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

1. TITLE OF CLINICAL RESEARCH STUDY

"**T**reg **A**doptive Therapy in **S**ubclinical Inflammation in **K**idney Transplantation" (TASK)
Protocol Number: CTOT-21
Short Title: Tregs in Subclinical Inflammation

2. YOUR PARTICIPATION IS VOLUNTARY

We will explain this research study to you. You may 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 received a kidney transplant between 3 and 7 months after transplant, and who recently had a kidney biopsy showing inflammation. *See Section 5, Introduction and Background*
- The study will test whether a new product called T-regulatory cells (Tregs) given one time through an intravenous line, is safe and will reduce inflammation in the kidney. *See Section 5, Introduction and Background; and Section 6, Purpose of the Study*
- The study requires participants to make 8 to 10 office or hospital visits over a one-year period. *See Section 7B, Study Overview/Visit Schedule*
- Study participants have procedures that are not part of routine care for kidney transplant recipients. These include:
    - Leukapheresis, in which some of their blood cells are collected by a machine, through intravenous lines.
    - An extra kidney biopsy, in which a piece of the transplanted kidney is removed with hollow needle
    - Extra urine and blood collections. *See Section 7C, Study Procedures*
- The risks of receiving Tregs are not known because they have only been given to a very small number of people. The reason for giving them is that they might act on the immune system to prevent or decrease damage to the transplanted kidney. However, they might affect the immune system in other ways. For example, the immune system might be less able to fight off infection or cancer. There is also a risk for an immediate bad reaction such as rash, swelling, or breathing problems when the Tregs product is given.

- There might 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. Some subjects may benefit if inflammation in the transplanted kidney can be decreased. *See Section 10, Potential Benefits*

5. INTRODUCTION/BACKGROUND

This research study is for people who received a kidney transplant about 3 to 7 months after transplant, and who recently had a kidney biopsy showing inflammation.

Inflammation occurs when the body's defense system recognizes a foreign object (such as a transplanted kidney), and responds by sending white blood cells to attack the foreign object. These cells and the substances they produce can damage the transplanted kidney. There is currently no standard treatment for inflammation in the kidney; some transplant centers do not treat inflammation at all. *Rejection* is a more severe form of inflammation and injury. Both inflammation and rejection are diagnosed by looking at a piece of kidney (a kidney biopsy) under a microscope. Kidneys that have inflammation and/or rejection do not work as well or last as long as kidneys without injury.

People who have a transplant take immunosuppressive drugs (IS) to prevent inflammation and rejection. Although kidney transplant recipients usually do well in the first five years after transplant, transplant researchers are interested in finding ways to prevent inflammation and rejection without IS, or with lower doses of IS in order to avoid side effects.

While some white blood cells cause inflammation, other types of white blood cells, called T regulatory cells (Tregs), can control inflammation. Tregs may have an important role in controlling or preventing inflammation and rejection. A person's Tregs can be grown in the laboratory to increase their number. These Tregs can be given back through a needle placed in a vein (IV). When given to the recipient, Tregs might reduce inflammation in the transplanted kidney. However, this effect has not yet been shown.

One of the IS drugs used in kidney transplant is Everolimus. Everolimus has been shown to help Tregs survive better than other types of IS drugs.

6. PURPOSE OF THE STUDY

The purpose of this study is:

- To see if Tregs can reduce inflammation in a transplanted kidney.
- To find out what effects, good or bad, Tregs will have in the kidney recipient.
- To find out what effects, good or bad, taking everolimus after Tregs will have in the kidney recipient.

Kidney transplant recipients who agree to participate in this study will be assigned to one of two groups. Group 1 will receive standard of care IS. This means that Group 1 will receive the same IS drugs that are given to kidney transplant recipients who are not in the study. Group 1 subjects will not receive Tregs. Group 2 will receive Tregs. Participants who are assigned to group 2 will have a kidney biopsy 2 weeks after receiving Tregs. If that biopsy shows inflammation is reduced, their IS drugs will be changed to include everolimus. Subjects who do not have a decrease in inflammation on the biopsy will remain on their current IS medication.

Neither you nor your doctor can choose which group you are in. The assignment is made using a computer program and will be based on whether your donor is available and how many people are in the study already.

