are eligible by reviewing the results of the following tests and procedures that were done as part of your routine care:

1. A complete physical examination and medical history including any medications you are currently taking, since there are some medications you cannot take while you are in this study.

2. A neurological evaluation using either the NIH Stroke Scale (NIHSS) or the ABCD2 score.

(If you have already had a physical examination and neurological assessment as part of your routine care, they may not need to be repeated for the study. If they were not done, or need to be repeated, the examination and neurological assessment will be done at no cost to you.)

3. If you are female and not post-menopausal or have not had a prior hysterectomy, you will undergo a blood or urine test to determine if you are pregnant. The drugs in this study can affect a fetus, so pregnant women may not participate in this study.

You may not be in this study until all of these tests and procedures have been reviewed.

During the study… (Day 1 – about 2 hours)

After those procedures are completed, and it is determined that you are eligible to be in this study, you will be randomized. Randomization means that you are put into a group by chance. You will have an equal (a 50:50) chance of being placed in group 1 or group 2.

This is a double-blind study, which means that neither your study doctor nor you will know which of the study drug groups you are in. However, this information will be available in the case of an emergency. Everyone will take 8 tablets on day 1 and 1 tablet daily for the next 89 days plus a daily dose of aspirin.

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- Group 1 takes 8 tablets of 75mg clopidogrel with 50-325 mg of aspirin
- Group 2 takes 8 tablets of 75mg placebo (nothing) with 50-325 mg of aspirin

In both groups the dose of aspirin will be determined by your study doctor.

Just before you leave the hospital, we will schedule your next visit for about 90 days from the day you enrolled. You will also be given a list of medications to be avoided while taking study medications as well as a study medication log and study information sheet. Information about how to contact the study doctor in case of an emergency will be given to you on a card to keep in your wallet. This wallet card tells everyone that you are in a study using blood thinners. We will try to contact your regular doctor to inform him or her that you are in this study. You will be asked for your contact information, such as your email address and any alternative contacts, so that we can keep in touch with you throughout the study. You can choose not to provide alternative contacts.

Study Visits:

One Week (about 15 minutes)
About 1 week after you enroll, we will call you to ask if you've been taking your study medications. You will be asked about any changes in your health. We will also ask you about your other drugs and question you about any symptoms you may have had since your discharge.

30 Day Telephone Contact (about 15 minutes)
About 30 days after your first dose, a member of the study team will contact you to ask you whether you've been taking your study medications, and whether you are experiencing any side effects or other possible events.

Event Visit (about 2 hours)

- If you feel like you are having a stroke, TIA (feeling weak, or numb on one side, blurry vision, or no vision usually in one eye, unable to talk clearly, dizziness or falling, or severe headache) or heart attack (chest pain during rest or exercise)call the study number listed on your wallet card as soon as possible. If it is thought that based on information you provide, you might have had a stroke, a TIA or a heart attack, you will be scheduled for an evaluation.

If the visit is done in-person, you will:

- have your blood pressure and heart rate checked
- have tests performed as part of your regular care, including a CT or MRI of your head, an ECG and blood tests
- answer questions about your study medications and any side effects or adverse events
- be evaluated using both the modified Rankin Scale and the NIHSS, which are commonly used after TIA and stroke

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- complete the Stroke-Free and the Morisky Questionnaires, which are surveys about any neurological symptoms you may have had since enrolling in the study

If the visit is done by telephone, you will:

- answer questions about your study medications and any side effects or adverse events
- be evaluated using the modified Rankin Scale
- complete the Stroke-Free and the Morisky Questionnaires

90 Days (about 2 hours)

- You will need to come back to the **Neurology Office**. This follow-up visit may be done either in person or by telephone and will include the same questions and tests described under the Event Visit.

If the visit is conducted in-person, you will:

- have your blood pressure and heart rate checked
- answer questions about your study medications and any side effects or adverse events
- be evaluated using the modified Rankin Scale and the NIH Stroke Scale
- complete the Stroke-Free and the Morisky Questionnaires

Other tests may be performed as part of your regular care, including a CT or MRI of your head, an ECG and blood tests.

If this visit is done over the telephone, (visit will take less than 1 hour) then you will:

- answer questions about your study medications and any side effects you may have had.
- be evaluated using the modified Rankin Scale
- complete the Stroke-Free and the Morisky Questionnaires.

At the end of the study, we will discuss with you the best choice of medication for you. You will not be told which drug you were on until the study is finished and the results are known.

