HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Protocol Title:	**HOPE in Action Prospective Multicenter, Clinical Trial of HIV+ Deceased Donor Kidney Transplants for HIV+ Recipients, Version 4.0, February 5, 2019**
Principal Investigator:	Emily Blumberg, MD 3 Silverstein Pavilion, Philadelphia PA 19104 **(215) 662-7066**
Project Manager:	Eileen Donaghy, MSN, CRNP
24 hr. Emergency Contact:	Immunodeficiency Program Doctor on call (215) 662-6059

1.YOUR PARTICIPATION IS VOLUNTARY

We will explain this research study to you. You may ask questions.

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

We are discussing this study with you now, while you are waiting for your transplant. We want to give you enough time to decide. After the study has been explained to you and if you agree to take part in it, we will look at your medical records to make sure you meet the study criteria. Ask your study doctor and/or study staff member to explain any words or information that you do not fully understand in this document.

2. **KEY INFORMATION ABOUT THE HOPE IN ACTION MULTICENTER KIDNEY STUDY**

We are asking if you want to join a research 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 important things you should know about this study:

- This is a **research study**. In this research study, we want to find out if it is safe to receive an HIV-positive organ and if HIV-positive patients who receive an HIV-positive organ do as well as HIV-positive patients who receive an HIV-negative organ.
- This research study is for adults who are HIV-positive and need a kidney transplant.
- You are being approached because you may qualify for this study.
- To take part, you must be willing to accept an HIV-positive or an HIV-negative organ.

If you decide to join this study, the following things will happen:

- Your blood will be drawn every 3 to 6 months prior to your transplant. This is for the study doctors to look at your immune system and the amount of HIV in your blood to make sure you still qualify for the study.
- You will have your blood drawn around the time of your transplant.
- A biopsy will be taken from the donor kidney before your transplant.
- After your transplant, you will have research blood and biopsy tissue samples collected at scheduled study follow-up visits described below in this consent form.
- After your transplant, you will have study follow-up visits for at least 1 year and possibly up to 4 years depending on when the study ends.

IRB APPROVAL FROM:
05/23/2019 TO: 05/22/2020

- There may be additional risks associated with accepting an HIV-positive organ such as organ rejection and HIV superinfection, which means you may become infected with another strain of HIV. This could make it more difficult to treat your HIV disease.
- All of the risks are outlined below in this consent form. Please take as much time as you need to read this section carefully and ask any questions.
- There may be no direct medical benefit to you. If you accept an HIV-positive organ, you may receive a transplant sooner than if you wait for an HIV-negative organ.
- You do not have to join this research study. It is **your choice** whether to join. You can choose to stop **at any time.**

3. INTRODUCTION/BACKGROUND

Previously, HIV-positive (HIV+) patients in need of a transplant could only receive HIV-negative (HIV-) organs. However, in November 2013, the HIV Organ Policy Equity (HOPE) Act made it possible for a HIV+ recipient to receive a HIV+ organ as a part of a research study.

Over the last several years, HIV+ recipients have received organs from HIV- donors and in general, these recipients have done well after transplant and still maintained control of their HIV. This study will look at whether it is safe to receive a HIV+ organ and if HIV+ patients who receive a HIV+ organ do as well as HIV+ patients who receive a HIV- organ.

4.PURPOSE OF THE STUDY

This research is being done to learn whether organ transplantation from HIV+ deceased donors is as safe and effective in HIV+ recipients as transplants from HIV- deceased donors.

You are being asked to participate in this study because you are infected with Human Immunodeficiency Virus (HIV) and are in need of a kidney transplant.

5.STUDY COMPONENTS

This study is sponsored by the National Institute of Allergy and Infectious Diseases. There are approximately 19 study sites across the United States participating in this research. A total of 360 participants are expected to participate (80 kidney recipients from HIV+ donors and 80 kidney recipients from HIV- donors in the main study) as well as a group of approximately 200 recipients in an observational group with HIV- donors.

At the University of Pennsylvania, a total of 5 to 10 participants are expected to be enrolled.

You are being evaluated or are already waitlisted to receive a transplant as a part of your standard clinical care. If you agree to be in this study and meet all eligibility criteria, you and your transplant team can receive organ offers from HIV+ deceased donors for transplant. You will also remain on the standard organ waitlist. You will have the option to accept or decline an HIV positive or negative donor organ at the time of the offer. If you do not participate in this study, you and your transplant team will not be able to consider HIV+ organ offers.

