Title Of Research Study: Randomized Conversion Of EBV + Kidney Transplant Recipients Of Living Or Standard Criteria Donors At Three Months Post Transplantation To Belatacept With MPA Or Belatacept With Low-Dose Tacrolimus (50% Of Dose) Compared To Patients Remaining On Center Specific Standard Therapy Of Tacrolimus And MPA

Investigator: Lorenzo Gallon, MD

Sponsor: Northwestern University
Supported By: Bristol-Myers Squibb

Financial Interest Disclosure:

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to take part in this research study:

Your doctor, who is also the person responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because you received a kidney transplant.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study is investigating the impact of changing your current immunosuppressant medications to low calcineurin inhibitors (CNI) dose (for example, tacrolimus) with belatacept (Nulojix®) between three (3) and six (6) months after your transplant. The main purpose of this research study is to evaluate the effects of two (2) different immunosuppressive treatments on the occurrence of rejection episodes. The immune system is your body's defense against infection and other disease. After transplant, the body sees the new organ as "foreign" and tries to destroy or "reject"

it. Immunosuppressive medications help to prevent your immune system from attacking your transplanted organ.

Three of the immunosuppressants used in this study- mycophenolic acid (MPA), mycophenolate mofetil (MMF) and tacrolimus- are medications approved by the United States Food and Drug Administration (FDA) to be used after transplant to prevent your body from rejecting your transplanted kidney. These medications are routinely used by kidney recipients here at Northwestern University.

In addition, belatacept (the "study drug") has been approved by the FDA for use at the time of transplant. However, the use of belatacept in this study is considered experimental as it has not been FDA approved for use beginning at 3 months after transplant.

How long will the research last and what will I need to do?

Your participation in this study will last for 21 months after the time of enrollment.

As a subject in this study, you will be asked to come to Northwestern Medicine's Transplant Clinic (676 North St. Clair Street, Suite #1900), Chicago, IL. About 3 months after your surgery, you will be assigned to one of two study treatment groups:

- **Belatacept Group**: In this group you will receive the study drug, Belatacept, with a low calcineurin inhibitors (low CNI) dose
- **Standard of Care Group**: In this group you will receive standard of care immunosuppression treatment

Your group will be assigned by chance using randomization, a process similar to the flip of a coin. Neither you nor your study staff will select the group to which you are assigned.

If you are taking the study drug, you will be asked to have weekly labs to monitor blood counts and kidney function. Throughout the study, the study staff and doctor will let you know when you should have labs drawn. These tests are considered standard of care for patients who change immunosuppression medication after transplant.

Regardless of the group to which you are assigned, you will have blood (3.5 Tablespoons) urine (1.5 Tablespoons) collected for research at your 3, 6, 12 and 24 month visits.

Optional Tissue Collection and Biopsy

We would like to collect an additional tissue sample for research during each of your standard of care (SOC) biopsies: 3 months, 12 months, and 24 months post-transplant. You will be able to tell us if you allow for this optional added tissue collection at the end of this consent form.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

Immunosuppressant Treatment: Regardless of the group you are assigned to, you will be taking anti-rejection medications as part of this study. An increased risk of infection is a common side effect of all the immunosuppressant drugs in this study. These medications are also associated with a slightly increased risk of cancer because the immune system plays a role in protecting the body against some forms of cancer.

Optional Tissue collection and biopsies: The most common complication of a kidney biopsy is bleeding. Bleeding that is serious enough can require a blood transfusion.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved long-term kidney function. In addition, taking part in this study may help doctors establish new standard of care immunosuppression therapies that have better long-term kidney results.

What happens if I do not want to be in this research?

Taking part in research is completely voluntary. You decide whether or not to participate. If you choose to not to take part, there will be no penalty to you or loss of benefit to which you are entitled.

Instead of being in this research study, your choices may include treatment with other medications available either by prescription from your doctor or from other studies.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Lorenzo Gallon, MD, the person in charge of this research study. You can call him at (312) 695-4457. If problems arise evenings or weekends, you may call (312) 695-8900 and ask to speak to the kidney research coordinator on call.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
  - You cannot reach the research team.
  - You want to talk to someone besides the research team.
  - You have questions about your rights as a research participant.
  - You want to get information or provide input about this research.

How many people will be studied?

This study will involve 51 adult kidney transplant recipients at Northwestern Medicine's Transplant Clinic.