If for some reason we are unable to locate you for the 90 day follow up visit, we will ask your alternate contact and/or review you medical chart to find out if you have been seen by another doctor within your hospital. We will also check to see if you have had a stroke, TIA or heart attack during the 90 day follow up period. In order to make sure that we include the full 90-day period in our review, we will need to review your chart after the 90 day study period has ended. This means that we may continue to collect information about you up to 150 days from your enrollment.

How long will I be in the study?

About 3 months. About 5 months after you have joined the study, the researchers will no longer collect information about you. If you decide you want to the study team to stop collecting information about you before then, then you must write to the study doctor (Dr.

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Pia Chatterjee) and ask to be removed from the study. The researchers will use the information that they collected about you up until that point.

Can I stop taking the study medication?
Tell the study doctor if you are thinking about stopping or decide to stop; your study doctor will tell you how to stop safely. It is important to tell the study doctor if you are thinking about stopping so that your study doctor can evaluate any risks from the study drugs, and discuss what alternative follow-up care and testing could be most helpful for you. Even if you stop the study medication we would like to continue to contact you at day 7, day 30, and day 90.

If you decide to stop participating or are withdrawn from the study, information about whether you had a stroke, heart attack or other complication during the 90 days of the study will still be helpful to the research. Giving consent will allow study personnel to collect this information by asking you or your alternative contact on the phone, asking you in-person, accessing your medical record and/or performing a chart review for up to 150 days from your enrollment.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped. The entire study could also be stopped on the recommendations of a safety committee that will monitor this study or by the sponsors of the study.

8) What are the possible risks of being in the study?

You may have side effects while on the study. You should talk to your study doctor and your doctor who usually takes care of you about any side effects you experience while taking part in the study.

Risks and side effects related to the study drugs include:

a. Placebo risks: If you are in the group that receives placebo, you will not have clopidogrel for about three months.

b. Side effects from study drugs: Patients who have a known allergic reaction to any of the study medications should not participate in this study. Many side effects go away soon after you stop taking the medicine. In some cases, side effects can be serious, long lasting, or may never go away.

c. Side effects from clopidogrel**:** Clopidogrel thins the blood in order to help blood flow more easily. Blood clotting may take longer than normal while taking clopidogrel. You may have longer bleeding from cuts, and you may also bruise more easily. Superficial and internal bleeding, including bleeding into the brain, are also

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side effects of clopidogrel. Internal bleeding and bleeding into the brain are serious conditions that can result in death.

The most common side effects of clopidogrel include abdominal or stomach pain, diarrhea, skin reactions (rash, itching), aching muscles and/or joints, dizziness, fever, headache and a decrease in the number of a type of white blood cell called a neutrophil. In rare cases, clopidogrel may cause stomach bleeding.

Symptoms of stomach bleeding include darker (sometimes black), tarry stools, stomach pain and sometimes vomiting blood or coffee grounds. There have also been rare reports of a serious bleeding disorder called thrombotic thrombocytopenic purpura (TTP). This side effect is most likely to occur during the first two weeks of treatment.

Please call right away: During the trial, you must immediately tell your study doctor and your doctor about any abnormal or unexpected events and in particular about

- Any warning sign of brain attack (feeling weak, or numb on one side, blurry vision, or no vision usually in one eye, unable to talk clearly, dizziness or falling, or severe headache)
- Any anginal pain (chest pain during rest or exercise)
- Any bleeding,, spontaneous bruise, bleeding from an unusual site or that takes a very long time to stop)
- Infection (fever, shivering, sore throat. extreme tiredness)
- Skin rash
- Severe diarrhea, or
- Jaundice (yellow discoloration of the skin).
- Feeling generally unwell

If you are hospitalized or go to an Emergency Room where the study doctor does not work, whatever the reason is, you (or one of your relatives) should inform your study doctor as soon as possible. You must tell the doctor treating you at the hospital or Emergency Room that you are taking part in this study. You can show him or her the wallet card that explains the study and gives a phone number to call for questions.

d. Side effects from aspirin: Aspirin has two main types of side effects: it can cause gastrointestinal upset and it can increase bleeding. The feelings include stomach pain, heartburn, nausea and/or vomiting. Like clopidogrel, it may cause stomach bleeding. Symptoms of stomach bleeding include darker (sometimes black), tarry stools, stomach pain and sometimes vomiting blood or coffee grounds. In rare cases, more serious effects, such as bleeding, have been observed in people who take aspirin for a long time. Even less commonly, hemorrhagic stroke (bleeding in the brain) can occur. The side effects of aspirin are generally dose-related, and tend to occur more often in doses that are higher than the dose of aspirin taken in this study.

