Post-transplant Flotetuzumab for AML

NCT05506956

1/11/2023

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **A Phase Ib to Investigate the CD123-targeted DART Flotetuzumab Following Allogeneic Transplant for Patients with CD123+ Acute Myeloid Leukemia**

Application No.: **IRB00235421**

Sponsor: **National Cancer Institute**

Principal Investigator: **Jonathan Webster, MD**
1650 Orleans Street, CRB1, Room 245
Baltimore, MD 21287
Phone: 410-614-9106
Fax: 410-614-7279

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this research study is to determine if the study drug, flotetuzumab, is safe and tolerable when given to participants with acute myeloid leukemia (AML) that has relapsed after transplant.

The duration of your participation will last for up to 2 years. All participants will receive one cycle (28 days) of flotetuzumab. After one cycle, all participants will undergo a bone marrow biopsy to assess response and based on the response, you may receive additional cycles up to a total cycle of six cycles. Throughout the study, procedures will be performed to find out if you are eligible to go on study and remain on study, to evaluate the status of your leukemia, and to determine whether or not you have any side effects. In addition, blood and tissue samples will be taken to see if the biomarkers may be related to how you respond to the study drug and any side effects you have from the study drug.

While on this study, you are at risk for side effects, which are detailed later in this document. Some risks could be serious and not all of the side effects/risks are known.

Participation in this study may or may not help to control your disease.

2. Why is this research being done?

This research is being done to determine the safety and tolerability of study drug called flotetuzumab when given following a bone marrow transplant (BMT) for acute myeloid leukemia (AML).

In addition, substances (biomarkers) found in the blood and bone marrow that may indicate the effects of flotetuzumab on the immune system will be studied.

Are there any investigational drugs/devices/procedures?

The use of Flotetuzumab in this research study is investigational. The word "investigational" means that "Flotetuzumab" is not approved for marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of "Flotetuzumab" in this study. Flotetuzumab is an investigational drug that engages your immune system to attack cells expressing CD123, a protein, which is commonly expressed on malignant cells in patients with AML.

Who can join this study?

People 18 years and older with relapsed/refractory AML after bone marrow transplant may join.

How many people will be in this study?

About 16 participants will be enrolled in this study.

3. 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:

PROCEDURES

Throughout the study, procedures will be performed to find out if you are eligible to go on study and remain on study, to evaluate the status of your leukemia, and to determine whether or not you have any side effects. In addition, biomarker samples will be taken to see if the biomarkers may be related to how you respond and any side effects you have. Some of these procedures are done as part of your standard care, and others are done as part of this research study. This section will first describe all the procedures in detail. This will be followed by a section that describes each visit and which procedures are performed.

• **Informed Consent:** Written informed consent (this document) will be obtained after your informed consent discussion with your study doctor. Throughout the study, if there is any new safety information or changes to procedures, you will be asked to consider this information and decide whether you want to continue your participation and sign an updated written informed consent form.

• **Medical History:** Your study doctor will ask you questions about your health, medical history, allergies, recent and current medication use (including vitamins and herbal treatments) and other treatments you have received for your cancer.

• **ECOG Score:** The study staff will speak with you to determine your overall status according to the Eastern Cooperative Oncology Group (ECOG) Performance Status Scale. The ECOG scale is an assessment of how well you are able to perform your normal day-to-day activities.

• **Physical exam and weight:** Your study doctor will perform a full exam of all body systems to evaluate any physical changes. Weight will be taken to see if there are any changes and to calculate your drug doses. At screening, your height will also be measured.

• **Vital sign measurements:** Your pulse rate, temperature by mouth, blood pressure, and respiration (breathing) rate will be measured.

• **Blood draw for viral infections:** All patients must have testing for human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS), and testing for chronic infections with hepatitis B and C. Patients with poorly controlled HIV or chronic infections with hepatitis B or C cannot receive flotetuzumab. You may be asked to sign a separate State of Maryland consent form for this HIV test. If an HIV test is positive, you will need further testing and you will receive counseling. The law requires us to report positive tests to the health department. This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as required by Maryland law. The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases.

