National Institute of Allergy and Infectious Diseases (NIAID)
Division of Allergy, Immunology and Transplantation (DAIT)
Recipient 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 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 participants to make 18 office or hospital visits over a one-year period. *See Section 7B, Study Overview/Visit Schedule*
- Study participants will have to see a nurse or study team member to get a study drug injection every week for 12 weeks (about 3 months); then every other week until 24 weeks (about 6 months after transplant). Study participants will also have a study drug infusion about once a month during the study. *See Section 7B, Study Overview/Visit Schedule*
- Study participants will have procedures that are not part of routine care for kidney transplant recipients. These include:
    - *<Customize per site standard of care>* 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 the study drugs used in combination are not known. However, the risks of anti-rejection drugs in general include cancer and serious infections. There is also a risk for rejection of the

transplanted kidney if the drug combination does not work as expected. *See Section 8A, Risks of Study Drugs*

- 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. *See Section 10, Potential Benefits*

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 a new combination of five drugs to see if this combination is safe for kidney transplant recipients. The table below shows the five drugs, how it 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 parts of the immune system 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, everolimus and myophenolate mofetil 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 you qualify for the study. Your eligibility to continue in the study might change, depending on laboratory test results.

The study will start when you have your kidney transplant, and you will receive study drugs for one year after the transplant. We will also collect additional information about your kidney function and overall health status two years after transplant. Study participants will have:

- 23 study visits for blood draws, vital signs, physical exam, and to meet with a study team member. You will also get medications at some of these study visits. Study visits usually take about 1-2 hours to complete.
- 13 medication visits to get study drugs. Medication visits for Lulizumab or tocilizumab SC injections usually take about 30 minutes to complete. Medication visits for Belatacept IV infusions will usually take less than 1 hour to complete. The schedule for each drug is:
    - Lulizumab SC injections on day 1 after transplant, then every week for the first 12 weeks after transplant.
    - Tocilizumab IV on day 2 after the transplant, then SC injections every other week for the first 6 months after transplant (week 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24)
    - Belatacept IV injections every month starting at 12 weeks after transplant.
- Everolimus by mouth twice a day starting at 2 weeks after transplant
  As described in the *Kidney Biopsy* section, you might have extra visits to the transplant center if your doctor thinks a kidney biopsy is needed.

Visits early after transplant will occur while you are still in the hospital. After your hospital stay from transplant surgery, study and medication visits will be combined to save time whenever possible.
The following table summarizes the study. Visits marked with (*) are times when you will be asked to go to the transplant clinic even if you are not in the study.

Additional details about study procedures are in other sections of this document.

Study or Medication Visit After Transplant			**Blood Draw**		**Physical Exam/ Vital Signs**	**Kidney Biopsy**	**Medication** Luli = lulizumab Toci = tocilizumab Bela = belatacept SC = Sub-Cutaneous IV = Intravenous
			Research Lab Tests	**Hospital Lab Tests**			
Screening Visit				X	X		
Time Point	**Study Visit**	**Medication Visit**					
Transplant Day	X	X	X		X		
Day 1	X	X		X	X		Luli SC
Day 2	X	X		X			Toci IV
Day 7/ Week 1	X	X		X	X		Luli SC
Day 14/ Week 2	X	X		X	X		Luli & Toci SC
Week 3		X		X			Luli SC
Day 28/ Week 4	X		X	X	X		Luli & Toci SC
Week 5		X		X			Luli SC
Week 6	X			X	X		Luli & Toci SC
Week 7		X		X			Luli SC
Week 8	X	X		X	X		Luli & Toci SC
Week 9		X		X			Luli SC
Week 10	X	X		X	X		Luli & Toci SC
Week 11		X		X			Luli SC
Week 12	X	X	X	X	X		Toci SC & Bela IV
Week 14	X	X		X	X		Toci SC
Week 16		X					Toci SC & Bela IV
Week 18	X	X		X	X		Toci SC
Week 20		X					Toci SC & Bela IV
Week 22	X	X		X	X		Toci SC
Week 24		X					Toci SC & Bela IV
Week 26	X		X	X	X	X	
Week 28		X					Bela IV
Week 30	X			X	X		
Week 32		X					Bela IV
Week 36	X	X		X	X		Bela IV
Week 40		X					Bela IV
Week 42	X		X	X	X		
Week 44		X					Bela IV
Week 48		X					Bela IV
Week 52	X	X	X	X	X		Bela IV
2 years	Medical records review and data collection						
Possible Extra Visits			X	X	X	X	

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 (Hospital Lab Tests) for the study without drawing more blood. In addition to local lab testing, 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 and compared at different time points.
- 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 6 tablespoons (87.5 ml) of extra blood drawn for research tests at a single visit.