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***e. Side effects from aspirin and clopidogrel*:** Both drugs thin the blood. Combining them is likely to increase that risk. This combination has not been tested right after a TIA. Rates of hemorrhage must be estimated from other studies of stroke and heart attack (acute coronary syndrome). It is likely, based on the results of those studies, that clopidogrel combined with aspirin has a little higher risk of major bleeding. The combination of aspirin and clopidogrel may increase the risk of complications with surgeries or other procedures, or may delay the performance of these procedures (due to concerns about bleeding risk). A delay could increase your risk of stroke.

***f. Side effects from discontinuing medications for study purposes*:** If you are currently taking a drug that blocks platelets (such as clopidogrel or dipyridamole) or blocks clotting (such as warfarin), your regular doctor may not want you to enroll in this study. Please try to discuss this study with your regular doctor before you consent. Other medications may be changed if they interfere with aspirin or clopidogrel. These changes will be discussed with you and the doctor who usually takes care of you. Also, some doctors treat patients with TIA with clopidogrel and aspirin together.

Taking other medications while on the study: Certain medications may make clopidogrel less effective. If you receive any new prescriptions while you are on the study, you should tell the study doctor.

g. Risks of blood draws: The risks and discomforts of drawing blood include temporary discomfort from the needle stick, the possibility of pain or bruising at the site of the blood draw, occasional feelings of lightheadedness and, rarely, infection at the site of the blood draw.

h. Unknown Risks: The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study. For more information about risks and side effects, ask your study doctor.

9) What are the possible benefits of being in the study?

There is no guarantee that you will benefit from joining this study. You may benefit if clopidogrel stops a stroke or heart attack. Being in this study may help us learn how to prevent a stroke in patients with a TIA or minor stroke. The knowledge gained from being in this research study may help other TIA patients in the future.

10) What are your other choices?

If you do not want to join this study, you will get the usual treatment for a TIA. There are several drugs approved by the Food and Drug Administration to stop a stroke.
Aspirin is available without a prescription, and clopidogrel is available from you doctor. Other drugs are available to you from your doctor without being in this study.

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You may also choose not to receive any drugs. You may wish to discuss your treatment with your doctor before you decide to be in this study.

11) What information do we keep private?

In this study we will keep your personal information private. We will hide your identity. All data will be kept in a secure location. We will not show your identity in any results of the study. However privacy cannot be guaranteed; your information may be disclosed if so required by the Federal Privacy law.

Federal law protects your right to privacy concerning Individually Identifiable Health Information (IIHI). There are certain things you need to know, IIHI is any information from your medical record, or obtained from this study, that can be linked to you, and that refers to your mental or health conditions in the past, the present or the future.

For this study we will create, use or report the following IIHI:

- Information from your medical records including name, age, sex, race, and medical history.
- Information obtained from this study, including physical examination, laboratory tests, ECG heart tracing, brain scan including CT or MRI.

The researchers, their staff and the staff of Kings County Hospital Center participating in the research will use your protected IIHI for this research study.

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.

Authorization to use and disclose personal health information

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to x-rays, physical examinations and medical history, and

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- Billing records.

Information about your health may be used and given to others by the study doctor and staff.

They might see the research information during and after the study.

Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- The Data Safety Monitoring Board that reviews the safety of this study,
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Health and Hospitals Corporation (HHC) Corporate Research Staff members
- Accrediting agencies
- Data Safety Monitoring Boards
- Health Insurers/ Payors
- Study monitors from the POINT CRC Coordinating Center (The EMMES Corporation, Rockville, Maryland) and the NETT (University of Michigan)
- Staff from the Neurological Emergencies Treatment Trials Network(NETT) (University of Michigan),
- Staff from Statistical Data Management Center (Medical University of South Carolina)
- The University of California at San Francisco (UCSF)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health confidential.

If you give permission to give your identifiable health information to a person or business (for example, the sponsor NIH or the Emmes Corporation), the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to

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governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you chose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any affect on your medical care and you will not lose any benefits or legal rights to which you are entitled.

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

Some IIHI that is obtained in this study will not be shared with you. This includes which group of the study you are in. This information can be shared with you at the end of the study.

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 Shweta Malhotra, PhD at 451 Clarkson Ave, Box 1228, Brooklyn, NY 11203. If you withdraw we will stop collecting and accessing your IIHI, but we will collect and report any adverse event (bad effect) that you had in the study. Your IIHI collected before you withdraw your authorization will still be used and reported. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to care or other benefits to which you are entitled.

