National Institute of Allergy and Infectious Diseases (NIAID)
Division of Allergy, Immunology and Transplantation (DAIT)
Donor Consent Template

1. TITLE OF CLINICAL RESEARCH STUDY

"Regulatory T Cell Modulation in Kidney Transplantation with Biologic Blockade of Dual Effector Pathways, CD28 and IL-6"
Protocol Number: CTOT-24
Short Title: Treg Modulation with CD28 and IL-6 Receptor Antagonists

2. YOUR PARTICIPATION IS VOLUNTARY

We will explain this research study to you. You have the right to ask questions.
Research is different from regular medical care. When you receive standard medical care, your physician makes decisions based only on what is in your best interest. When you are in a research protocol, your physician is still bound to act in your best interest, but some medical decisions will be directed by the research study.

- Taking part in this study is your decision.
- You may change your mind about being in this study at any time.
- You will be given a copy of this consent form for your records

3. PRINCIPAL INVESTIGATOR

(Insert site Principal Investigator as well as other investigators if desired.)

4. KEY INFORMATION FOR THE STUDY

This document contains information that will help you decide whether to take part in a research study. We encourage you to read the entire document. All the information is important, but here are some key points to help you understand the study. Additional information is available in the document, in the sections noted in italics, below.

- This research study is for people who will receive a kidney transplant from a living donor. The living donor is also asked to participate by giving blood for research tests.
- The study will see if a new combination of 5 anti-rejection drugs is safe and will prevent rejection of the transplanted kidney with fewer side effects than the standard treatment. While each drug has been used separately in humans and has been found to be safe, this combination of drugs will be used for the first time in this study. *See Section 5, Introduction and Background; and Section 6, Purpose of the Study*
- The study requires donors to make 1 office visit for a blood draw. *See Section 7B, Study Overview/Visit Schedule*
- Study donors will have one extra blood draw that is not part of routine care for kidney transplant donors.
- The risks of blood draws are pain, bruising, infection, redness, and swelling at the sight of needle entry. There is a chance you may feel dizzy while your blood is being drawn.
- There is no direct medical benefit to you from being in this study. The information learned from this study might someday benefit future kidney transplant recipients. *See Section 10, Potential Benefits*
- The risk of kidney rejection for the recipient could be higher, lower, or remain the same compared to standard of care.

5. INTRODUCTION/BACKGROUND

This research study is for adults who are planning to have a kidney transplant from a living donor.

People who have a transplant take immunosuppressive drugs (IS) to prevent the body from rejecting the transplanted organ. Rejection occurs when the body's defense system (immune cells) recognizes the transplant as a foreign object. These immune cells and the substances they produce can damage the transplanted kidney. It is important to prevent rejection episodes, so the kidney transplant lasts as long as possible.

Most transplant doctors in the United States give two or three drugs by mouth to prevent rejection. People with a transplant must take these drugs every day. These drugs can have several long-term side effects including damage to the kidney (which shortens the life of the kidney). New or worsening of conditions such as high blood sugar (diabetes), high blood pressure, and high cholesterol can also occur. Although kidney transplant recipients usually do well in the first five years after transplant, researchers want to find new ways to prevent rejection and long-term side effects while extending the life of the kidney.

This study will test five drugs to see if this combination is safe for kidney transplant recipients. The table below shows the five drugs, how each is given, and the current use:

Drug Name	**How Drug is Given**	**Use of Drug**
Lulizumab	Injection under the skin (sub-cutaneous or SC)	Research studies in animals, healthy volunteers, research in subjects with lupus, and Sjogren's
Tocilizumab	SC injection	FDA approved for treatment of arthritis, research in subjects with kidney and heart transplant
Belatacept	Injection in a vein (intravenously or IV)	FDA approved for preventing rejection in kidney transplant recipients
Everolimus	By mouth	FDA approved for preventing rejection in kidney transplant recipients
Mycophenolate Mofetil	By mouth	FDA approved for preventing rejection in kidney transplant recipients

Belatacept, Everolimus, and mycophenolate mofetil are already approved for use as anti-rejection drugs in kidney transplant recipients. Lulizumab and tocilizumab block the activity of immune cells and target different immune cells than the older rejection drugs.