What happens if I say "Yes, I want to be in this research"?

As a subject in this study, you will be asked to come to Northwestern Medicine's Transplant Clinic (676 North St. Clair Street, Suite #1900), Chicago, IL. About 3 months after your surgery, you will be assigned to one of two study treatment groups. Your group will be assigned by chance using randomization, a process similar to the flip of a coin. Neither you nor your study staff will select the group to which you are assigned.

The two treatment groups are described below:

Group	Medications	Belatacept	CNI (calcineurin inhibitors)	MPA/MMF*
Belatacept Group	Belatacept + Low CNI Dose	Loading dose: Belatacept given via IV every other week for the first 5 visits You will then continue to receive Belatacept IV monthly for 19 months	Reduced slowly over the first month From Day 30 until the end of the study, you will maintain a target trough level ≤ 5 mg/mL	Stopped at time of randomization.
Standard of Care Group	CNI + MPA/MMF	N/A	Given according to standard of care dosing guidelines	Given according to standard of care dosing guidelines *MPA/MMF dose changes will be made for diarrhea or low white blood count

Additional Standard of Care Labs for Belatacept Group
Subjects in the Belatacept Group will be asked to have weekly labs to monitor blood counts and kidney function. Throughout the study, the study staff and doctor will let you know when you should have labs drawn. These tests are considered standard of care for patients who change immunosuppression medication after transplant.

Study Visit Schedule for All Subjects
Regardless of the group to which you are assigned you will have blood, urine and tissue samples collected for research as outlined:

Time (Month)	Blood Draw	Urine Sample	Biopsy
3	3.5 tablespoons	1.5 tablespoons	During your standard of care kidney biopsy, with your permission, an additional tissue sample will be collected for research
6	3.5 tablespoons	1.5 tablespoons	No biopsy sample
12	3.5 tablespoons	1.5 tablespoons	During your standard of care kidney biopsy, with your permission, an additional tissue sample will be collected for research
24	3.5 tablespoons	1.5 tablespoons	During your standard of care kidney biopsy, with your permission, an additional tissue sample will be collected for research

Blood and Urine Collection
We will collect and store a sample of your blood and urine from each study visit. From your blood, we plan to examine the genes behind your body's immune response (how your body recognizes and protects itself from germs and other things that seem foreign and unsafe). In addition, we will

examine your white blood cell function. From your urine, we plan to examine proteins to see if they can give us new information about how well your kidneys work.

Optional Tissue Collection and Biopsy

We would like to collect an additional tissue sample for research during each of your standard of care (SOC) biopsies: 3 months, 12 months, and 24 months post-transplant. You will be able to tell us if you allow for this optional added tissue collection at the end of this consent form.

End of Study Procedures

Regardless of the group to which you are assigned, you will be scheduled for a standard of care clinic visit at 24 months after transplant, and this will be the last time we collect samples for this study. At this time you will talk with the study physician about whether you are going to stay on the medicine you were taking for the study, or whether you will switch to another anti-rejection medication.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Follow the instructions of your study doctor.
- Come to all your scheduled study visits and procedures.
- If you see a doctor outside the research study, tell the doctor you are in a research study.
- Do not change any of your other medications or start any new medications without checking with your study doctor and your medical practitioner.
- Tell the study staff if you wish to stop being in the study.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the study doctor or the study staff. You will be asked for further information or samples. Already collected information may not be removed from the research study database and will continue to be used to complete the research analysis.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Data and samples collected and analyzed prior to when you withdraw from the study will be used. If you choose to withdraw and your samples and they have not yet been analyzed, you can choose to have your samples destroyed. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

If you agree, this data will be handled the same as research data

Detailed Risks: Is there any way being in this study could be bad for me?

Taking part in this study may involve the following risks from the study procedures:

Blood Draws

The risks of drawing blood include a bruise at the point where the blood is taken, redness and swelling of the vein and infection. There is a rare chance of getting dizzy or fainting. Care will be taken to avoid these complications.

Biopsies and the Collection of Additional Tissue Samples for Research

When patients have kidney tissue samples taken, 3 – 4 out of 100 people have bleeding in the kidney (3.5% chance) and 2 – 3 out of 100 people have bleeding around the kidney (2.5% chance). Bleeding in or around the kidney can lead to a fall in blood pressure and rise in heart rate. One out of 100 people who have a transplant kidney biopsy require a blood transfusion or placement of a urinary catheter (1% chance). In 1 out of 1,000 people, a kidney biopsy may lead to a need for surgery or loss of the kidney (0.1% chance). Additional risks include pain and/or bleeding at the site of the biopsy, infection, discomfort, and blood-stained urine.

