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

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Role of IgE Bearing Cells in Chronic Idiopathic Urticaria

Application No.: IRB00105590 **National Clinical Trial Number:** NCT03111628

Sponsor: National Institutes of Allergy & Infectious Disease (NIAID)

Principal Investigator: Sarbjit S. Saini, M.D.
5501 Hopkins Bayview Circle
Baltimore, Maryland 21224
Phone: 410-550-2129
Fax: 410-550-2527

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 it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. 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 participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- 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.
- Biospecimens will be collected in 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.
- 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.

2. Why is this research being done?

This research is being done to improve our understanding of what white blood cells are involved in the disease call Chronic Idiopathic Urticaria (CIU).

In this study, we will use an U.S. Food and Drug Administration (FDA) approved therapy called omalizumab (Xolair) for patients with CIU who continue to have symptoms despite taking antihistamines.
By using this therapy, we aim to better understand which cells are involved in creating hives lesions.

Omalizumab (Xolair) is considered a standard care option for patients who are not fully controlled on an antihistamine.

People aged 18 years or older, with chronic hives without a known cause for at least 3 months not controlled by an antihistamine may join this study.

How many people will be in this study?
About 30 people are expected to take part in this study at the Johns Hopkins Asthma and Allergy Clinic.

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:

The study involves 11 visits over 15 weeks.

First visit, Screening Visit (Day -21):
At the first visit we will do the following:

- Review this consent form and answer any questions you have.
- *History and physical exam*: We will ask you questions about your medical history and perform a physical exam, which will include checking your vital signs (for example, heart rate, blood pressure, weight, and height), looking at your skin, and listening to your heart and lungs. At this initial screening visit, the study doctor will review the clinical care of your hives.
- *Blood Draw*: This will be done by putting a needle into your vein, which is the standard method used to obtain blood for tests. At this visit, about 1 tablespoon of blood will be drawn. This blood will be sent to the lab for basic blood counts, electrolytes (salts in your blood) and liver and kidney tests.
- *Urine Test*: We will do a pregnancy test on all women who are capable of having children. The results of this test must be negative to continue in this study.
- *Urine Collection*: We will collect approximately 10 cc of urine from all participants to test for prostaglandins (inflammatory markers).
- We will dispense a one week diary for recording your hive symptoms every day.

Screening period:
During the screening period (first 7 days), you will be asked to keep a diary of your daily symptoms (two entries per day). You will visit the study doctor's office at the end of the screening period to discuss your symptoms of hives and to review your diary. Your daily symptom scores will be used to

determine if you are eligible to continue in the study. Accurate maintenance of the diary is important for the study and will be required in order to continue the study.

Second visit, Run-in period (Day -14):

At this second visit, we will review your diary and eligibility criteria to determine if you can continue in the study. You may be asked to leave the study based on your symptom diary, labs from the previous visit, or your response to antihistamine treatment.

If you are able to continue to take part in the study, the following things will be done:

- *Focused History and physical exam*: We will ask you about any adverse events and other medications you are taking. We will ask you questions about updates to your medical history and perform a brief physical exam, which will include checking your vital signs (for example, heart rate, blood pressure), looking at your skin, and listening to your heart and lungs.
- *Blood Draw*: This will be done by putting a needle into your vein, which is the standard method used to obtain blood for tests. At this visit, about 2 tablespoons of blood will be drawn. This blood will be sent to the lab to perform studies on the cells we believe are involved in producing hives.
- *Urine Collection*: We will collect approximately 10 cc of urine from all participants to test for prostaglandins (inflammatory markers).
- *Urine Test*: We will do a pregnancy test on all women who are capable of having children.
- *Dispense Rescue Drug*: We will dispense to you a two week supply of diphenhydramine (Benadryl).
- *Run-in period*: During the run-in period (2 weeks), you will then be asked to keep an electronic diary of your daily hive symptoms (two entries per day) and record your use of as needed Benadryl. You will be asked maintain you daily anti-histamine throughout the rest of the study. Accurate maintenance of the diary is important for the study and will be required in order to continue the study. Based on your symptom diary, you may be asked to leave the study.

Third Visit, First Treatment (Day 0):

At the start of this visit we will review your run-in period symptoms. Based on your symptom diary, you may be asked to leave the study. Otherwise, you will proceed to the treatment phase of the study.

