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# SUPPLEMENTAL GENETIC CONSENT FORM

***University Hospital of Brooklyn at SUNY Downstate Medical Center***

***Optional Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke (POINT) Biomarkers Ancillary Study***

We are asking if you want to be in a research study. This study is for people who have already **agreed** to be in the Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke (POINT) study.

## 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.
- There may be risks to your privacy for participating in the 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?*

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. 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.

## *2) Who is doing the study?*

Dr. Adrian Marchidann is in charge of this study at this location. About 250 people will be in the study at this location. About 5,840 people will be in the study around the country.

## *3) What will happen to you if you decide to be in this study?*

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 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. 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.

## *4) What are the possible risks of being in the study?*

If your specimens are used for genetic research, they will not be labeled with your name or other personal identifier, and the results will not be put in your medical records.

However, your doctor will put in your medical record that you are in a research study, and then an employer or court could demand to see your research records, including genetic results. 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. We will do as much as possible to prevent others from finding out your genetic information, but we might not be able to prevent them from finding it out.

You do not give up any recognized legal rights by signing this consent, however, courts have ruled that you lose ownership over your blood, body fluids, excretions, and/or tissue samples once those materials leave your body.

## *5) What are the possible benefits of being in the study?*

There is no direct benefit to you from being in this study. Others in the future may benefit from the gain in knowledge about disease or treatments for disease.

## *6) If you have any questions or problems, whom can you call?*

If you have any questions about this study, you can call Dr. Adrian Marchidann at 718-270-1259. If you think you have been injured because of the research, you should call Dr. Adrian Marchidann at 718-270-1259.

If you have questions about your rights as a research subject, you can call the IRB office at (718) 613-8480, or you can contact the SUNY HSCB University Hospital Medical Director's Office at (718) 270-2401.

## *7) What information do we keep private?*

In this study we will keep your personal information confidential. We will hold your identity confidential and all data will be kept in a secure, place where only a few known people can see it. We will not reveal your identity in any publication or presentation of the results of the study. However confidentiality cannot be guaranteed; your personal 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 SUNY Downstate Medical Center participating in the research will use your protected IIHI for this research study.

Your IIHI will be shared with the following persons or agencies for purposes related to the conduct of the research:

- The sponsor of the study, NIH/NINDS
- The Data Safety Monitoring Board that reviews the safety of this study,
- The Institutional Review Board of SUNY Downstate Medical Center, the applicable DMC officials, and the federal Office for Human Research Protections,
- Study monitors from the POINT CRC Coordinating Center (The EMMES Corporation,Rockville, Maryland)
- Staff from the Neurological Emergencies Treatment Trials Network (University of Michigan),
- Staff from Statistical Data Management Center (Medical University of South Carolina)

We will have to use and report your health information an indefinite period of time.

You need to know that some of the individuals or groups mentioned above are <u>not</u> obligated to protect the privacy of your IIHI. For example, the sponsor NIH or the Emmes Corporation does not have the same obligation to protect your IIHI under the federal privacy laws.

Some IIHI that is obtained in this study will be not shared with you. Unless the genetic information gathered as part of the study leads to a specific diagnosis or treatment, we will not share it with you.

You can withdraw this authorization for the use or reporting of your IIHI. You have to write

to us to withdraw: Attention: Sarah Zelonis; 450 Clarkson Ave, Box 1213, 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.

You can withdraw from the study as long as your sample can be linked to you personally. We will destroy your sample, but not information obtained from the sample before you withdrew.

## *8) 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.

## *9) Subject Consent*

By signing this consent form you accept that you read this form, or had it read to you. You agree to have your blood sample taken to be in the Optional POINT Biomarker Ancillary (secondary) 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. We will give you a copy of this form and of Downstate Medical Center's Notice of Privacy Practice.

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|---|---|---|
| _____ | _____ | |
| Signature of Subject | Date | Print name |
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Date | Print Name |
| _____ | _____ | |
| Signature of Witness (if applicable) | Date | Print name |

My blood sample may be kept for use in research to learn about biomarkers related to TIA and stroke.(Sign next to your choice)

YES _____

NO_____