• **Bone Marrow Aspiration/Biopsy:** A test in which a liquid sample and/or a solid core of the bone marrow, usually from the rear hip bone, is removed by needle aspiration (suction) and examined under a microscope. Bone marrow aspiration and biopsy are done to diagnose and follow the progress of leukemia. On certain visits, additional liquid and/or tissue will be obtained for biomarker studies as described below. Information from the bone marrow sample taken at the time of your diagnosis and prior to consent for this study will be collected.

• **Blood/bone marrow sample collection for biomarker analysis:** A biomarker is any gene or protein that may be related to a condition or disease, how that condition or disease behaves, and how a condition or disease is affected by treatment. In this study, biomarker analysis will include looking at many proteins and genes expressed by your white blood cells (lymphocytes) to determine how they respond to study drug flotetuzumab following a bone marrow transplant. At some visits, blood will be drawn for these tests from your vein. Additionally, when you undergo a bone marrow biopsy as part of the routine monitoring of your leukemia or as part of this study, extra fluid from the bone marrow (aspirate) will be collected for these studies. Results from these tests will not be available until later in the study, and you will not receive results for these. For each blood or bone marrow sample, five tubes (about 3 tablespoons) will be obtained. Samples will be stored in the Jones Laboratory in Cancer Research Building 1 on the Johns Hopkins Medical Institution campus. Stored samples will be coded with a unique ID number for each participant that will be kept separately by the study team. Researchers at off-site locations will not have access to your personal health information including your name, date of birth, or other personal identifiers. All analyses will be performed at the Johns Hopkins Medical Institution.

• **Adverse Event Assessment:** Adverse events are any changes in your condition or side effects that may or may not be associated with the study drug but happen while you are in the study. Your study doctor must collect information about them. Your study doctor will ask you questions about how you are feeling, including any new or different symptoms you may have. Your doctor will also use the procedures listed above to see if there are any changes in your condition.

• **Other Medication and Treatment Review:** Your doctor will ask you detailed questions about any current and new medications you are taking including vitamins, over the counter medications, and other non-medication treatment. You may be asked to bring in medications to confirm what dosage or formulation you are taking.

• **Transfusions:** During the study you may require blood transfusions of platelets, red blood cells, or whole blood if your blood counts are too low. Information on any transfusions you receive will be collected throughout the study.

• **Pregnancy Test:** Your doctor or a nurse will discuss with you throughout the study if you think you may be pregnant and a pregnancy test may be done, if needed. Pregnancy tests will be done prior to each cycle of study drug (the tests, blood or urine, would be considered regular care).

• **Electrocardiogram (ECG):** ECG or heart tracing will be performed prior to the start of the research study.

STUDY DRUGS

In addition to the medications that your doctor would normally ask you to take after a bone marrow transplant, you will be asked to take the following study drugs as part of this study:

• **Flotetuzumab:** Flotetuzumab is given as a continuous infusion into your vein. There is an increased risk of complications, such as low blood pressure, fever, and difficulty breathing, so you will need to be hospitalized for administering flotetuzumab cycle. All participants will receive one cycle (28 days) of flotetuzumab. After one cycle, all participants will undergo a bone marrow biopsy to assess response and based on the response, participants may receive additional cycles up to a total cycle of six cycles.

To receive this study drug, your doctor will arrange for the insertion of a catheter into a central vein in your neck or chest, if you do not already have one. This device is necessary to give you flotetuzumab and other medications, and to collect blood samples. This is a standard procedure done for participants receiving this and other types of chemotherapy. You will be asked to sign a separate consent for this procedure, which will explain the risks, and must be done under local anesthesia and with sterile conditions.

