HIVTR-CCR5

CONSENT TO BE A RESEARCH PARTICIPANT

**Version of the Informed Consent – DAIDS-ES 20730**

**Impact of CCR5 Blockade in HIV+ Kidney Transplant Recipients**

**RECIPIENT CONSENT**

CONSENT VERSION 4.0 /February 28, 2019
PROTOCOL VERSION 4.0 /February 28, 2019

***[NOTE: Site specific sections are identified in bold italics, and will be tailored at each center accordingly]***

**INTRODUCTION**

We invite you to take part in a medical research study at the ***[ NAME OF CENTER].*** Your study doctor(s) **[NAMES, MD]** from the **[NAME OF CENTER]** will explain the study to you.

First, we want you to know that:

- Taking part in this research is entirely voluntary.
- You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled..
- You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your ***[NAME OF CENTER]*** doctors or research team before you agree to the study. Also, if you have a living donor, they will be informed that you are HIV-positive.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at ***[NAME OF CENTER],*** or with family, friends or your personal physician or other health professional.

**Study Team**

Your study team consists of doctors, nurses and other specialized medical professionals, who are experienced in taking care of patients with HIV. You will be interacting with some if not all of the study team members at specific study visits. However, a study team member will always be available to you if you have a question about the study, your response to treatment, or the study drugs.

**Why is this study being done?**

A research study is being conducted to find out if maraviroc (a drug used to treat HIV infection) and immunosuppressant drugs (drugs that prevent your body from attacking/rejecting your transplanted kidney) will prevent rejection and help HIV positive subjects keep their transplanted kidney longer. You are being asked to join this research study because you have HIV infection and end-stage kidney disease

and plan to have a kidney transplant. Kidney transplantation is a good option for people with kidney disease but there is still a lot to learn about how to best care for the HIV infected kidney transplant patients.

The purpose of this study is to evaluate the safety and tolerability of maraviroc in the HIV+ kidney transplant recipient, and to find out if using both immunosuppressant drugs and maraviroc (an HIV drug) will help your transplanted kidney work better. Although maraviroc is an HIV drug, it is being used to see if it can reduce rejection in your transplanted kidney.

This research study is sponsored by the National Institute of Allergy and Infectious Disease (NIAID). The drug will be provided free to you by the manufacturer, ViiV Healthcare.

**How many people will take part in the study?**

This study will enroll about 130 participants. **[X]** participants are expected be enrolled at this center.

**What will happen if you take part in this research study?**

Your participation in this study may last up to about 3 years after your kidney transplant surgery. You will be assigned by chance to one of two groups. One group will receive the study drug (maraviroc) and one group will receive a placebo (inactive substance). You will be asked to take either maraviroc or placebo for the duration of the study. You have a 50/50 chance of being assigned to either group. This is a double-blind study, which means that neither you nor the study doctor or study staff will know which treatment you are receiving. However, in an emergency, the study doctor can get this information.

Samples (blood, lymph nodes, biopsy slides, and tissue) are collected during the study. Some of these samples will be collected as part of your standard of care if you are in the study or not, but will be recorded in your research record. Some samples will also be collected for research tests. Research tests help us learn more about your disease, the immune system and response to drugs or treatment. The results of the research tests will not be shared with you. The research samples will not identify you. Before any study procedures are completed, your study doctor will discuss this study with you. You will have the opportunity to ask questions and time to think about whether you wish to participate. Once you have signed this consent, you will need to come in for some tests to see if you are eligible to be in this study.

If you have a living donor, your donor will be asked if they would like to participate in this study by providing a blood sample at the time of the organ donation. This blood sample will also be used to help us learn more about your disease, the immune system and your response to drugs or treatment. Their decision to participate will not be disclosed to you.