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. Kidney tissue is needed for research tests at the following times:

- Visit 14/ 26 Weeks (about 6 months) after transplant

<Customize per site standard of care surveillance biopsy schedule>

A biopsy is done at this time even in people who are not in the study. However, some of the tissue samples from the biopsy will be used for this study. No additional needle sticks are needed for the study.

OR

Up to two needle passes will be made to collect tissue samples for this study. For each time point listed 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.
- Gene Expression – Researchers will look for evidence that certain genes are turned on or off

Possible Extra Visits

There are different reasons when extra visits might be needed during the study. Examples include:

- Collection tube breakage, shipping problems, and/or other human error that can ruin laboratory samples. This may require new samples to be collected.
- Your screening visit may have to be repeated if your transplant is delayed, to ensure you still qualify for the study.

If an extra visit is required, your study team will let you know and ask permission for repeating research procedures. If any laboratory tests need to be repeated, the blood draw amount will be no more than the first time.

In addition, 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. No extra kidney tissue will be collected for this study at

the time of a for-cause or other routine biopsy (not study related) but we will use the same sample for research tests. Less than 2 tablespoons (27.5 ml) of blood will be collected for the study you have a for-cause biopsy.

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.

D. Study Drugs
This section describes drugs you will have during the study. Your study doctor will talk to you about the best combination of medications to take at the end of the study. You might continue with some of the study drugs or switch to other ones.

Lulizumab
Lulizumab is a new drug not yet approved for use in kidney transplant recipients. Lulizumab is known to work against CD28 cell activity which may play a part in rejection. So far, lulizumab has been studied in animals, healthy human volunteers, and patients with diseases called lupus and Sjogren's. The study in lupus showed that lulizumab is safe but not effective for that disease. It is not known if lulizumab is helpful in Sjogren's, but no safety concerns were seen in that study. The next step is to see if the drug works as researchers think it will in people with kidney transplants.

Lulizumab is given with a small needle under your skin (SC injection). You will get the first dose one day after transplant and then every week for 12 weeks. You will have to return to the transplant center to get the injections.

Actemra® (tocilizumab)
Tocilizumab is FDA approved to treat rheumatoid arthritis and reactions to certain types of cancer treatments. Tocilizumab works against IL6, a molecule that can help cause organ rejection in addition to inflammation (your body's reaction to injury or infection) which is seen in other diseases. Tocilizumab has been used in small studies to fight rejection in people with kidney transplants and was found to be safe. There is a study using tocilizumab in heart recipients. However, there is still more to be learned about how the drug works in people with transplants because larger studies have not yet started or are still ongoing.

You will receive the first dose 2 days after transplant as an IV infusion. Tocilizumab is also given as a SC injection. After you leave the hospital, you will have 12 more tocilizumab injections SC every other week (week 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 after transplant).

Nulojix® (belatacept)
Belatacept is a FDA-approved anti-rejection medication used after kidney transplantation. Although belatacept is not as widely used as other anti-rejection medications, it is well studied and used in thousands of kidney transplant patients. Belatacept is not generally used in combination with the drugs in this study.

Belatacept is given as an intravenous (through the vein, IV) solution about once a month. Each infusion takes about 30 minutes. The first dose will be given at the time of transplant and then monthly until the end of the

study. You will be monitored closely during and after each infusion. It is important for you to keep all your appointments for belatacept infusions to prevent rejection.

Zortress® (Everolimus)
Everolimus is a FDA-approved anti-rejection medication used after kidney transplantation. Although everolimus is a newer drug and not as widely used as other anti-rejection medications, it has been well studied and used in thousands of kidney transplant patients. You will start taking everolimus about 2 weeks after transplantation.

Everolimus is taken by mouth twice a day (morning and evening). The dose of everolimus is changed based on levels of the drug in your blood.

Cellcept® (*Mycophenolate Mofetil* -MMF) or Myfortic® (*Mycophenolic Acid* -MPA)
MMF and MPA are both FDA-approved anti-rejection medications used after organ transplantation. These medications are also widely used "off-label" to treat other diseases. MMF and MPA are medications with the same active ingredient, and one or the other is usually given with at least one other drug to prevent rejection after organ transplantation. You will likely be prescribed MMF or MPA even if you are not in this study. Your doctor will decide whether MMF or MPA is better for you. In this study, MMF or MPA will be given starting on the day of transplantation for about 2 weeks. MMF or MPA will be discontinued when Everolimus drug levels are high enough. The study team will give instructions for medication dose changes.

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.

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.

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.

B. Risks of Study Drugs

Anti-rejection drugs suppress or weaken the body's response to reject a transplanted organ. However, these drugs generally affect the entire immune system and not just the transplanted kidney. Because people with transplants must take anti-rejection drugs, the risks exist even if you are not in this study.

You will take some drugs (like Thymoglobulin, prednisone and myophenolate mofetil) as a study participant even if you are not in the study. However, you will receive belatacept and everolimus as a study participant which might not be prescribed to you if you are not in the study. It is not known whether the combination of drugs used in this study will change that risk – it may be lower than, the same as, or greater than standard anti-rejection drugs.