If you agree to be in this study, you will participate regardless of the HIV status of the organ you accept. The only difference is in the number of study visits and routine kidney biopsies. If you receive a HIV- organ, you will either be randomized (like flipping a coin) to participate in the main control group or in an observational group. The main control group follows the same schedule as the participants who received a HIV+ organ. They also have blood and biopsy tissue collected for research.

The observational group will not have research blood or additional biopsy tissue collected. The main purpose of this group is to collect information about your transplanted kidney and HIV disease over time. Additional detail about follow up is included below.

A Patient Advocate who is not on the research team will contact you as part of this research. They will discuss this study with you and make sure you understand the risks associated with this study.

If you agree to be in this study, we will ask you to do the following things for research purposes:

You will visit with the study doctor and/or study staff member as described below. Depending upon when the study completes, you will have a minimum of 1-year follow-up and up to 4-years follow-up after your transplant.

Screening
After you sign this consent form, we will evaluate you for inclusion in this study. This evaluation will consist of reviewing your medical record, current medications, blood test results, and other tests.

Pre-Transplant
If you meet all the criteria to be included in the study, your study doctor will collect certain tests while you wait for your transplant. First, a CD4 cell count will be reviewed every 16 weeks, which tells your doctor how your immune system is functioning. Next, your study doctor will follow your HIV viral load measurements. This tells the study doctor how much HIV is in your blood. In order to move forward with transplant on this study, you must continue to meet the study criteria. If you are a woman of childbearing potential you will have a urine or serum pregnancy test. You will not be able to participate in this study if you are pregnant.

Transplant
When you are called in for transplant, the study team will make sure you still meet the study criteria and discuss the organ being offered to you. If you are receiving a HIV+ organ, your study doctor will need to make sure the donor did not have any known drug resistance to HIV medications that would make it difficult to treat you following your transplant.

If you receive a HIV- organ, you will either be randomized (like flipping a coin) to participate in the main control group or in an observational group. The control group will follow the same schedule as the group who receives a HIV+ organ and have additional tests done for research. The observational group will have the same follow-up they would have if they were not participating in a research study except the study team will collect information from this group to look at later.

Study Visits after Transplant
The visits below are for participants who receive a HIV+ organ and participants who receive a HIV- organ and are included in the control group.

Following transplant, we will meet with you at your regularly scheduled post-transplant visits:
weeks 1, 2, 3, 4, 8, 13, 26, 39, 52 (1 year), 78 (year 1.5), 104 (year 2), 130 (year 2.5), 156 (year 3), 182 (year 3.5), and 208 (year 4) after your transplant.

At these visits, we will do the following:

- Review your medications and health

- Perform a physical examination including checking your vital signs
- Review blood results that show your immunosuppressant level(s)
- Collect blood and urine to find out how well your transplanted kidney is functioning
- Review your chart and ask about any post-transplant infections or complications
- Take blood to look at your CD4 count and HIV viral load

Study Visits for the Observational Group

If you receive a HIV- organ and are not included in the control group of the study, you will included in an observational group that involves the collection of data about your transplant and HIV disease. If you had blood collected for research before being randomized into the observational group, your samples will be kept but no further research blood will be collected.

Study information will be collected during your routine post-transplant follow-up visits at weeks 26, 52 (1 year), 104 (2 years), 152 (3 years) and week 208 (4 years) after your transplant. At this time, we will collect the following:

- Your current medications
- Blood test results that show how your transplanted organ is functioning and how well your HIV disease is under control
- Any biopsy results since your prior visit in order to record any problems with your transplanted organ
- Immunosuppressant blood levels
- Review your chart and ask about any post-transplant infections or complications so that this can be collected as a part of the study
- Information about your physical exam
- Blood test to look for antibodies against your donor

Study Procedures

Blood Sample

Prior to transplant and at weeks 13, 26, 52 (1 year), 104 (2 years), 152 (3 years), and week 208 (4 years) after your transplant we will take approximately 7 tablespoons of your blood for research. At your study visits on week 1, 2, 3, 4, and 8 we will take approximately 2 tablespoons of your blood. We may also take approximately 2 tablespoons of blood if you need a biopsy for clinical care or your HIV becomes detectable.

Blood collected for research are to:

- Examine antibodies. Antibodies form when the immune system sees something foreign in your body, such as an organ transplant. We will be looking for antibodies against your kidney donor.
- Your HIV disease. The study doctors will be looking at the amount and type of HIV circulating in your blood.