**Before you begin the main part of the study…**

Before your transplant, your medical records will be reviewed and tests will be done as standard care to see if you can be in this study. These are called "screening" tests. Some of these tests will be done by your primary medical care provider (the person that sees you for regular visits and checkups). All test results that may affect your health or treatment will be discussed with the primary medical care provider. The following screening procedures will be done before your transplant: physical exam, medical records review, blood tests, TB screening and vaccination review, and chest x-ray.

To be eligible to participate in this study, you will need to be on a non-protease inhibitor based HIV regimen (preferably an integrase-based regimen). The reason for this is that drugs classified as "protease inhibitors" can make it difficult to control the drug levels for some medications you will be taking after your transplant. Regardless of your participation in this study, it is typically advised to not be on a protease inhibitor based HIV regimen post-transplant. If you need to change regimens, the study team will discuss this with your primary care provider who will determine if it is safe for you to switch. Your primary provider will make the switch if they feel it is safe.

Once eligible, you will be enrolled in the study. You will then have your primary provider send your HIV viral load and CD4 T cell counts to the study center every 3 – 4 months until you receive your transplant or are no longer eligible for transplant and/or the study. Table 1 below outlines what will happen at each study visit. An explanation of all the study procedures is listed in **Table 2. (Description of Procedures)** below.

**During the main part of the study**

After you receive your transplant you will have 12 study visits. During these visits you will receive blood tests for standard of care lab results. At some visits, you will have blood drawn for research, and a kidney biopsy. The biopsy will occur around 6 months after your transplant. If you do not receive a biopsy as part of your regular transplant care, you will receive it for this study. You will also have a biopsy if your study doctor thinks you may have early signs of rejection. See **Tables 1 and 2** below for more information.

| Table 1. Pre and Post Transplant Procedures | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Procedures** | **Screening** | **Day 0** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 13** | **Week 26** | **Week 39** | **Week 52** | **Years 2-3 (53-156)** Every 6 months |
| | **Visit 1** | **Visit 2** | **Visit 3** | **Visit 4** | **Visit 5** | **Visit 6** | **Visit 7** | **Visit 8** | **Visit 9** | **Visit 10** | **Visits 11-14** |
| **Review of Medical Records plus Physical Exam** | ✓ | ✓ | | | | | ✓ | ✓ | ✓ | ✓ | ✓ |
| **Blood Draw for standard of care labs** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| **TB Screening/ Vaccination Review** | ✓ | | | | | | | | | | |
| **Chest X-ray** | ✓ | | | | | | | | | | |
| **Pregnancy Test** | | ✓ | | | | | | | | | |
| **Biopsy** | | | | | | | | ✓ | | | |
| **Iohexol GFR samples drawn** | | | | | | | | | | ✓ | |
| **Blood Draw for research studies** | ✓ | ✓ | | | ✓ | | ✓ | ✓ | ✓ | ✓ | **Y2,Y3** |
| **Urine collection for banking** | ✓ | ✓ | | | | | | ✓ | | ✓ | |
| **Lymph nodes collected for research studies** | | ✓ | | | | | | | | | |
| **[UCSF Participants only: PK Study]** | | | | | | | ✓ | | | | |

| Description of Procedures | |
|---|---|
| **Medical Records Review/Physical Exam** | The study doctors will review all of your medical history, all the medications you are taking, and how your body is feeling. |
| **Blood Tests for standard of care labs.** | About **2.5 tablespoons** of blood will be drawn to look at your overall health and how well your immune system (the body's natural defense against illness) is working. The blood tests will also look for any current or past infections. |
| **Tuberculosis (TB) Screening and Vaccination** | You will be asked to have a skin test for tuberculosis (an infection of the lungs and other organs) called a PPD test. For this test, a small injection is placed just |

