



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

DONOR 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.

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.

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 the body from attacking/rejecting the 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 are donating a kidney to someone that is enrolled in this research study. 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 recipients, and to find out if using both immunosuppressant drugs and maraviroc (an HIV drug) will help the transplanted kidney work better. The purpose of requesting a blood sample from you (the donor) is to perform research tests that will help us understand how to best care for HIV infected kidney transplant patients, and will be used to estimate the strength of the immune response in the recipient of the kidney that you donated.

This research study is sponsored by the National Institute of Allergy and Infectious Disease (NIAID).

How many people will take part in the study?

This study will enroll about 130 participants on the list to receive a kidney transplant. [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 will end after your blood draw on the day of your organ donation. These samples are used for research tests. Research tests help us learn more about kidney transplant, 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.

On the day of your organ donation (before your procedure) your blood will be drawn and your medical records will be reviewed. Table 1 below outlines what will happen at each study visit. An explanation of all the study procedures is listed in Table 2 below.

Table 1. Procedures	
Procedures	Day of organ donation
Review of Medical Records	✓
Blood Draw	✓

Table 2. Description of Procedures	
Medical Records Review	The study doctors will review all of your medical history.
Blood Tests	About 2 – 3 tablespoons of blood will be drawn for research.

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?

- **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.
- **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.

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.

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.

Your decision to participate or not to participate in this study will not be disclosed to the person that you are donating your kidney to.

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.

What are the costs of taking part in this study?

The blood draw will be provided to you at no cost.

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 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 blood 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 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 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, or longer if additional funding is obtained.

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, efforts will be made to locate all remaining stored samples to 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) and information for genetic tests not currently planned.

Yes No

Initials of Research Participant

I agree to the storage and sharing of samples (blood) 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.)