The study team will collect information about your medical history, laboratory test results, medication doses, and any problems that may arise in the study. Blood, kidney tissue, and urine will be collected for research tests.

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 14 kidney transplant recipients in this study at 6 transplant centers in the United States.

B. Study Overview/Visit Schedule

This study will last one year.

- There are 8 study visits for subjects in Group 1.
- There are 10 study visits for subjects in Group 2.

Screening is when the study team checks to be sure you qualify and that it is safe for you to continue in the study. Your eligibility to continue in the study might change, depending on laboratory test results. The following table and list below summarizes the study. Additional details about study procedures are in other sections of this document.

Study Visit / Study Procedure	**Group 1**	**Group 2**	
Screening Visit and Blood Draw/ Study Group Assignment	X	X	
16 Days before Infusion Study Visit/ WBC Collection		X	
Day 41 (Group 1) / Infusion Day (Group 2) Study Visit and Blood Draw	X	X	
• Tregs Infusion		X	
Day 1 after Infusion Study Visit and Blood Draw		X	
Day 48 (Group 1) /Day 7 after Infusion (Group 2) Study Visit, Physical Exam, Blood Draw	X	X	
Day 55 (Group 1)/ Day 14 after Infusion (Group 2) Study Visit, Physical Exam, Blood Draw	X	X	
• Study Kidney Biopsy		X	
Day 69 (Group 1)/ Day 28 after Infusion (Group 2) Study Visit, Physical Exam, Blood Draw	X	X	
Day 125 (Group 1)/ Day 84 after Infusion (Group 2) Study Visit, Physical Exam, Blood Draw	X	X	
Day 223 (Group 1)/ Day 182 after Infusion (Group 2) Study Visit, Physical Exam, Blood Draw	X	X	
• Standard of Care Kidney Biopsy	X	X	
Day 405 (Group 1)/ Day 364 after Infusion (Group 2) Study Visit, Physical Exam, Blood Draw	X	X	
Possible Unscheduled Visits	X	X	

All Groups

- Study Screening and Group Assignment
    - Blood Draw – The study team will schedule an appointment with you at the transplant center. You will be asked to sign this consent form. A blood draw will be done to see if you continue to qualify for the study. Blood tests will include pregnancy test, if applicable, and kidney function tests. If you are still eligible, you will be assigned to one of the two groups.

You will have a transplant center visit for blood draw, physical examination, and general assessment at the following time points after study group assignment.

- Day 41(Group 1) / Infusion Day (Group 2)
  For Group 2, see Treg Screening and Infusion below; no physical exam required at this visit
- Day 48 (Group 1) /Day 7 after Infusion (Group 2)
- Day 55 (Group 1)/ Day 14 after Infusion (Group 2)
  For Group 2, see Day 14 after Infusion below
- Day 69 (Group 1)/ Day 28 after Infusion (Group 2)
- Day 125 (Group 1)/ Day 84 after Infusion (Group 2)
- Day 223 (Group 1)/ Day 182 after Infusion (Group 2) (approximately 1 year after transplant)

- This study visit will coincide with your standard of care biopsy. Research specimens will be collected for the study.

- Day 405 (Group 1)/ Day 364 after Infusion (Group 2)

Group 2 Only

Infusion Day and Day 14 after Infusion visits will be different for subjects in Group 2. There are also 2 more visits than Group 1.

- WBC Collection 16 Days before Infusion**.** The blood draw to collect cells for making Tregs will be done at this visit.
- Treg Screening and Infusion (overnight hospital stay)
    - This visit will be an overnight stay for participants in Group 2. Tregs (Group 2) infusion will take place approximately 41 days after study group assignment. If you are a woman of child bearing potential, a negative pregnancy test is required before the Tregs infusion.

You will have a transplant center visit for blood draw, physical examination, and general assessment at the following time points after Tregs infusion.

- Day 1 after Infusion (no physical exam required at this visit)
- Day 14 after infusion
    - You will have a kidney biopsy done at this visit, requiring a 6-8 hour observation period before leaving the hospital.
    - Switch to everolimus for subjects who are eligible

Unscheduled Visits

As described in the *Kidney Biopsy* section, you might have unplanned visits to the transplant center if your doctor thinks a kidney biopsy is needed.