This treatment with omalizumab (Xolair) requires two injections (150 mg each) of omalizumab (Xolair) one right after the other. You will have to remain at the study center for 2 hours after the injection.

You will be given an epipen and information on how and when to use it.

We will also draw 6 Tablespoons of blood and perform a skin biopsy (take a pencil eraser sized piece of skin). We will also collect approximately 10 cc of urine.

During the treatment period (12 weeks), you will be asked to keep an electronic diary of your daily hive symptoms (two entries per day) and record your use of as needed Benadryl.

You will be asked to come for frequent visits in the next month to test how your symptoms and blood cells may be changed by the drug.

You will fill out a survey on your hives (Skindex).

Fourth and Fifth Visits (Day 1 and Day 3):

You will return to the center 1 day and 3 days after the first drug injection for blood sampling for lab study. On each of these visits, 2 tablespoons of blood will be drawn. We will also collect approximately 10 cc of urine. In addition, we will review your symptoms of hives recorded in your diary and ask you about current symptoms.

Sixth Visit (Day 6):
On the 6th day after the first drug injection, you will visit the center for review of the diary, a blood sample (2 to 6 tablespoons, depending on your symptoms), and another skin biopsy. The timing of this skin biopsy and larger blood sample (6 tablespoons) will depend on your symptoms. We will also collect approximately 10 cc of urine.

It is important to maintain an accurate symptom diary for the treatment phase of the study and it will be required in order to continue in the study.

Seventh and Eighth Visit (Day 10 and 20):
You will return to the center on the 10th and 20th day after the first drug injection. We will perform blood sampling (2 Tablespoons) and review of the diary. The second skin biopsy and larger blood sample (6 Tablespoons) can occur on visits 7 or 8 if not completed at visit 6 based on your hive symptoms. We will also collect approximately 10 cc of urine.

Ninth Visit, Second Drug treatment (Day 30):
About 1 month after the first drug injection, you will visit the center for a second drug treatment. This treatment with omalizumab (Xolair) requires two injections of omalizumab (Xolair). You will have to remain at the study center for 2 hours after the injection.

We will draw 6 Tablespoons of blood and perform the second skin biopsy if not done at an earlier visit. We will also collect approximately 10 cc of urine.

We will also review your diary. It is important to maintain an accurate symptom diary for the treatment phase of the study and it will be required in order to continue in the study.

We will supply you with more Benadryl if needed.

Tenth Visit, Third Drug treatment (Day 60):
About 1 month after the second drug injection, you will visit the center for a third and final drug treatment. This treatment with omalizumab (Xolair) requires two injections of omalizumab (Xolair). You will have to remain at the study center for 2 hours after the injection.

We will also draw 2 Tablespoons of blood, collect approximately 10 cc of urine and review your diary. It is important to maintain an accurate symptom diary for the treatment phase of the study and it will be required in order to continue in the study. We will supply you with more Benadryl if needed.

Eleventh Visit, Final Visit (Day 90):
About 1 month after the third drug injection, you will visit the center for the final visit. This visit will involve a physical exam, urine sample (10 cc), skin biopsy and blood sample (3 Tablespoons). We will collect your diary. You will fill out a survey on your hives (Skindex). We will inform you of the results of the tests for basic blood counts, electrolytes (salts in your blood) and liver and kidney tests.

Future Contact
We would like your permission to contact you about other studies that you may be eligible for in the future.

Please check box and sign to indicate your choice below:

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

Request to collect and store biospecimens for future research
As part of this research study, we would like to ask you to let us store your biospecimens and health information for future research on CIU and other allergic diseases.

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

Will you allow us to store the biospecimens we collect for this study for use in future research*?*

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

How long will you be in the study?
You will be in this study for 15 weeks total.

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

Omalizumab (Xolair)
In CIU patients, the most commonly observed adverse reactions from 3 CIU studies for omalizumab (Xolair) at 300 mg, were: headache 6%), nasopharyngitis (inflammation of the throat and nasal passages) (7%), arthralgia (joint pain) (3%), viral upper respiratory infection (1%), nausea (3%), sinusitis (5%), upper respiratory tract infection (3%), cough (2%), urinary tract infection (2%), fungal infections (2%), anxiety (2%) and swelling of the hands and feet (2%). Injection site reactions of any severity occurred during the trials in more omalizumab (Xolair) treated patients; [2.7%] at 300 mg, compared with 0.8% in placebo-treated patients.