| | |
|---|---|
| **Review** | under the skin of the arm. If you test positive, or have tested positive in the past and have never been treated for TB, you will begin a 9-month course of medications before being eligible to receive a transplant. If you have ever had a positive skin test for TB, you will have chest x-rays instead of a skin test.<br><br>Your study doctor will review your vaccination history. Your study doctor will let you know if you need to get additional or new vaccinations. |
| **Chest X-ray** | X-rays are painless tests that use radiation to create pictures of the structures inside of your chest like your lungs, heart and blood vessels. No instruments are inserted into your body and no surgery is done for this test. |
| **Pregnancy Testing** | If you are a female who can have children, you must have a negative pregnancy within 30 days prior to the transplant procedure. If you become pregnant during the study you should notify the study doctor immediately. The outcome of any pregnancy test will be recorded. |
| **Biopsy** | The biopsy site will be cleaned and a numbing medicine will be injected into the area where the biopsy will be done. Usually a small cut (less than ¼ inch in size) is made in the skin. A small needle is inserted just under the skin and a small piece of the kidney is removed. You will be asked not to breath and to remain completely still during this procedure. Medications may be given to help you relax. You will be asked to sign a separate consent form for this procedure. |
| **Iohexol Glomerular Filtration Rate (GFR)** | GFR can tell doctors how well your kidneys are working. The GFR test will begin with an injection of a dye, Iohexol, intravenously. Iohexol is a non-toxic dye regularly used in special X-ray studies. Over the course of the test, 3 blood samples will be collected. To avoid multiple needle sticks, a catheter may be placed in a vein (intravenous catheter or IV) and used to draw blood. The total amount of blood collected is no more than 2 tablespoons. The samples taken will measure your kidneys' ability to remove the contrast agent from your blood. No urine samples are needed for this test. |
| **Blood Draw for research studies** | About 5 – 6 tablespoons of blood will be drawn at specified study visits to be used for research. You will not receive any results from these tests. |
| **Urine collection for banking** | About 50 – 100ml of urine will be collected at specified visits to be banked for future testing if funding becomes available. You will not receive any results from these tests. |
| **Lymph nodes collected for research studies** | A lymph node sample will be collected during the transplant procedure to be used for research. You will not receive any results from these tests. |
| **[UCSF Participants only: PK Study]** | Because we do not know how the medications you are taking will interact with each other, multiple blood samples will be collected during a day-long stay in the General Clinical Research Center (GCRC) at various times over a 12 hour period. This will be done 3 months after your transplant. You will be required to fast overnight prior to this visit.<br><br>A small plastic tube will be inserted in a vein in order to avoid multiple needle sticks for the collection of these blood samples. Approximately 1 teaspoonful of blood will be collected at each of multiple time points over 12 - 24 hours (a total of approximately 10 teaspoonfuls). |

In addition to the visit based procedures, if you have a kidney biopsy for suspected rejection, we will also collect blood samples for research as well as a urine sample for future testing.

Genetic information will be recorded from specimens collected for this study. The specimens will be used in experiments planned for this study and with your permission for future studies not yet planned. Your samples will not be looked at for other genetic conditions, genetic cloning, or paternity testing. We will keep all information recorded private as much as possible. However, because genetic information is unique to you, complete confidentiality cannot be guaranteed.

**What side effects or risks can you expect from being in the study?**

Treatment and procedures in this research study may involve risks that are not possible to predict. You will be informed of any new risks that may be identified during the study. These unforeseen risks might affect you during your participation in the study and/or some point in the future. Please ask your study doctor or the research staff to explain any procedures or risks that you do not understand.

As a result of participation in this research study, you are at risk for the following side effects.

- ***Risk of Maraviroc (Selzentry)***

  The following serious side effects have been associated with the use of MVC:

  Liver problems (liver toxicity) have occurred in people who took MVC. An allergic reaction may happen before liver problems occur. Stop taking MVC and call the study doctor right away if you get any of the following signs or symptoms:

  - Rash on your body (allergic reaction)
  - Yellowing of the skin or whites of your eyes
  - Dark urine
  - Vomiting
  - Stomach pain
  - If your healthcare provider informs you that you have an elevated liver-related function test. People who are co-infected with hepatitis B or C might be at higher risk of having liver problems.

  Heart problems, including heart attack.