Lymph Node(s) for Research

At the time of your transplant (during surgery), your study doctor will take one large lymph node or 2-3 small lymph nodes for research. Study doctors plan to examine your lymph nodes to look for the amount and type of HIV that may be present.

Urine Sample

A urine sample will be collected prior to transplant (if you are still making urine) and at weeks 26, and 52 (1 year). An additional sample may also be collected if you have suspected rejection.

Kidney Biopsy

A biopsy will be taken from the donor kidney before it is transplanted into your body. You will also have a kidney biopsy at 6 and 12 months after your transplant and at any other times when your doctor is concerned about the health of your transplanted organ. These biopsies are used to detect rejection of the transplanted organ and may be done even if you did not take part in this study. However, if you take part in this study, a portion of the tissue will be stored for research for future testing. Your study doctors will be looking for HIV and any sign of injury in your transplanted kidney. There may also be tests that are that are not currently known, but are discovered in the future.

Genetic Studies

Genetic information will be recorded from specimens collected for this study. The specimens will be used in experiments planned for this study and with your permission for future studies not yet planned. Your samples will not be looked at for other genetic conditions, genetic cloning, or paternity testing. We will keep all information recorded private as much as possible. However, because genetic information is unique to you, complete confidentiality cannot be guaranteed.

Quality of Life Assessment

You will be asked to complete a questionnaire regarding your health and well-being prior to your transplant and again at weeks 26, 52 (1 year), 104 (2 years), 152 (3 years), and 208 (4 years) after your transplant.

Patient Reported Outcomes

You will be asked to complete a 2nd questionnaire regarding your feelings about the transplant. This will be collected at weeks 26, 52 (1 year), 104 (2 years), 152 (3 years), and 208 (4 years) after your transplant.

6.RISKS AND/OR DISCOMFORTS

Although transplantation in HIV+ individuals using HIV- donors has been successful, the use of organs from HIV+ donors could be more risky. In this study, you can decide whether to accept an HIV+ organ or an HIV- organ.

Rejection

There is a higher risk of rejection of the new organ in HIV+ patients, but nothing is known about rejection of organs from HIV+ donors. This is one of the reasons we are doing this study. One idea about this is that the medicines used to control HIV may interfere with the medicines used to avoid rejection of the new organ. In order to try to avoid this risk, we will try not use HIV medicines that may cause this problem whenever possible. Also, we will pick rejection medicines that are individual to you and may give you the best chance of not rejecting your new organ. However, there is still a risk that your body may reject your new organ.

HIV Related Kidney Disease

Some doctors have found that there is a higher risk of kidney disease in HIV+ kidney transplant patients. Other groups have found this is not true. If you are receiving a kidney transplant, we will very closely watch how your kidney is working. This will not remove the risk of kidney disease, but will allow us to discover and treat the problem more quickly.

In African American kidney transplant patients with HIV, some doctors have found a form of a gene that is related to kidney disease. With your permission above, we will test to see if you have this form of the gene. Again, this will not remove the risk of kidney disease, but we will know there might be a greater risk and will closely watch your new kidney for problems.

Infections

There is a high risk of infections in HIV+ transplant patients that are so serious that they must be admitted to the hospital. We also know that some of these viral infections can also cause cancer that in rare cases can lead to death. However, very little is known about this in patients with organs from HIV+ donors. This is one of the reasons we are doing this study. In order to try to reduce this risk as much as possible, we will make sure that you are as healthy and free from other infections as possible before your transplant. We will also give you medicines that may stop infections before they happen. However, there will still be a high risk of infection after your transplant.

HIV Superinfection

If you can accept an HIV+ organ, there is also a chance that your transplanted organ may contain a type of HIV that cannot be controlled by the HIV medicines you use now. You would have to change your HIV medicines to control this new type of HIV, and the new medicines may interfere with the drugs you are given to prevent rejection of your new organ. In order to try and reduce this risk as much as possible, the transplant team will carefully review the HIV history of the donors. We will only use organs from donors where we expect that there is a safe and tolerable HIV medication combination that will work to control virus from you and the donor. Also, if the HIV that the donor had cannot be controlled by the HIV medicines you use now, we will pick new HIV medicines that are individual to you and may give you the best chance of controlling the new HIV. However, there is still a risk that your HIV will be more difficult to control.

Blood Draws

Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

Lymph Node Collection

The collection of lymph node (s) will occur during your transplant surgery. There is a slight chance of bleeding, infection and/or fluid collection from the area where the lymph nodes are taken. In addition, you may experience some tenderness in this area.