• **Dexamethasone:** Dexamethasone is a steroid medication that has been shown to reduce the risk of complications from the study drug flotetuzumab. For this reason, you will be given dexamethasone (by vein) prior to the initiation of each flotetuzumab infusion, as well as at multiple other time points during the first week of infusion.

• **Acetaminophen:** Acetaminophen (Tylenol) is a medication that has been shown to reduce the risk of complications from study drug flotetuzumab. For this reason, you will be given acetaminophen (by mouth) prior to the initiation of each flotetuzumab infusion, multiple times during the first nine days of infusion, and again if any complications should arise during your infusion.

• **Diphenhydramine:** Diphenhydramine (Benadryl) is an antihistamine medication that has been shown to reduce the risk of complications from study drug flotetuzumab. For this reason, you will be given diphenhydramine (by vein or by mouth) prior to the initiation of each flotetuzumab infusion, multiple times during the first nine days of infusion, and again if any complications should arise during your infusion.

ASSESSMENTS AND PROCEDURES AT EACH VISIT

This section describes when procedures will be done throughout the study.

All Cycles	
Day	**What you will be asked to do**
Within 2 weeks before starting the study	• Get routine blood tests • Get a urine sample • Get a pregnancy test • Get an Electrocardiogram (ECG) • Get tested for HIV, Hepatitis B and Hepatitis C • Get insertion of a central venous catheter, if you do not already have one. • Review your medical history • Review other medications • Get a physical examination including height, weight, and vital sign measurement • Assess your ECOG score • Get a bone marrow aspirate and biopsy (if indicated) • Collect samples for biomarker analysis from the blood and bone marrow
Day 1	• You will be admitted to the hospital • Review other medications • Review your medical history • Get a physical examination including weight, and vital sign measurement • Get routine blood tests • Assess ECOG score • Undergo an adverse event assessment • Begin flotetuzumab infusion • You will receive dexamethasone, acetaminophen, diphenhydramine, and famotidine
Days 2-9	• You will remain in the hospital • Get routine blood tests • Continue flotetuzumab infusion • You will receive dexamethasone, acetaminophen, diphenhydramine, and famotidine • Collect samples for biomarker analysis from the blood on Day 8 ONLY
Day 10	• You will remain in the hospital • Get a physical examination including vital sign measurement • Get routine blood tests • Undergo an adverse event assessment • Continue flotetuzumab infusion
Day 15 and 22	• You will remain in the hospital • Get a physical examination including vital sign measurement • Get routine blood tests • Undergo an adverse event assessment • Collect samples for biomarker analysis from the blood • Continue flotetuzumab infusion
Day 28	• Get a physical examination including vital sign measurement • Get routine lab tests • Undergo an adverse event assessment

	• Get a bone marrow aspirate and biopsy • Collect samples for biomarker analysis from the blood and bone marrow • You may need to continue to have follow-up visits that include physical exam and laboratory tests if you experienced side effects attributable to the study drug until these side effects improve or resolve. The frequency of visits will depend on your symptoms and need to manage them. • If you have had no significant side effects from flotetuzumab, you may leave the hospital
Every 6 months for 2 years	
	What you will be asked to do
	• Review your medical history • Get a bone marrow aspirate and biopsy • Get routine blood tests

Will research test results be shared with you?
It is uncertain if the research tests will produce results that would be relevant for your clinical care, so we will not share these results with you.

How long will you be in the study?
You will be in this study for up to 24 months.

4. What happens to data and biospecimens that are collected in the study?

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data/biospecimens collected in this study for future research purposes and may share some of the data/biospecimens with others.

Because science constantly advances, we do not yet know what future use of research data or biospecimens may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data and/or biospecimens may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

We (Johns Hopkins) will do our best to protect and maintain your data/biospecimens in a safe way.

One of the ways we protect data/biospecimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups within Johns Hopkins.

If data/biospecimens are used or shared with types of information that may be likely to identify, you such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required. Generally, if your data/biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data/biospecimen sharing could change over time, and may continue after the study ends.