You will receive a shot of medicine that numbs the biopsy area before the biopsy. The risks of local anesthetics include infection or burning sensations around the area of the shot, and allergic reactions to the medication (such as a rash). You will be asked about any allergies before the biopsy.

Risks of Belatacept (Nulojix®)

Some patients in kidney transplant studies have received belatacept for up to 13 years, and in general, the rate of side effects decreases over time. About 1000 kidney transplant patients have received belatacept in clinical trials comparing belatacept and the approved drug cyclosporine. They received one drug or the other, in addition to basiliximab, MMF and steroids, to prevent transplant rejection. In general, patients treated with belatacept had the same overall rates of side effects, including infections and cancers, as patients who received cyclosporine. In the first 36 months of follow-up in the three trials done in kidney transplant patients, the frequencies of side effects in the groups taking belatacept and cyclosporine were similar. Some side effects were serious and required hospitalization. Some were fatal.

The most commonly-reported side effects (in ≥ 20 % of subjects) among belatacept subjects were:

- Urinary tract infection
- Diarrhea, constipation, or nausea
- Swelling
- Decreased transplanted kidney function
- Fever or cough
- High blood pressure
- Decreased white blood cell count

The following occurred in 10-20% of patients:

- Infections
- Low levels of phosphorous, calcium, or potassium in blood
- High levels of potassium in the blood (which can cause nausea and an irregular heartbeat)
- Increased creatinine, glucose and cholesterol
- Vomiting with abdominal pain
- Operation-site complications and pain
- Decreased red blood cell counts
- Blood or protein in the urine
- Low blood pressure
- Graft dysfunction
- Headache
- Back pain
- Trouble sleeping

PML

Rarely, progressive multifocal leukoencephalopathy (PML) has occurred in kidney transplant

recipients and in patients taking belatacept as part of multi-drug immunosuppressive regimens. One kidney transplant recipient developed PML, an often fatal infection of the brain. There was one occurrence of PML in these clinical trials.

PTLD
Post-transplant lymphoproliferative disorder (PTLD) occurs when tumors of white blood cells start to grow after transplantation. PTLD developed in 14 out of 949 patients who received belatacept and in 3 out of 949 patients who received cyclosporine. In addition, 9 of the PTLD cases in belatacept patients involved the brain, and this was a higher number than expected.

PTLD is almost always linked to the Epstein - Barr virus (EBV). EBV is the same virus that causes infectious mononucleosis, or "the kissing disease." You have a higher risk of PTLD if you don't have EBV antibodies. Most transplant patients have been exposed to EBV before, and have antibodies that can fight the virus, thus making them less likely to develop PTLD. You are being approached for this study because you have been exposed EBV.

Overall, it is unknown if these side effects are caused by belatacept, as some of these side effects were reported by patients who received cyclosporine, and all patients received other immunosuppressive drugs. Similarly, there may be other side effects of belatacept that are unknown. Therefore, if you experience these or any other symptoms, notify your study doctor or study staff as soon as possible.

Risks of Tacrolimus
Common side effects of tacrolimus include:
- High blood pressure
- High blood sugar and diabetes
- Increased kidney function blood tests
- Trembling
- Headaches
- Burning in the hands and/or feet and itchy skin
- Increased levels of potassium, cholesterol and/or triglyceride levels in the blood
- Unsteady movements or clumsiness
- Thickening of the heart muscle
- Trouble sleeping
- Abdominal pain, diarrhea, or nausea
- Infection

Less common but more serious side effects include:
- Inflammation of the lung tissue
- BK nephropathy (a kind of kidney infection)
- Posterior reversible encephalopathy syndrome (PRES): a combination of side effects including headaches, confusion, seizure, and vision problems
- Progressive multifocal leukoencephalopathy (PML), a serious infection that can lead to disability or death.

Risks of Mycophenolic Acid (MPA, or Myfortic®) or Mycophenolate Mofetil (MMF, or CellCept®)
More common side effects include:
- Infections (CMV or urinary tract infections)
- Constipation, diarrhea, nausea, or vomiting
- Low white blood cell count
- Low red blood cell count

Genetic Information

As part of this study, information about your genes and your immune response to the study medications will be taken from your blood samples. Any information that could be used to identify you will be kept in password-protected computers, or in files stored in locked offices to ensure that your personal information is only accessible to project staff.