C. Study Procedures

Blood Draw

All transplant patients have blood drawn as part of their routine care. Whenever possible, the study will use test results from your routine blood work for the study without drawing more blood. In addition to routine blood draws, you will have blood drawn for research tests. (See Study Schedule).

Blood collected for research will be examined for the following:

- T Cells – Different types of T cells will be identified in the blood. For subjects receiving Tregs, we will also try to find these Tregs in your blood over time. Different cell types will be compared amongst the 2 groups.
- Antibodies – Antibodies form when the immune system identifies something foreign, such as an organ transplant. We will be looking for antibodies to your kidney donor.
- Gene Expression – Researchers will look at when certain genes are turned on or off when the kidney is working normally, and when there is inflammation or rejection.
- Biomarkers – Researchers will look for certain molecules in the blood to see if any correlate with the kidney's health.

You will not have more than 3 tablespoons (40 ml) of extra blood drawn for research tests at a single visit.

Collection of White Blood Cells by Leukapheresis or Blood Draw (Group 2)

White blood cells (WBCs) will be collected by blood draw or leukapheresis. Tregs will be taken from the WBCs and used to make the Tregs product that you will receive if you are in group 2. Your study doctor will decide whether whole blood draw or leukapheresis is best for you based on lab values like hemoglobin (a part of your blood that carries oxygen). For whole blood draw, you will have about 2 cups (450 ml; one unit) taken for manufacturing. If your hemoglobin level and cell count in your blood is too low, you will have WBC collected by leukapheresis (see below), a process that removes only the WBCs and does not lower your hemoglobin.

About 2 cups (450-500 ml) of blood is needed if WBC's are collected by blood draw. If there are not enough cells from the first blood draw, a second blood draw might be done.

Leukapheresis is a procedure that collects WBCs from blood by using a machine that separates the WBCs from the red blood cells and other blood components. Leukapheresis can be done using a central venous catheter (central line) or using two intravenous (IV) catheters, one in each arm. If leukapheresis is needed, the study team will look at your veins to see which method of leukapheresis is best for you.

A central line is a catheter (long tube) that is placed through the skin into one of the large veins near your heart. Inserting the central line will take approximately 1 hour.

The leukapheresis procedure removes blood from a vein in one arm. The blood is then passed through a machine that selects and stores WBCs. The rest of the blood is returned to you through the IV in your other arm. The equipment used is sterile and never re-used. During the procedure, you will receive salt water and a drug to prevent blood clotting through your IV. The procedure takes 2 to 3 hours.

Kidney Biopsy

A kidney biopsy is a procedure in which a small piece of kidney tissue is removed with a needle so that it can be examined under a microscope. Two biopsy time points are considered standard of care at the study sites:

- 3 to 7 months after transplant
- 12 months after transplant

Biopsies are done at these times even in people who are not in the study. However, tissue samples and information from the biopsy will be collected for this study. An additional needle pass might be required during these two procedures to collect enough tissue for research tests.

For Group 2 only, a research biopsy will be done about 14 days after the Treg infusion. Up to two needle passes will be made to collect a tissue sample.

In addition to these biopsies performed for research alone, you might have a 'for-cause' kidney biopsy done during the study. For example, your doctor may perform a biopsy if kidney function tests are abnormal. At the time of a for-cause biopsy, kidney tissue will also be collected for this study. Up to one additional pass of the biopsy needle might be needed to collect a research specimen.

For each procedure described above, kidney tissue about ¾ - 1 inch in length and the width of a pencil lead will be collected for research tests.

Kidney tissue collected for research will be examined for the following:

- Changes in the number of cells or cell type seen.
- Other evidence of a change in the health of the kidney.
- For group 2, the study team will look to see if the Tregs can be found in the kidney.
- Gene Expression – Researchers will look for evidence that certain genes are turned on or off

Urine Collection

You will be asked to collect 100 ml (less than ½ cup) of urine in a cup for study tests. Researchers will look for molecules in the urine that might provide information about the health of the kidney.

Tregs Infusion (Group 2)

Tregs are given (infused) through an IV catheter placed in the arm. Before the infusion, you will be given acetaminophen (Tylenol®) and diphenhydramine (Benadryl®). The Treg infusion will be given over 20-30 minutes. Your vital signs (heart rate, blood pressure, temperature, and breathing rate) will be monitored during and after the infusion. You will stay overnight at the hospital after the infusion to continue monitoring vital signs.