Studies have shown that tocilizumab and lulizumab are successful in preventing rejection in animals with transplanted organs. The combination of lulizumab and tocilizumab has not been used in humans so far. However, based on the animal studies, the study team thinks this drug combination can work well in humans with a transplant. This study will help find out if this drug combination can prevent rejection without causing bad side effects in kidney transplant patients.

6. PURPOSE OF THE STUDY

The purpose of this study is to see if it is safe to use lulizumab with tocilizumab, belatacept, and everolimus in kidney transplant recipients. The study team will look for effects, both good and bad, that the drug combination will have in the kidney recipient.

7. STUDY COMPONENTS

A. Number of Study Sites and Participants

This study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID). The lead study doctor is Dr. Flavio Vincenti at the University of California, San Francisco. Dr. <insert site principal investigator name> is in charge of the study at <insert institution>. Up to <insert expected number for your site> subjects will be enrolled at <insert institution>. We plan to treat 10 kidney transplant recipients in this study at 7 transplant centers in the United States.

B. Study Overview/Visit Schedule

There will be a screening visit to see if your recipient qualifies for the study. Your recipient's eligibility to continue in the study might change, depending on laboratory test results. You will be asked to have a blood draw and information collected from your chart after it is confirmed your recipient is eligible to be in the study.

C. Study Procedures

Blood Draw

All kidney donors have blood drawn as part of the evaluation to donate and to check on your health status after donation. If possible, the study will have research blood drawn when you are already coming to the transplant center.

Donor blood collected for research will be used to obtain donor cells. These cells will be stored and used by researchers to see whether the recipient's immune system is reacting to the donor at different times during the study.

You will not have more than 3 ½ tablespoons (50 ml) of extra blood drawn for research tests.

With any laboratory sample, there is a chance of collection tube breakage, shipping problems, and/or other human error that can ruin the collected specimen. If this happens, your study team will let you know and ask permission for a 2nd blood draw. If needed, the second blood draw amount will be no more than the first time.

8. RISKS AND DISCOMFORTS

A. Risks of Study Procedures

Blood Draw

The risks of blood draws are pain, bruising, infection, redness, and swelling at the sight of needle entry. There is a chance you may feel dizzy while your blood is being drawn. Blood collection for research may be delayed or canceled if you have severe anemia (low red blood cell count). Your doctor will treat your anemia if needed as normally would occur in your care as a kidney transplant recipient.

9. POTENTIAL BENEFITS

There will be no direct medical benefit to you for being in this study. The information learned from this study might someday benefit future kidney transplant recipients.

10. ALTERNATIVES TO PARTICIPATION

Your doctor will talk with you about this study and other options available to you and your kidney recipient. Your decision to participate in this study will not affect the care you would otherwise receive.

11. NEW FINDINGS

Your doctor will tell you about any new findings from this or other research that may affect your willingness to allow testing and use of your cells for this study. If new information is provided to you, we will ask for your consent to continue in the study.

12. VOLUNTARY WITHDRAWAL FROM STUDY

You may decide to withdraw consent at any time during this study. If you decide to withdraw, 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. Your doctor or research staff will destroy your samples at your request.

13. REASONS WHY YOU MAY BE TAKEN OFF STUDY WITHOUT YOUR CONSENT

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:

- Your study doctor determines that it is in your best interest not to take part.
- You are unable to complete required study procedures.
- The study is stopped by the Institution, the Sponsor, or health authorities.

14. COSTS TO THE SUBJECT (YOU)

There will be no charge to you, your health insurance company, or your recipient's insurance company for any costs which are done specifically for this study.

15. PAYMENTS (REIMBURSEMENT)

You will receive no payment for taking part in this study.