Since omalizumab (Xolair) has been approved, there have been reports of hair loss as well as some patients having a severe drop in blood platelets, the cells in the blood that help stop bleeding. Because the number of these cases is small, it is not possible to determine whether these events were associated with omalizumab (Xolair).

The most serious side effects seen in other studies are anaphylaxis and cancer. Anaphylaxis is a severe allergic reaction that could result in death. Signs and symptoms of anaphylaxis may include hives, swelling of the throat or tongue, trouble breathing, low blood pressure, lightheadedness, and loss of consciousness. Anaphylaxis has been reported to occur after administration of omalizumab (Xolair) in asthma clinical trials and in postmarketing spontaneous reports. Anaphylaxis has been reported to occur after administration of omalizumab (Xolair) in clinical studies (1 out of every 1000 subjects, 0.1%) and in post-marketing experience (at least 2 out of every 1000 subjects 0.2%). Reactions have occurred after the clinic observation period post-injection, so you need to be aware of the signs and symptoms of anaphylaxis and contact your study doctor immediately. A severe allergic reaction would require immediate medical treatment and could result in permanent disability or death. A study showed that among omalizumab (Xolair) users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with omalizumab (Xolair). Based on this, The American Academy of Allergy, Asthma & Immunology (AAAAI) guidelines support monitoring patients for 2 hours for the first 3 injections of Xolair and the prescription of an epipen injector.

You must remain in the clinic after your injection(s) as part of routine monitoring. You will be dispensed an epi-pen to use in case you have signs or symptoms of anaphylaxis. You will be instructed on how and when to use the epi-pen. You should carry this with you during the study. If you need to use the epi-pen, you will be instructed to contact 911 for further medical care, and notify the study doctor after you have received emergency care.

Other severe reactions that have been seen with omalizumab (Xolair) with less than 1% occurrence are: chest tightness and stroke like symptoms.

A small number of cancer cases have been reported in research studies of omalizumab (Xolair). More subjects who received omalizumab (Xolair) (5 out of every 1000 subjects 0.5%) reported cancer than those subjects who received placebo or other control treatment (2 out of every 1000 subjects 0.2%). The types of cancer observed in omalizumab (Xolair)-treated subjects were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. While the total number of affected subjects is too small to demonstrate that omalizumab (Xolair) causes cancer, the possibility of a relationship between omalizumab (Xolair) and the development of cancer cannot be ruled out.

The FDA review of the 5-year safety study in September 2014 found no difference in the rates of cancer between those patients being treated with omalizumab (Xolair) and those who were not being treated with omalizumab (Xolair). However, due to limitations in the 5-year study, we cannot rule out a potential risk of cancer with omalizumab (Xolair).

FDA review of a 5-year safety study found a slightly higher rate of heart and brain blood vessel problems occurred in patients being treated with omalizumab (Xolair) compared to those patients not treated with omalizumab (Xolair). The heart and brain blood vessel problems included mini-strokes known as transient ischemic attacks or TIAs; heart attacks; sudden, unexpected chest pain; high blood

pressure in the arteries of the lungs called pulmonary hypertension; and blood clots in the lungs and veins. Although the data are suggestive of a serious safety signal, due to weaknesses in how the safety study was designed and carried out, we are unable to definitively confirm or determine the exact increased level of these risks with omalizumab (Xolair).

Omalizumab (Xolair) contains a small amount of a specific sugar (sucrose). The amount of sucrose in a vial of omalizumab (Xolair) is 145 mg, and one dose of omalizumab (Xolair) will be composed of up to 2 vials. Subjects with certain disorders related to how their bodies handle sugar (diabetes mellitus, glucose-galactose malabsorption syndrome, fructose intolerance, or sucrose-isomaltase deficiency) should discuss the specific impact of this small amount of sugar and the associated risks with the study doctor.