Notice Concerning HIV-Related Information
If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.

12) Can your participation in the study end early?

Being in this study is voluntary. You do not have to be in the study if you don't want to. You can agree to be in the study now and change your mind later. If you want to quit the study, you should talk to Dr. Chatterjee, MD or one of the study staff members.

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The study staff, the sponsor, federal authorities, and HHC can take you out of the study or stop the study without your permission. Possible reason for involuntary withdrawal would be continuing on the study would be harmful, adverse event, or pregnancy. HHC is empowered to suspend or cancel the research.

Also, the sponsor of the study may end the study early. If your being in the study ends early, we may ask you to visit the study doctor for a final visit.

13) What if I become injured due to participating in this study?

You might be injured by being in this study. It will be very difficult to distinguish an injury caused by treatment of your condition from one caused by taking part in a study. If you are, emergency care will be available and you will be treated as immediately and appropriately as you would for usual treatment of similar medical issues. It is important that you tell your study doctor.

Payment for medical treatment, both standard and experimental, as well as treatment of any side effects will be assumed in the usual manner by you personally or through your medical insurance. There are no plans for this hospital or the Sponsor to pay you or give you other compensation for the injury.

If you are injured, HHC will treat you regardless of your inability to pay.

You do not give up your legal rights by signing this form. No other compensation will be offered by NINDS, Kings County Hospital Center, the Biomedical Research Alliance of New York, or the sponsor.

14) What else do you need to know?

If we find out any new information that might affect your decision to stay in the study, we will give it to you.

Optional POINT Biomarkers Ancillary Study

If you take part in the main study, you will also be asked for an optional one-time blood sample as part of an ancillary, or secondary, study of biomarkers. Biomarkers are molecules found in blood, other body fluids, or tissues that are signs of a specific condition or disease. If you agree to participate in the secondary study, we will collect about 2 teaspoons of blood (two 5 mL tubes) from you for a type of test called a “biomarker test” on your blood. The biomarker test will help us learn if you have specific biomarkers for the genes named ABCB1 and CYP2C19 which may affect how your body responds to being treated with clopidogrel, the medication being studied in this trial. The results of the biomarker tests can help us learn more about how effective clopidogrel can be for preventing stroke in people who have had a TIA and also have those specific biomarkers in their blood.

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The blood will be prepared for genetic analysis and stored at the Neurogenetics Laboratory at the Mayo Clinic in Jacksonville, Florida (MCF) for 20 years. The stored blood samples may be used in future studies for TIA and stroke. We will do our best to make sure that the personal information that we have collected is kept private. We will assign numbers to label the blood samples and no personal information will be on the tubes used to store the blood samples. The genetic test results will be provided to the Principal Investigator and statistician in the study. You will not receive the genetic test results.

The secondary study is optional and you can decide to participate in just the main study. You can decide to stop participating in the secondary study at any time by letting your study doctor know and your blood sample will be destroyed.

15) If you have any questions or problems, whom can you call?

If you have any questions relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, you may contact Dr. Chatterjee or study staff at 718-245-4790. If you have any questions about your rights as a research subject, or you are unable to reach the research staff, or if you have any complaints regarding this research study, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877.

Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board on the World Wide Web at the following URL: http://www.branyirb.com/concerns-about-research

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16) Subject Consent

By signing this consent form you accept that you read this form, or had it read to you. You agree to be in the study and authorize the use and reporting of your individual identifiable health information (IIHI) as explained in this form. You will not be giving up any of your legal rights by signing this consent.

_____	_____	_____
Signature of Subject	Date	Print name
_____	_____	_____
Signature of Person Obtaining Consent	Date	Print name

Optional Ancillary (Secondary) Study

Please indicate if you wish to also participate in the optional ancillary study by reading each sentence below and entering your initials in the "Yes" box. If you have any questions about the optional ancillary study, please talk to the study doctor or nurse. No matter what you decide to do, it will not affect your care.

1. My blood sample may be taken for this research, as described in the Optional POINT Biomarkers Ancillary Study section above.

YES _____ NO_____

2. My blood sample may be kept for use in research to learn about biomarkers related to TIA and stroke.

YES _____ NO_____

Alternative Contacts

Please indicate whether you wish to allow alternative contacts to be contacted regarding your participation in this study by entering your initials in the “Yes” or “No” box to the right.

YES	***NO***

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