If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

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# **RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM**

Protocol Title: Gene Transcripts and Proteomics in Families with Platelet Hyperaggregation

Application No: NA\_00093747

Sponsor: National Heart, Lung and Blood Institute

Principal Investigator: Lewis C, Becker, MD

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1. **What you should know about this study:**
* You are being asked to join a research study.
* This consent form explains the research study and your part in the study.
* Please read it carefully and take as much time as you need.
* Please ask questions at any time about anything you do not understand.
* Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
* You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
* During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
* Information from this study is for research purposes only and will not be included in any medical records.
* When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children’s Hospital.
* During this study, you will not have access to certain test results collected for research study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you.
1. **Why is this research being done?**

This research is being done to learn how genes regulate the function of platelets in clotting. Platelets are small particles in the blood that help it to clot.

We want to better understand platelet function and clotting as may affect heart attacks and strokes. Platelets are important to researchers who study coronary heart disease and stroke as they are the sticky cells in blood that are in part responsible for clots that may predispose people to these health problems.

The study will examine certain substances (called RNAs) produced from your DNA that cause proteins to be formed in your platelets and may cause your platelets to stick together. We already have your DNA from your prior GeneSTAR Study. This study will give us a better understanding of the ways in which platelets function and could result in better treatments to prevent heart attacks and strokes. There will be no direct benefit to you of participation. All information is being collected for research only.

People who have already participated in the prior genetic study of platelet function before and following two weeks of aspirin (GeneSTAR) and who have already had the genetic testing on their DNA are eligible for this study if they are over 21 years of age and do not have cardiovascular disease, any new known bleeding disorder, AIDS, cancer under treatment, or autoimmune diseases, like lupus for example.

***How many people will be in this study?***

There will be 280 people in the study.

1. **What will happen if you join this study?**

If you agree to be in this study, we will ask you to do the following things:

You will come in for one visit that will take about an hour. We will get a blood sample (consisting of about 6 ½ tablespoons) to use for research laboratory tests associated with platelet function. These tests have no clinical meaning, so there will be no results that we will give back to you or to your doctor. There will be no results in any hospital or clinical record at Johns Hopkins.

Before we take your blood we will check your hematocrit (amount of red blood cells in your blood) using a fingerstick to be sure you are not anemic. If your hematocrit is below 35%, we will let you know at that time and recommend that you see your doctor to have your blood counts done again. We will not give you an exact value for the fingerstick hematocrit, nor will we keep that in your record, only the fact that it was normal or below the value we considered appropriate for the blood draw.

Future Contact

We would also like to contact you again for further GeneSTAR studies as we have in the past. If this is acceptable to you, please check the YES box below. If you would rather that we not contact you again, please check the NO below.

**Please sign and date your choice below:**

**Yes € \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant

**No €** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant

**Request to collect and store blood for future research**

As part of this research study, we would like to store a small amount of your blood for future research. This small amount (1 tablespoon) is included in the total 6 ½ tablespoons we will take at this visit. Research on your blood samples in the future will only include factors related to cardiovascular disease and stroke and the blood will not be available to anyone outside of the GeneSTAR Study and its collaborators.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your blood specimens can be found in this consent document under the heading *What happens to Data and Blood Specimens collected in the study?*

Will you allow us to store the blood we collect for this study for use in future cardiovascular and stroke disease related research*?*

**Yes € \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant

**No €** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant

**How long you will be in the study**

This particular study only involves one visit.

1. **What are the risks or discomforts of the study?**

**Blood Draw:** Taking blood may cause discomfort, bleeding or bruising where the needle enters the skin. In rare cases, it may result in fainting. This is typically 1 in 10,000 blood draws, but we have had this occur in far fewer than that number. There is also a very small risk of infection. This is also rare. We have not observed any infections in over 15,000 blood draws in this study.

**Confidentiality:** There is little to no risk that any information about you will become known to people outside this study. The blood sample is labeled by a number that is different from your main study identification number. Only your main study identification number has any link to you identity and that is kept in a secure electronic database in the GeneSTAR Study Center only, and managed by a single programmer/analyst. No one else can see this master list.

We will strictly limit the use blood to be stored and used by any other approved research collaborators to study heart disease and stroke

1. **Are there benefits to being in the study?**

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

1. **What are your options if you do not want to be in the study?**

You do not have to join the study if you do not wish. This is purely research and has no effect on any care you may need now or in the future at Johns Hopkins or any other institution. If you do not join, your care at Johns Hopkins will not be affected.

1. **Will it cost you anything to be in this study?**

There are no costs to the study.

1. **Will you be paid if you join this study?**

You will be paid $100 for your time and effort in the study, plus $12 parking fees at Johns Hopkins.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

1. **Can you leave the study early?**
* You can agree to be in the study now and change your mind later.
* If you wish to stop, please tell us right away.
* Leaving this study early will not stop you from getting regular medical care*.*

If you leave the study early, Johns Hopkins may use or give out your health information they have already collected if the information is needed for this study or any follow-up activities***.***

1. **How will your privacy be protected?**

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator’s name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

1. **What other things should you know about this research study?**
	1. **What is the Institutional Review Board (IRB) and how does it protect you?**

The Johns Hopkins Medicine IRB is made up of:

* Doctors
* Nurses
* Ethicists
* Non-scientists
* and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

* 1. **What do you do if you have questions about the study?**

Call the principal investigator, Dr. Lewis Becker at 410-955-5997. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

* 1. **What happens to any data and blood specimens that are collected in the study?**

We are collecting no new data about your health or your health status.

Johns Hopkins and our research partners work to understand and cure diseases. The blood specimens you provide are important to this effort.

If you join this study, you should understand that you will not own your blood specimens and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your blood specimens with our research collaborators only after a thorough review of any proposal by the GeneSTAR team to assure the research integrity of the proposal and adherence to our restrictions to only use for cardiovascular disease or stroke related research.

1. **What does your signature on this consent form mean?**

 Your signature on this form means that:

* you understand the information given to you in this form
* you accept the provisions in the form
* you agree to join the study

 You will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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Signature of Participant (Print Name) Date/Time

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Signature of Person Obtaining Consent (Print Name) Date/Time

**NOTE**: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD.**

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.**