Kidney Biopsy

If you agree to take part in this study, an additional sample of kidney tissue will be removed at the time of the kidney biopsy. The most frequent complications of a biopsy include pain and blood in the urine. In rare cases, bleeding from the biopsy may cause a drop in blood pressure or cause anemia. This may require the administration of intravenous fluids or blood. Surgery, to repair a tear or to stop persistent or massive bleeding is required in less than 1 per 500 biopsies and in less than 1 per 2000 cases is it necessary to remove the kidney. Other uncommon complications include puncture of other organs (liver, spleen, bowel) or the creation of a fistula (a connection between an artery and vein).

Genetic Information

This research includes genetic testing. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information. We believe the chance these things will happen is very small, but we cannot make guarantees.

A federal law (Genetic Information Non-Discrimination Act, GINA) helps reduce the risk from health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long term care insurance. If you want to learn more about GINA, you can find information about it on the internet or ask the study staff.

Genetic information is unique to you and your family, even without your name or other identifiers. The research team follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you.

There is the risk that information about you may become known to people outside this study.

Unforeseen Risks

Treatment and procedures in this research study may involve risks that are not possible to predict. You will be informed of any new risks that may be identified during the study. Please ask your study doctor or the research staff to explain any procedures or risks that you do not understand.

7. POTENTIAL BENEFITS

If you accept an HIV+ donor organ, it is possible you may receive a transplant sooner than if you wait for an HIV- organ. This may have a survival benefit. You may also receive a better quality organ. If you take part in this study, you may also help others in the future.

8. ALTERNATIVES TO PARTICIPATION

The study doctor and/or study staff member will talk with you about this study and other options available to you. You do not have to join this study. If you do not join, your clinical care will not be affected.

9. NEW FINDINGS

The study doctor will tell you about any new information that may affect your willingness to continue in this study.

10. VOLUNTARY WITHDRAWAL FROM STUDY

You may decide not to take part or to leave the study at any time. If you decide to leave the study, there is no penalty or loss of benefits in your routine medical care or any other benefit(s) that you would otherwise be entitled to receive.

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

In addition, you should talk to your study doctor who will discuss future treatment and procedures for your continued care.

If you leave the study early, [insert study site] may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. 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:

- You are pre-transplant and no longer meet the study criteria.
- The study doctor feels it is not in your best interest to continue in this study.
- You are unable to complete required follow-up and examinations.
- The study is stopped by the Institution, the Sponsor(s), or by the Food and Drug Administration (FDA) or other health authorities.

12. PREGNANCIES, BREASTFEEDING AND BIRTH CONTROL

You cannot participate in this study if:

- You are currently pregnant or breastfeeding.
- You or your partner plan to get pregnant.

Treatments 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 performed prior to your transplant.

If you participate in this study, you and your partner must agree to use an approved method of birth control by the U.S. Food and Drug Administration (FDA) during the study. You and your study doctor will discuss acceptable methods of birth control. If you or your partner should become pregnant while participating in this study, or if you suspect that you have become pregnant, you must contact your study doctor immediately.

13. COSTS TO THE PARTICIPANT (YOU)

Costs related to your routine clinical care of your HIV disease, transplant or other medical problems will be billed to you and/or your insurance provider(s). There will be no charge to you or your health insurance company for any costs which are directly related to this study, such as the research blood draws.

14. PAYMENTS (REIMBURSEMENT)

While you are an in-patient, you will receive no compensation. When you need to come to the clinic for follow-up you will receive $25 for each visit attended. Compensation will be given as a ClinCard (a secure, passcode protected debit card) or cash.

There is no other form of compensation available such as reimbursements for parking, tokens or child care. In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

15. RESEARCH-RELATED INJURY

If you are injured or become ill because of taking part in this study, it is important to tell your study doctor. Emergency treatment will be available to you, however the costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

There are no funds available for this purpose and the study will not pay for medical care. In case of injury resulting from this study, you will not lose any legal rights by signing this form.