IS Medications

Tacrolimus, mycophenolate mofetil, and prednisone are IS medications that you would take after kidney transplant even if you were not in this study.

Everolimus (Group 2 only)

Everolimus is also an IS medication used after kidney transplantation. However, everolimus is a newer drug in kidney transplantation and is not as widely used as tacrolimus, mycophenolate mofetil, and prednisone. Patients usually take everolimus or tacrolimus, not both. The study team will review the biopsy results performed two weeks after Tregs infusion. If there is a decrease in inflammation on the biopsy after the infusion when compared to the screening biopsy, you will start taking everolimus. The study team will tell you how to lower tacrolimus and increase everolimus over a 4 week period. You may need additional blood draws (less than 1 teaspoon, up to once a week) to make sure you have the right drug level. Tacrolimus will be stopped when the everolimus target blood level is reached. At the end of the study, your transplant doctor will discuss the best IS medication for you.

8. RISKS AND DISCOMFORTS

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.

Central Line Insertion (Group 2 only)

The risks of getting a central line catheter include the following: failure to place the catheter, arterial puncture (where artery is entered instead of vein), catheter placed incorrectly, pneumothorax (punctured lung), hemothorax (punctured lung that bleeds), bruising, heart rhythm disturbance or stoppage, blood clot, bleeding, air embolism (air gets into your vein), infection, or pain at the catheter insertion site. The catheter might leak or become accidentally dislodged. The chance for these risks are low.

Leukapheresis (Group 2)
The chance of a serious problem from leukapheresis is very low. The risks and discomforts of leukapheresis include those described for blood draws. In addition, an embolus (an air bubble in your blood stream), muscle cramping, numbness, chilliness, tingling sensations, anxiety, heart rhythm disturbances, and headaches may occur when blood is returned to your body. There is a very small chance of an infection when your blood is returned. Your WBC count will be lower after the procedure. Your body and your WBC count will return to normal again in one or two days. You may have difficulty fighting infections during this period.

Kidney Biopsy
Risks of a biopsy include bleeding in or around the kidney that can lead to a fall in blood pressure and rise in heart rate. This may require a blood transfusion, or very rarely, lead to a need for surgery or loss of the kidney. Additional risks include pain and bleeding at the site of biopsy, infection, discomfort and bloodstained urine.

Urine Collection
There are no known risks of urine collection.

Treg Infusion (Group 2)
Tregs have been given to adults after bone marrow and kidney transplantation, and in both adults and children with diabetes. There might be risks that are not known.

Risks of Treg infusion include transfusion reaction, infections, lymphoproliferative disease, cancer, and rejection.

Deuterium: The Tregs you will receive have a substance called deuterium in them. Deuterium is also known as heavy hydrogen, and can be found naturally in ocean water or as a gas. Deuterium is incorporated as a tracer when making the Tregs in the laboratory. The deuterium tracer allows study doctors to detect infused cells in blood and in the kidney. Deuterium is not radioactive and is not known to be toxic. The use of deuterium in Tregs is not thought to be a risk to study participants.

Transfusion Reaction: Side effects may include fever, chills, and/or nausea. You will be given acetaminophen (Tylenol®) and diphenhydramine (Benadryl®) prior to the Tregs infusion to prevent this reaction. These medications may be repeated every six hours as needed.

Infections: Tregs work by slowing or stopping the immune system response. After receiving Tregs, it is possible that some part(s) of the immune system might be temporarily weakened and not work normally. This can put you at higher risk for getting infections, typically until 3 months following treatment. These can be infections caused by bacteria, viruses, parasites or fungi.

Study doctors will look closely for signs of infection. You should avoid direct contact with anyone who has a known infection during this time (like the flu) but we expect that you can go back to usual daily life activities as soon as you are released from the hospital.