Opportunistic Infections: Opportunistic infections are infections that occur more frequently and are more severe in people with weakened immune systems, including kidney transplant recipients who must take immune suppressing drugs. Serious fungal infections have been reported in people using tocilizumab, belatacept, and everolimus. People using these types of drugs are also at higher risk for bacterial, viral, and other infections.

PTLD: Taking immune suppressing drugs increases the risk of post-transplant lymphoproliferative disorder (PTLD) more than other anti-rejection drugs. 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 is the most common type of cancer after transplant but 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 (known as mono). 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. You have evidence of previous EBV infection. This study only enrolls patients who have had previous EBV infection.

Cancer: People taking anti-rejection drugs that weaken the immune system are at higher risk of getting cancer. Although also very rare, the second most common type of cancer after transplantation is skin cancer. All participants will be monitored for this or other complication as part of the study. After the study, you will be monitored for cancer as part of routine care after transplant.

PML: Progressive multifocal leukoencephalopathy (PML) is a rare but serious brain infection caused by JC virus. People with weakened immune systems are at risk for getting PML. PML can result in death or sever disability. There is no known treatment or cure for PML.

Other serious infections: Serious infections including tuberculosis and BK virus can occur in people taking anti-rejection drugs. Because of the weakened immune system, these and other infections caused by bacteria, viruses, or fungi can cause illness that may lead to death. The BK virus can affect how your kidney works and cause your transplanted kidney to fail.

Rejection: It is possible that the combination of study drugs can increase the risk of rejection. Typically, rejection can be treated in kidney transplant recipients. There is, however, no experience in treating rejection that happens when using the study drugs. Your kidney tests will be monitored very closely to ensure early diagnosis of kidney rejection.

There have been 3 subjects who experienced rejection after starting the drugs in this study. The study team stopped the study each time this occurred, then reviewed and changed the study to make it less likely for rejection to occur. The study's data safety monitoring board, as well as each participating site's institutional review board reviewed each study change and agreed that the study can proceed.

Lulizumab

Lulizumab is a new drug so there is not as much information about side effects as for drugs that have been used longer. The most frequent side effects reported in a study of 108 healthy volunteers receiving lulizumab are: headache, feeling hot, pain in the mouth and throat, back pain, itchiness, and upper respiratory infection. Seven of these study participants had infusion reactions. 18 people who received lulizumab also had minor abnormalities in liver tests.

In a larger study of 346 patients with lupus, serious events happened in one out of ten participants receiving lulizumab. Side effects related to lulizumab include: high blood pressure, shingles (herpes zoster), abscess (bacterial skin infection with a pocket of pus under the skin), lung and respiratory infections, serum sickness (fever, muscle aches, feeling unwell without infection), and systemic inflammatory response syndrome (fever, nausea, vomiting, diarrhea, muscle aches, abnormal blood cell counts without infection). There were no deaths related to lulizumab.

Information about any side effects will be recorded for this study.

Actemra® (tocilizumab)

Tuberculosis: People taking tocilizumab are at higher risk of getting tuberculosis (TB). TB is an infection mainly affecting the lungs. People who get TB must take several types of medications for many months to cure the infection. TB can be very serious and difficult to treat in kidney transplant recipients because of the ongoing need for immune suppressing drugs. You must have a negative TB test or have completed treatment for TB to be in this study.

Ruptured Bowel: People in studies using tocilizumab have had ruptured bowel, usually after problems with an existing disease called diverticulitis (inflamed and/or infected bowel).

Drug Reaction: Anaphylaxis leading to death has been reported in people after being given tocilizumab by IV. Anaphylaxis is a severe, potentially life-threatening allergic reaction. The reaction can occur within seconds or minutes after exposure to a drug or other substance you are allergic to. You will receive the first dose of tocilizumab by IV while in the hospital. The rest of the study doses will be given by SC injection. You will be monitored for anaphylaxis and other reactions after the first injection in the hospital.

Side effects for people taking tocilizumab every other week to treat rheumatoid arthritis are listed below. The number next to the side effect is the percentage of people who had the side effect.

- Injection site reactions, such as redness and swelling at the site of needle entry (7%)
- Low white cell count (4%)
- Abnormal liver tests (3%), also see below about liver failure
- High cholesterol level (20%)

There have been extremely rare instances (2 in a million patients) of liver failure in people using tocilizumab. Your liver tests will be monitored closely during the study. The study team will pause or stop tocilizumab and/or other medications, as needed, if your liver tests are abnormal.

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 start the study and will also be done about every 4 weeks for the first year.

If you are female of childbearing potential 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. Male participants must agree to always use condoms during any sexual activity for at least the first three months while taking lulizumab.

If you 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.

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 recipient'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.

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