  Low blood pressure when standing up, which can cause dizziness or fainting. People who have serious kidney problems may be at increased risk for dizziness and fainting.

  In addition to the serious side effects listed above, additional side effects include:

  - Colds
  - Cough
  - Fever
  - Rash
  - Diarrhea
  - Swelling of parts of the body
  - Flu and flu-like symptoms

- Muscle aches, spasms and pain
- Stomach pain and bloating
- Sleeping problems
- Runny, congested nose
- Problems with urination
- Low white blood cell counts (neutropenia)

NOTE: Because of how the drug works in your body, there is a possible increased risk for getting other infections or cancer, although there is no evidence from the clinical trials of an increase in serious infections or cancer.

Maraviroc contains soy lecithin. If you have a medical history of allergy to soy (soya or soybeans) or peanuts, you may develop an allergic reaction to maraviroc. Before starting maraviroc, you should inform your health care provider if you are allergic to soy or peanuts.

- ***Randomization risks***
  You will be assigned to a treatment program by chance. One group will receive the study drug (maraviroc) and one group will receive a placebo (inactive substance). The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments. Neither you nor the study doctor or study staff will know which treatment you are receiving. However, in an emergency, the study doctor can get this information.

- ***Use of Combination Antiretroviral Drugs***
  The use of potent antiretroviral drug combinations may be associated with an abnormal placement of body fat and wasting. Some of the body changes include:
  - Increase in fat around the waist and stomach area
  - Increase in fat on the back of the neck
  - Thinning of the face, legs, and arms
  - Breast enlargement"

  Maraviroc is not known to cause these symptoms, however.

- ***Risk of blood draw***
  The risks of having blood taken are discomfort, bleeding, fainting, small blood clot or swelling to the vein and area surrounding where the blood is drawn, bruising where the needle enters the skin and infection. There is also a very small chance of infection at the needle puncture site. You will never have more the 10 tablespoons of blood collected during a 6-week period for research.
- ***Risk of Biopsy***
  In this study, you will have more kidney biopsies than you would usually get with standard care. These additional kidney biopsies will be done to look for early signs of rejection and for research purposes. The risks of a kidney biopsy include bleeding, infection, pain and, very rarely, loss of the transplanted kidney due to hemorrhage (uncontrolled bleeding of the kidney) and bleeding in or around the kidney that may cause a fall in blood pressure and rise in heart rate. In very rare cases, a hole between blood vessels can form, called a fistula. Complications of the biopsy procedure may require a blood transfusion; or very rarely this may require surgery or cause loss of the kidney. Other risks include pain and bleeding at the site of biopsy, infection, discomfort,

and bloodstained urine. To lessen these risks, the biopsy procedure will be done using ultrasound guidance. There is a very small chance that a small scar may form.

- ***Risk of Iohexol Glomerular Filtration Rate (GFR)***
  The risks with the GFR test are associated with the dye injected intravenously and blood draws. The risks associated with the injection and blood draws are bruising, infection, redness, swelling, tenderness at site of the needle entry, and a remote chance of fainting. There are minimal risks from the dye used in the GFR test. The most common side effects are nausea, warmth, headache, and dizziness. You could also experience cough, vomiting, and anxiety. There is a risk of allergic reaction, which will be treated as needed. If you experience an adverse event associated with this test, then the test may be stopped and you will be followed closely.

- ***Risk of Chest X-Ray***
  Chest x rays have few risks. The amount of radiation used in a chest x ray is very small. A lead apron may be used to protect certain parts of your body from the radiation. The test gives out a radiation dose similar to the amount of radiation you're naturally exposed to over 10 days.

- ***Risk of Privacy and Stored Samples***
  There may be unknown risks associated with the storage and analysis of your samples or the information resulting from the analysis of your samples. For example, if future research involves genetic testing there's a potential risk associated with the release of private health information, though every effort will be made to maintain your confidentiality.