The use and sharing of your data and biospecimens is required for participation in this research study. If you are not comfortable with the use and sharing of your data/biospecimens in future research without further consent, you should not participate in this study.

5. What are the risks or discomforts of the study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- The study approach may not be better, and could possibly be worse, than the usual approach for your leukemia.
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

The *drugs* including study drug used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health. Because of this, it is very important to tell your study doctors about all medicines you are taking before you start this study. It is also important to tell them if you stop taking any regular medicine, or if you start taking a new medicine while you take part in this study. When you talk about your medicines with your study doctor, include medicine you buy without a prescription at the drug store (over-the-counter remedies), or herbal supplements.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

Drug-Related Risks or Discomforts

The table below shows the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Flotetuzumab:

COMMON, SOME MAY BE SERIOUS In 100 people receiving flotetuzumab, more than 20 and up to 100 may have:
• Diarrhea, nausea, vomiting • Fever, chills • Fatigue • Weakness • Pain including muscle pain and abdominal pain • Low potassium, low magnesium, low calcium, low phosphorus, low sodium, and low albumin • Swelling (edema) • Decreased appetite • Itching • Low white blood cell count • Trouble sleeping (insomnia) • Increased blood sugar (hyperglycemia) • Cough • Increased liver enzymes and bilirubin • Shortness of breath (dyspnea) • Water on the lungs (pleural effusion) • Increased blood pressure (hypertension) or decreased blood pressure (hypotension) • Infusion-related reactions • Low platelets (thrombocytopenia) • Infection, especially when white blood count is low • Headache • Weight gain • Nosebleeds (epistaxis) • Anemia, which may require blood transfusion • Rash
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving flotetuzumab, more than 3 and up to 20 may have:
• Increased heart rate • Abnormal heart rhythm • Delirium • Confusion • Respiratory failure

RARE In 100 people receiving flotetuzumab, 3 or fewer may have:
• Heart attack (myocardial infarction) • Blurred vision • Trouble swallowing • Heartburn • Pancreatitis • Difficulty remembering (amnesia) • Balance disorder • Difficulty speaking (aphasia) • Change in taste (dysgeusia) • Tremor • Neuropathy • Seizure • Syncope • Hallucinations • Nephrotic syndrome • Coughing up blood (hemoptysis) • Low oxygen (hypoxia) • Hair loss • Dry skin • Flushing

Cytokine Release Syndrome
Flotetuzumab may cause a severe infusion reaction called cytokine release syndrome. This can happen when part of the body's immune system is activated by the study drug when it is first given, causing them to release substances called cytokines.

In addition, signs and symptoms of the syndrome include swelling in your body, especially in the arms and legs, fluid in your lungs which makes breathing difficult, decrease in mental alertness, seizure and in extreme situations, organ failure and death. If you experience difficulty breathing or swallowing, wheezing, flushing, hives or rash, fever, headache, nausea, lightheadedness, shaking or chills, inform the study doctor right away. Your study doctor will give you some drugs, including tocilizumab, to treat these symptoms. Most patients have a mild reaction, but sometimes, the reaction may be severe or life threatening.

Neurotoxicity
Flotetuzumab may have potential for neurotoxicity. Neurotoxicity alters the normal activity of the nervous system. This can eventually disrupt or even kill neurons, key cells that transmit and process signals in the brain and other parts of the nervous system. You may experience headache, insomnia (sleep problems), dizziness (lightheadedness) and confusional state. Please inform the study doctor right away, if you experience any of the above events. ***Due to the potential for neurotoxicity with Flotetuzumab administration, you should not drive or operate heavy machinery while you are receiving Flotetuzumab and for 30 days after your last dose of Flotetuzumab administration.***