(or)

You will receive (*insert amount*) to cover the travel and parking cost for your visit to the transplant center to give your blood specimen. *(Specify what test/procedures will result in compensation, as well as the amount. Explain the method of prorating the payment(s))*

(*Payments are pro-rated and not held until completion of the study. If participant payments are tied to completion of specific study benchmarks, these stipulations should be noted in this section as well as other reimbursement specific to the study -i.e. parking, meal tickets, etc.*

16. RESEARCH-RELATED INJURY

<Insert your IRB required language.>

If are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research. No funds have been set aside to compensate you in the event of injury. Your insurance company will be billed for the costs of any care for injuries.

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

17. CONFIDENTIALITY

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

As an NIH funded study, you are further protected through a policy that prevents the investigator from disclosing sensitive study information that would lead to your identity. This does not prevent you or a family member from voluntarily releasing information about yourself or your involvement in this research.

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.

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.

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

- 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
- other State and Local health authorities

18. STORING INFORMATION/DATA FOR FUTURE STUDIES

As a NIH-sponsored clinical study, we are expected, as described in the Funding Opportunity Announcement and/or Terms of Award, to share research data with the scientific community. We will store information resulting from this study in a central data repository. Data is information organized for a reason, like this study. A central data repository is a place that collects and stores data from many different studies. The purpose of this collection is to make scientific information available for future studies which may help future patients. Your data may be stored indefinitely. Any information released to a central data repository will not contain traditional information such as name, birthdate, address, etc. that is considered your personal information.

19. PROBLEMS OR QUESTIONS

If you ever have questions about this study or in case of research-related injuries, you should contact Dr. *<Insert name>* at *<Telephone Number>*, or if you have questions about research subjects' rights you can call *<Insert the name and title of the appropriate country/site-specific person>* at *<Insert the number>*, or if you prefer, direct your questions to the following address*: <Insert address of IRB patient representative here>*.

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 Subject's Name *(Typed or printed)*	**Research Subject's Signature**	**Date**

Signature of person(s) explaining and obtaining the consent:

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

_____	_____	_____
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 subject. A copy should be placed in the research subject's medical record, if applicable.)

20. STORAGE OF SAMPLES and/or INFORMATION FOR FUTURE USE

(This consent is optional, and agreement is not required for participation in the study)

We are asking your permission to store samples of biological specimens (e.g., cells) collected for this study to be used in the future for tests that are not yet planned. These tests may or may not be related to the study of transplantation.

Some information about a research specimen will always be linked to it (also see section 6c, Genetic Information). For example, researchers might know a sample is from a kidney transplant recipient. Because of this, allowing for specimens to be stored for future use also means allowing for the linked information to be stored and used when the specimens are needed.

Genetic Testing on Stored Samples

Your samples may be used to look at genetic information in relation to kidney transplantation (for example, the rejection process). However, your samples could also be used in studies that are not related to transplantation (for example, the immune system as a whole).

Confidentiality

All samples will be labeled with a randomly assigned unique barcode. They will not contain personal information like name, initials, or date of birth. Reports on these stored samples and genetic tests will not be given to your study doctor and they will not be in your medical record. Doctors will not know that your samples are being used for other studies and it will not affect your routine medical care.

Benefits of Stored Material and Genetic Testing

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.

Samples will be stored at the core laboratories involved in this trial. If you agree, your samples and information may be stored for an unknown length of time.

Risks of Stored Material and Genetic Testing

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 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.

Making a Decision for Stored Human Subject Material and Genetic Testing

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.

Please indicate your response below:

Choose yes or no to allow the storage and sharing of your sample (cells) and information for genetic tests.

☐ Yes ☐ No

_____
Initials of Research Subject

Choose yes or no to allow the storage and sharing for future use of remaining sample (cells) and information for other research tests not currently planned (not genetic).

☐ Yes ☐ No

_____
Initials of Research Subject