Unforeseen Risks:

In addition to the risks listed above, the study drugs and procedures may have unknown side effects. There is always the possibility that you will have a reaction that is currently not known or not expected. All drugs have the risk of causing an allergic reaction that, if not treated promptly, could be life-threatening. It is important that you report any and all symptoms or possible reactions to your study doctor or nurse. You will be monitored for side effects by study staff and the study doctor. Based on unforeseen risks, you could be withdrawn from the study.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

What do I need to know about reproductive health/sexual activity if I am in this study?

The procedures in this research are known to harm a pregnancy or fetus in the following ways:

Mycophenolic acid (MPA) and mycophenolate mofetil (MMF) are known to increase the risk of loss of a pregnancy and to cause congenital birth defects.

The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. The effects of belatacept and tacrolimus on human sperm and eggs have not been studied and the effects on the developing fetus using these study drugs during pregnancy and risk of birth defects are also unknown and may be unforeseeable.

You should not be or become pregnant, father a baby, breastfeed or donate eggs/sperm while on this research study.

If you are sexually active, both men and women should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or your partner become pregnant while taking part in this research study or for 6 weeks after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

If you or your partner [are/is] considered to be postmenopausal, you are not required to use contraception while taking part in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study or for 6 weeks after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

Will it cost me anything to participate in this research study?

Taking part in this research study may lead to added costs to you.

If you are assigned to the Belatacept Group, you will receive belatacept, the study drug, free of charge, for the duration of the study. However, the cost of the belatacept infusion procedure will be billed to you or to your health insurance company.

There will be other tests and procedures that are part of your routine medical care that are not part of research:

- Routine blood and urine tests
- Drug levels when a immunosuppression medicine is changed

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved long-term kidney function. In addition, taking part in this study may help doctors establish new standard of care immunosuppression therapies that have better long-term kidney results.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, Bristol-Myers Squibb and its partners and contractors and the US Food and Drug Administration**.**

De-identified specimens retained after the study for future research (an optional element of this study), will be stored, in the Tarry Building, 14th floor, 303 E. Chicago Avenue, Chicago, IL 60611, until they are used up.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at 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.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you become ill or get injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your taking part in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

Travel Expenses:

You will receive a voucher for free parking for your study visits. This voucher is only valid if you park in the 222 E. Huron Street Garage which is connected to the Galter Pavilion (clinics) and the Feinberg Pavilion (hospital) by the street overpass on the second floor. The garage is also known as "University Parking Garage A." If you park in any other garage, this parking voucher will not be valid and you will need to pay for your own parking. If you do not drive in for your study visits, the study staff will discuss other options of equal value.

Genetic Information:

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Tissue or blood samples stored for future research

Allowing for the storage and future testing of your tissue and blood samples will involve no cost to you. Your samples will be used only for research and will not be sold. The research done with your tissue and blood samples may lead to the development of new products in the future. No compensation will be given to you now or in the future for use of these samples.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Genetic health information: information about your genes and your immune response to the study medications will be taken from your blood samples.
- Records about radiological tests and results
- Records about medical procedures and results
- Records about microbiology tests and results
- Records about pathology tests and results
- Records about imaging tests and results

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except

that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Pharmaceutical Company ("Bristol Myers Squibb"), who is a funding entity for the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or presentations at scientific meetings. If your individual results are discussed, your identity will be protected by using a study code number rather than your name or other identifying information. Examples of identifying information include medical record number, Social Security number, and address.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Lorenzo Gallon, MD
Institution: Northwestern University
Department: Comprehensive Transplant Center
Address: 676 North St. Clair Street, Suite #1900, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may collect extra tissue during my routine 3-month, 12-month and 24-month post-transplant kidney biopsy procedures.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.
_____	_____	The researcher may retain any leftover blood or tissue samples taken during the study. These samples may be used for other research not related to this study. These samples will be retained in non-identifiable form, meaning that there will be no information associated with the blood or samples that will allow anyone to readily ascertain my identity.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Subject's Name (printed) Date

_____ _____
Subject's Signature Date

_____ _____
Name (printed) of Person Obtaining Consent Date

_____ _____
Signature of Person Obtaining Consent Date