Corticosteroids*:* Dexamethasone will be given to participants once before the start of each flotetuzumab infusion or when the dose of flotetuzumab is increased during usual infusion. Corticosteroids (dexamethasone or other types) may be given more frequently to manage side effects of flotetuzumab. Most common side effects of steroids that may occur with prolonged use include: vision changes, swelling, rapid weight gain, sleep problems (insomnia), mood changes, acne, dry skin, thinning

skin, bruising or discoloration, slow wound healing, increased sweating, increased blood pressure which may cause headache, dizziness, or spinning sensation, nausea, stomach pain, bloating, muscle and bone weakness, changes in the shape or location of body fat (especially in your arms, legs, face, neck, breasts, and waist), and increased glucose in your blood.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Procedure-Related Risks or Discomforts
Trained medical personnel will perform all listed medical procedures and will make every effort to lessen any discomfort. Your study doctor will explain to you the details of the procedures and answer any questions that you may have.

Bone Marrow Transplant
Due to the mechanism of action of flotetuzumab, you may be at an increased risk of graft versus host disease (GVHD). The use of flotetuzumab in the setting of bone marrow transplant may cause interactions with other drugs used during bone marrow transplant such as antibiotics, and medications used to prevent and treat complications of bone marrow transplant.

Blood Tests
Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection. Possible side effects include, but are not limited to: fainting, bleeding, bruising, discomfort, dizziness, infection and/or pain at the puncture site.

Bone Marrow Aspirate/Biopsy Collection
Bone marrow is collected using a needle under local anesthesia to aspirate (draw out) marrow tissue from the inside of your bone (usually pelvic or hipbone). The risks of bone marrow biopsy and aspirate include pain, bleeding, bruising, and/or discomfort at the biopsy site. Infection is also possible.

Electrocardiogram (ECG)
The ECG involves placing adhesive patches on the skin. A slight redness or inflammation may appear due to an allergic reaction to the adhesive used to attach the patches to the skin.

If any of the side effects become serious, or if you notice any side effects not listed in this document, please tell your study doctor.

For more information about any of the risks and side effects, ask your study doctor.

There may be side effects and discomforts that are not yet known.

6. Are there risks related to pregnancy?

This research may hurt an embryo or fetus in ways we do not currently know. You should not become pregnant or father a baby while on this study because the study drug in this study can affect an embryo or fetus. Any participant who becomes pregnant during the study will be promptly withdrawn from the study. If you become pregnant during the study, you must notify the study doctor, and we will collect information about your pregnancy and its outcome.

Women should not breastfeed a baby while on this study.

It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

It is unknown whether this research may hurt an embryo or fetus.

7. Are there benefits to being in the study?

You may or may not benefit from being in this study. If you take part in this study, you may help others in the future.

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

You do not have to join this study. Other options include standard of care. If you do not join, your care at Johns Hopkins will not be affected.

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

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet. This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

It may also include the following, if applicable for the study:

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

10. Will you be paid if you join this study?

No.

11. 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 share your health information that it has already collected if the information is needed for this study or any follow-up activities.

Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

12. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as zip code) about you to track which groups of people participate in research. You may contact the NCI if you have questions about how this information is used.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Your privacy is very important to the study researchers. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your samples and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your samples and information will not know who you are. They also must agree that they will not try to find out who you are.

3. Your personal information will not be given to anyone unless it is required by law.

4. If research results are published, your name and other personal information will not be used.

14. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

15. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

16. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

17. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator, Dr. Jonathan Webster at 410-614-9106. If you wish, you may contact the principal investigator by letter. The address is 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 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Dr. Jonathan Webster at 410-614-9106 during regular office hours and at 410-955-4331 after hours and on weekends. If this doctor is not available, the operator will page the “on call physician.”

18. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and 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

Signature of Participant	(Print Name)	Date/Time

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

Signature of Interpreter/Witness to Consent Procedures	(Print Name)	Date/Time

(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

Signature of Interpreter/Witness to Consent Procedures	(Print Name)	Date/Time

(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).