- ***Pregnancies, Birth Control***
  We do not know if the drug may have bad effects on an unborn baby. It is therefore very important that you do not take part in this study if you are pregnant, plan to become pregnant within at least 1 month of the end of the study, or are breast-feeding.

  If you become pregnant during the study, it is important that you tell us right away. All pregnancies will be reported to the Antiretroviral Pregnancy Registry.

  WOMEN : If you become pregnant, or if you think you are pregnant, tell the study doctor immediately. There could be risks to an unborn child in this study. If you become pregnant during the study, you may be discontinued from study participation for safety reasons. If you become pregnant within 28 days after you have stopped taking maraviroc, we ask that you contact your study doctor for safety monitoring. In either case, please make your obstetrician aware of your study participation. Your study doctor will ask that you, or your obstetrician, provide updates on the progress of your pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

**[OPTIONAL: For sites with an IRB approved HOPE Act Protocol]**

- ***HIV+ donor***
  If you are enrolled in a study at [SITE NAME] so that you can be offered a kidney from a deceased donor who is HIV+, you will also be required to sign a separate consent form for that study. You will be expected to complete all of the study visits and procedures for that study in addition to the study visits and procedures for this study.

The consent form for that study will explain the possible risks of accepting an HIV+ kidney. The main risk is that there is a chance that the transplanted organ may contain a type of HIV that cannot be controlled by the HIV medicines that you use now. If so, you may have to change your HIV medicines to control the new type of HIV, and the new medicines may interfere with the drugs you are taking to prevent rejection of your new organ.

**Are there benefits to taking part in the study?**

If you agree to take part in this study there may be no direct medical benefit to you. The information learned from this study may someday benefit future HIV positive kidney transplant recipients. You may benefit by being closely followed for your health status.

The study doctor will tell you about any new information (good or bad) that may affect your willingness to continue in this study. If new information is provided to you, your consent to continue participation in this study will be re-obtained.

**What other choices do you have if you do not take part in this study?**

The study doctor and/or study staff will talk with you about this study and other options available to you. You may choose not to be in this research study. Your decision to participate in this study will not affect your medical care.

**Can you stop being in the study?**

You may decide not to take part or to leave the study at any time. If you decide to leave the study, there is no penalty or loss of benefits in your routine medical care or any other benefit(s) that you would otherwise be entitled to receive. In addition, you should talk to your study doctor who will discuss future treatment and procedures for your continued care.

You may be discontinued from study treatment if the study doctor feels it is not in your best interest to continue in this study.

Also, you may be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to, the following:

- You are unable to complete required study treatments and examinations.
- If you are not predicted to receive a transplant by the end of year 4 of the study.
- The study is stopped by the Institution, the IRB (a committee that watches over the safety and rights of research participants), the Sponsor(s), pharmaceutical supporter(s) or designee, or by the Food and Drug Administration (FDA) or other health authorities.

If you are removed from the study, your study doctor will contact you to discuss stopping procedures and your future care.

**What are the costs of taking part in this study?**

Costs related to usual clinical care of your HIV infection, kidney transplant or other medical problems will be billed to you and/or your insurance provider(s). Your insurance company may cover costs associated with standard medical care provided to you during your participation in this study. These costs include routine clinic visits and procedures. Some health plans will not pay the costs for people taking part in a research study. Please contact your insurance company to find out what they will pay. If

your insurance company doesn't pay for all charges, you may be responsible for those charges. There will be no charge to you or your health insurance company for any costs which are directly related to this study.

**Will you be paid for taking part in this study?**
You will receive no payment for taking part in this study.

**What happens if I am injured because I took part in this study?**

It is important that you tell your study doctor, _____ *[investigator's name(s)]*, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ *[telephone number]*.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the **[name of center]** will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the **[name of center]** depending on a number of factors. The **[name of center]** and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at **XXX- XXX-XXXX**.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

The U.S. National Institutes of Health (NIH) does not have a mechanism to provide compensation for research related injury.

**How will information about you be kept confidential?**
Your medical and research records will be confidential to the extent permitted by law. Efforts will be made to keep your personal information private. However, we cannot guarantee complete confidentiality.