Fever, Arthralgia, and Rash: Some subjects taking omalizumab (Xolair) have experienced signs and symptoms including arthritis (joint inflammation), arthralgia (joint pain), rash, fever and lymphadenopathy (swollen/enlarged lymph nodes) starting 1 to 5 days after receiving an omalizumab (Xolair) injection. These signs and symptoms are similar to those seen in subjects with a condition called serum sickness, which is an immune reaction to certain types of medications. The study doctor will stop omalizumab (Xolair) if you develop these signs and symptoms.

If you experience dizziness, fatigue, syncope (fainting) or somnolence (drowsiness), you should not drive or use machines.

As is true for participation in any research study, there may be unknown and potentially serious or lifethreatening side effects that could occur with omalizumab (Xolair). There may be side effects and discomforts that are not yet known.

Benadryl (Diphenhydramine):
Diphenhydramine (Rescue medication) may cause sedation.

Epipen:
The most common side effects include increase in heart rate, stronger or irregular heartbeat, sweating, nausea and vomiting, difficulty breathing, paleness, dizziness, weakness or shakiness, headache, apprehension, nervousness or anxiety. These side effects usually go away quickly.

Blood Drawing Risks:
During this study, blood will be drawn from a vein to perform tests that allow your doctors to see how you are doing. Drawing blood may cause pain where the needle is inserted, and there is a small risk of bruising and/or infection at the place where the needle is inserted. Some people experience dizziness, upset stomach, or fainting when their blood is drawn.

Skin biopsy risks:
Risks of skin punch biopsy include pain, swelling, bleeding, bruising, infection, and scarring at the site of the biopsy. Allergic reactions to lidocaine are rare, but may cause hives, itching, asthma, hay fever, or a drop in blood pressure. Significant bleeding from biopsy sites is rare. Infection of a biopsy site is unusual, but may occur. A scar the size of a pencil eraser will result at the biopsy site. This scar will be

slightly raised or depressed below the surface of the skin and will be a little lighter or darker than the rest of your skin.

Confidentiality: There is the risk that information about you may become known to people outside this study.

5. Are there risks related to pregnancy?

Reproductive Risks

The effects of omalizumab (Xolair) on a fetus or embryo are unknown and may be harmful; therefore, you should not become pregnant or father a child while in this study.

Women must be sterile, postmenopausal, or using a highly effective form of birth control throughout the study.

To participate in this study, you must agree to use an effective method of birth control to prevent pregnancy. Woman capable of having children must use one or more of the following acceptable methods of contraception: surgical sterilization, hormonal contraception, and/or double-barrier methods. Check with your study doctor about the methods of birth control to use and how long to use them.

Women capable of having children will be required to take a pregnancy test prior to study entry and at each visit prior to dosing of omalizumab (Xolair). The result of the test must be negative for you to continue to take part in the study.

If you are pregnant, you cannot be in this study because of possible harm to the fetus. If at any time during the study you suspect that you have become pregnant, please notify the study doctor immediately.

You should not nurse (breastfeed) a baby while on this study because omalizumab (Xolair) may enter breast milk and the potential of harming your baby is unknown at this time.

This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in this study. However, your participation in the study may benefit society by helping us learn more about better ways to treat hives in the future.

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

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other options include:

- Getting no treatment
- Getting standard treatment for your condition without being in a study (including getting omalizumab (Xolair)).
- Getting a different experimental treatment/taking part in another study.

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

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

No.

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

- You will be paid $40 dollars for the 8 study visits that do not require skin biopsies (for a total of $320).
- You will be paid $75 for each of the 3 visits that involve skin biopsies (for a total of $225).
- This means that if you complete all study visits, you will be paid a maximum of $545 for taking part in the study.

You will be provided with a parking voucher at each visit.

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.

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

11. 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.

12. 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 ([which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

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.

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. 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 your participation. You may contact the NCI if you have questions about how this information is used.

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 redisclosed.

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.

13. 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.

14. 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.

15. What does a conflict of interest mean to you as a participant in this study?

A researcher has a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to Dr. Eric Oliver, 410-550-2007. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

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

a. 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.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Saini at 410-550-2129. 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.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Saini at 410-550-2129 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. Sarbjit Saini at 410-550-2129 during regular office hours and at 410-978-3706 after hours and on weekends.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, 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 biospecimens and information with our research sponsors and partners.

17. 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 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

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 (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

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

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 (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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