16. CONFIDENTIALITY

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

You will be identified by a code, and personal information from your records will not be released without your written permission. You will not be identified in any publication or in the sharing of your data about this study. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other traditional personal identifiers. The purpose is to share and make study data available to other researchers.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate cannot be used to refuse a request for information from personnel of the United States federal agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Allergy and Infectious Diseases (NIAID), which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Your personal information may be given out if required by law. If you test positive for infectious diseases (HIV, Hepatitis B or C) by law we have to report the positive test results to the City of Philadelphia Health Department and/or PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements of reporting infectious diseases to the PA Health Department, please visit www.health.pa.gov and type 'Reportable Diseases' into the site search bar.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HIPAA AUTHORIZATION

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What information about me may be collected, used or shared with others?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, email address, Social Security Number, Medical record number dates directly related to you such as date of birth and clinic visits.
- Personal and family medical history
- Current and past medications or therapies
- Information from questionnaires administered in the study
- Results of tests and procedures you will undergo during this research

Why is my information being used?

Your information is important for the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- see if the research was done right
- evaluate and manage research functions

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator and the Investigator's study team
- Other authorized personnel at Penn, including offices that support research operations.
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside the School of Medicine, might receive my information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures.

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.

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine be able to use or disclose your personal health information?
Your authorization for use of your personal health information for this specific study does not expire.
Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at Infectious Disease Division, 502 Johnson Pavilion Philadelphia PA 19104. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject Informed Consent form and HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR. Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

17. PROBLEMS OR QUESTIONS

If you ever have questions about this study or in case of research-related injuries, you should contact Dr. Blumberg at 215 662-7066 or if you have questions about research participant's rights you can call Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

I can call …	At …	If I have questions or concerns
Dr. Emily Blumberg Principal Investigator	Phone: 215 662-7066	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Eileen Donaghy, CRNP Research Nurse	Phone: 215 349-8092	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
University of Pennsylvania IRB	Phone:***215 898-2614***	▪ Rights of a research participant ▪ Use of protected health information ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints ▪ If investigator/study contact cannot be reached ▪ If I want to speak with someone other than the Investigator, Study Contact or research staff

18. STORAGE OF SAMPLES AND/OR INFORMATION FOR FUTURE USE

We are asking your permission to store unused samples and information resulting from the analysis of samples of biological specimens (e.g., blood, tissue, and urine) collected during the course of this study to be used in the future for tests that aren't yet planned.

This research could include other diseases and may involve research tools such as gene sequencing. Gene sequencing of your DNA provides researchers with the code to your genetic material. Genetic tests study an individual's inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate the human body.

Some information about a research specimen will always be linked to it. For example, researchers will know the 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.

The results of tests performed on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to a specific condition. The purpose of storage and sharing data is to make information available for use in health research. Collecting, storing, sharing information and making it available for other studies may help people in the future.

Samples will be stored at Johns Hopkins while the study is ongoing and possibly for years following study completion.

You can change your mind at any time and ask to have your samples destroyed. This request should be made in writing to the study doctor. If you make this request, all remaining stored samples will be destroyed. However, the results of any previous tests using your stored samples will be used. Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study.

Please indicate your response below:

I agree to the storage and sharing of samples (urine, blood and/or tissue) for genetic tests not currently planned.

☐ **Yes** ☐ **No**

_____
Initials of Research Participant

I agree to the storage and sharing of samples (urine, blood and/or tissue) and information resulting from the analysis of my samples for other tests not currently planned.

☐ **Yes** ☐ **No**

_____
Initials of Research Participant

I agree to be contacted for future research?

☐ **Yes** ☐ **No**

_____
Initials of Research Participant

IRB APPROVAL FROM:
05/23/2019 TO: 05/22/2020

CONSENT

This consent is the initial consent for this participant. The study staff will provide an overview of the study, required visits, treatment regimen, risk and all elements of consent. The physician investigator(s) or licensed Nurse Practitioner will conduct a focused discussion about risks, benefits and alternatives.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

RESEARCH STAFF CONSENT

_____	_____	_____
Name of Subject (Please Print)	Signature of Subject	Date/Time

_____	_____
Participant's Legally Authorized Representative (print) (As appropriate)	Legally Authorized Representative's Signature and Date/Time

_____	_____	_____
Name of Person Obtaining Consent (Please Print)	Signature	Date/Time

INVESTIGATOR CONSENT

The risks, alternatives, and benefits have been reviewed with me by the Investigator, and I understand what we have discussed.

_____	_____	_____
Name of Subject (Please Print)	Signature of Subject	Date/Time

I verify I have reviewed risks, alternatives, benefits with this subject, who demonstrates good understanding.

_____	_____	_____
Investigator Name (PRINTED)	Signature	Date/Time

IRB APPROVAL FROM:
05/23/2019 TO: 05/22/2020