You will be identified by a code, and personal information from your records will not be released without your written permission. You will not be identified in any publication or in the sharing of your data about this study. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other traditional personal identifiers. The purpose is to share and make study data available to other researchers.

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include:

- The Institutional Review Board involved in the approval of study conduct
- the National Institute of Allergy and Infectious Diseases, (NIAID) sponsor of the research ,
- NIAID representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring or analyzing the study.
- the U.S. Food and Drug Administration,
- the OHRP,
- other local, US and international regulatory entities,
- other State and Local health authorities, and
- Pharmaceutical or device companies(s) and their commercial partners may review your medical and research records for regulatory purposes.

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.

**Who can answer questions about the study?**

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s)_____ ***[name(s)]*** at _____ ***[telephone number(s)]*.**

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at XXX-XXX-XXXX. *[If there are additional informational sources related to the study (e.g., patient representatives or individuals at other study sites as appropriate), list here with contact information.]*

**Stored samples and Future Research**

The investigators conducting this study would like your permission to store and share extra/ leftover/unused samples and information resulting from the analysis of samples of biological specimens (e.g., blood, tissue, and urine) collected during the course of this study to be used in the future for tests that aren't yet planned. These tests may or may not be related to the study of HIV infection and kidney transplantation.

Your stored samples may be used to obtain knowledge about genetic information in relation to your HIV infection, end stage renal disease, related diseases, and/or the immune system. Research tests may include genetic tests. Genetic tests study an individual's inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate a human body. The results of tests done on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

Researchers are required to protect your privacy and to keep your information private to the extent permitted by the law. There may be risks in allowing the storage or analysis of samples and information. Once a study is complete, all personal health information (PHI) will be removed from the study database and sample labels. PHI that will be removed include your initials, clinical center name and location, dates (i.e., date of birth and date of transplant), and study identification numbers. Your samples will be randomly coded and cannot be linked to you. Although we remove all PHI, we cannot guarantee confidentiality. For example, if the research is for genetic testing it is possible that it could be traced back to you because your genes are specific to you.
There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to a specific condition. The purpose of storage and sharing data is to make information available for use in health research. Collecting, storing, sharing information and making it available for other studies may help people in the future.

Samples will be stored at Precision Bioservices. If you decide to allow storage, your samples and information may be stored for 5 years unless additional funding is available to continue storing them.

Although your stored research samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information

There may be unknown risks associated with the storage of samples and linked information. For example, if the future research involves genetic testing it is possible that it could be traced back to you because your genes are specific to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

You can change your mind at any time and ask to have your samples destroyed. This request should be made in writing to the study doctor. If you make this request, all remaining stored samples will be destroyed. However, the results of any previous tests using your stored samples will be used. Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

**Please indicate your response below:**

**I agree to the storage and sharing of samples (blood, urine and/or tissue) and information for genetic tests not currently planned.**

☐ **Yes** ☐ **No**

_____

**Initials of Research Participant**

**I agree to the storage and sharing of samples (blood, urine and/or tissue) and information resulting from the analysis of my samples for other tests not currently planned.**

☐ **Yes** ☐ **No**

_____

**Initials of Research Participant**

**SIGNATURE PAGE**

*(Site may use the site-specific signature page if required)*

**Please sign below if you agree to take part in this study.**

- **you have read the informed consent and/or had it explained to you**
- **you were given the opportunity to ask questions about the information, and**
- **you voluntarily agree to take part in the study**

| _____ | _____ | _____ |
|---|---|---|
| **Research Participant's Name** *(Typed or printed)* | **Research Participant's Signature** | **Date** |

**Signature of person explaining and obtaining the consent:**

| _____ | _____ | _____ |
|---|---|---|
| **Name and Title** *(Typed or printed)* | **Signature** | **Date** |

(NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the research participant. A copy should be placed in the research participant's medical record, if applicable.)