Cancer: One type of T cell is in charge of finding and stopping the growth of tumors in your body. Since Treg cells stop or slow the immune response, it is possible that tumors could grow unchecked by the immune system. The

most common type of cancer after transplantation is PTLD (see below). Although also very rare, the second most common type of cancer after transplantation is skin cancer. It is not known whether giving Tregs increases the risk for these or other types of cancers. Tregs have been shown to increase the growth of tumors in mice that are present when they receive Tregs. People eligible for this study are unlikely to have any tumors. However, it is not known what Tregs might do in people taking immunosuppressive drugs after kidney transplantation. All participants who receive Tregs will be monitored for this or other complication for at least one year after the infusion as part of the study. After the study, you will be monitored for cancer as part of routine care after transplant.

*Post-Transplant Lymphoproliferative Disease (PTL*D): PTLD is a type of cancer (tumor) that can develop in transplant recipients because they are required to take drugs that suppress the immune system over a long period of time. PTLD occurs in less than 1% of adults who receive kidney transplants. In lymphoproliferative disorders like PTLD, lymphocytes (a type of white blood cell) grow abnormally. PTLD is almost always linked with a virus called Epstein Barr (EBV), the virus responsible for infectious mononucleosis. The risk of PTLD is highest if a patient has his/her first EBV infection after kidney transplant and lower if a patient has had a previous EBV infection prior to kidney transplantation and has developed immunity. This study only enrolls patients who have had previous EBV infection or if both the donor and recipient have never had an EBV infection.

Rejection: It is possible the Tregs could change after the infusion in such a way that they increase the risk of rejection. Typically, rejection can be treated in kidney transplant recipients. There is, however, no experience in treating rejection that results from Treg infusion. Your kidney tests will be monitored very closely, especially after Treg infusion, to ensure early diagnosis of kidney rejection.

There are times when the manufacturing process will not be successful. For example, if there are not enough cells manufactured to meet the required dose or cells are deemed not suitable for infusion because of microbial growth. After your blood draw or leukapheresis procedure for manufacturing is done, there is a chance you might not be able to receive the infusion as planned.

While the cells grow in the laboratory, they are checked for contamination by microbes. Microbes are small organisms such as viruses, bacteria, and fungi that can cause infections. When a Treg product has successfully completed the manufacturing process, and all available tests show that the Treg product is free of microbes, the cells will be administered to you. Some microbes grow very slowly, and final test results are not available for several weeks. On very rare occasions, a final test will show signs of microbial growth after the infusion has been given to you. If this were to happen, the study team will monitor you closely for infection and make sure you receive appropriate treatment, if any treatment is necessary.

IS Medications
The side effects of, tacrolimus, Mycophenolate mofetil, prednisone and everolimus are expected to be the same as if you were taking these IS medications without being in this study.

Genetic Information
Genetic information will be recorded from the specimen collected for this study. However, the specimen will be used in experiments planned for this study only. Your sample will not be looked at for other genetic conditions, genetic cloning, or paternity testing. However, basic genetic information about you will be known to researchers

(e.g. sex, racial or ethnic group). We will keep all information recorded private as much as possible. However, because genetic information is unique to you, complete confidentiality cannot be guaranteed.

9. Pregnancy

You cannot take part in this study if:

- You are pregnant or breastfeeding
- You or your partner plan to get pregnant in the next 12 months.

Study drugs and procedures involved in this research project may involve unexpected risks to your unborn or nursing child. If you are female of childbearing potential, a pregnancy test will be done before you receive study drugs.

If you are female and take part in this study, you must agree to use birth control during the study. You and the study team will discuss acceptable methods of birth control. Female subjects in this study must agree to practice birth control as outlined above.

If you or your partner become pregnant while participating in this study, or if you think that you may be pregnant, you must contact the study team immediately.

The study doctor will talk to you about your care or the care of your pregnant partner.

10. POTENTIAL BENEFITS

There might 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.

Some subjects may benefit if inflammation in the transplanted kidney can be decreased.

11. ALTERNATIVES TO PARTICIPATION

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

12. 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.

13. 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.

14. 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.

15. COSTS TO THE SUBJECT (YOU)

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

16. 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.*

17. 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.

18. 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.

Your personal identifiers (for example, name and medical record number) will be used in the manufacturing process for the Treg infusion at the transplant center and at the UCSF laboratory (UCSF Human Islet and Cellular Transplantation Facility) where the products are made. Use of the identifiers is required to ensure the cells are tracked accurately through the manufacturing process. In all other parts of the study, 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

19. 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.

20. 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.)

21. 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