KEY INFORMATION FOR [Research protocol for organ transplantation from HIV+ donors into HIV+ recipients under the Final HIV Organ Policy Equity (HOPE) Act.]

We are asking you to choose whether or not to volunteer for a research study about the use of organs from people with HIV for transplant. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

In this study, we are giving organs from people with HIV to people like you who need organ transplants.

By doing this study, we hope to learn whether organ transplantation from HIV-positive donors is as safe and effective in HIV-positive recipients as transplants from HIV-negative donors.. Your participation in this research will last at least 1 year post-transplant, and up to 3-5 years.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The main benefit of participation would be the chance to receive an organ transplant. The waitlist for organs is long. Organs from donors with HIV are only available currently via research studies, and only to patients with HIV, and so participation in this study may be your fastest way to receive an organ transplant. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to volunteer because we do not know if organs from donors with HIV will last as long as organs from donors without HIV, or will be associated with more problems post-transplant such as infection or cancer. For a complete description of alternate treatment/procedures, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Yorg al-Azzi, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is: 111 East 210th St, Rosenthal C, 2nd floor, Bronx, NY 10467 (telephone #: (718) 920-6421).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einsteinmed.edu.

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

If you are the surrogate decision maker of an adult who may take part in this study, consent from you and the assent (agreement) of the study participant will be required. When the word "you(r)" / "my" / "me" / "I" appears in this consent form, we mean the participant; "we" means the research study doctors and research staff.

Introduction

You are being asked to participate in a research study called **[Research protocol for organ transplantation from HIV+ donors into HIV+ recipients under the Final HIV Organ Policy Equity (HOPE) Act.].** Your participation is voluntary. It is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." **[**His**]** name is [Yorg al-Azzi, MD.]. You can reach Dr. **[**Azzi**]** at:
Office Address: 111 East 210th St, Rosenthal C, 2nd floor, Bronx, NY 10467
Telephone #: (718) 920-6421
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einsteinmed.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

There is no external financial support being received for this study.

Why is this study being done?

The goal of this study is to learn whether organ transplantation from HIV-positive donors is as safe and effective in HIV-positive recipients as transplants from HIV-negative donors.

Why am I being asked to participate?

You are being asked to participate in this study because you are diagnosed with end-stage organ disease and have HIV infection, and qualify for organ transplantation. The specific organ or organs you will receive are:

_____ Kidney
_____ Pancreas
_____ Liver
_____ Heart
_____ Lung

How many people will take part in the research study?

You will be one of about **200** people who will be participating in this study

How long will I take part in this research?

You will be in this study for at least one year, and up to three or five years after your organ transplant. During this time, we will ask you to make at least 15 study visits to **Montefiore Medical Center**.

What will happen if I participate in the study?

You are already on the waiting list to receive a donated organ as part of your standard clinical care. Your pre- surgical evaluation, surgery and any follow-up will not be affected by your participation in 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 or a member of the study team at least 15 times as described below.

Screening

After you sign this consent form, you will be evaluated by a review of your medical record, current medications, blood test results, and other tests, and have a physical exam.

Study Visits

If after screening and your transplant, you are able to continue to take part in this study, we will meet with you at your regularly scheduled post-transplant visits. You will also have labs drawn as per the post-transplant protocol for the organ transplant(s) you are receiving. If you have any questions about the post-transplant monitoring protocol for your specific organ transplant, please discuss this with your transplant provider.

At the clinic visits, we will do the following:

• Review your medications and health
• Perform a physical examination including checking your vital signs
    - Take blood and urine samples as per the protocol for your transplanted organ to find out how well your transplanted organ(s) is/are functioning, to measure how much immunosuppressant medication is in your blood, and to see if you have certain infections

- On the day of your organ transplant and at 1, 2, 3, 4, 12, 24, 36 and 48 weeks afterward, and every 6 months thereafter, we will also test your blood to find out how your immune system (which is a defense system that defends the body against attacks by microbes such as virus, bacteria, parasites, and fungi that can cause infections) is functioning and how much HIV is present.

You will also have biopsies of the transplanted organ performed at the time of transplant. They will also be performed post-transplant when your doctor is concerned about the health of your transplanted organ (liver, kidney) or as per the standard post-transplant protocol (heart, lung). These biopsies are used to detect rejection of the transplanted organ and would 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 of things that may change the levels of harmful antibodies or allow your doctors to detect injury to the organ, if you agree, this may include tests for things that are not currently known, but are discovered in the future.

Will there be testing for HIV?

Yes, HIV testing will be done during this research study. The following is important information about HIV, HIV testing, and your test results:

- HIV causes AIDS and can be spread through sexual activity, sharing needles, by pregnant women to their fetuses, and through breastfeeding infants.
- There is treatment for HIV that can help you stay healthy.
- People with HIV or AIDS should adopt practices to protect people in their lives from becoming infected with HIV.
- HIV testing is voluntary and can be done anonymously at a public testing center. However, testing is required if you would like to be in this research study.
- The law protects the confidentiality of HIV related test results.
- The law prohibits discrimination based on your HIV status and services are available to address any discrimination.
- If as a result of participation in this study you are INITIALLY diagnosed with HIV, the results must be reported to the New York State Department of Health for contact tracing purposes.
- If as a result of participation in this study you are diagnosed with HIV, you will be given HIV counseling or a referral for HIV counseling.

Genetic Testing

This study will not involve genetic research or genetic testing.

Specimen Banking (Future Use and Storage)

We will store your specimens and information about you in a "biobank", which is a library of information and specimens (tissue and blood) from many studies. These specimens and information cannot be linked to you. In the future, researchers can apply for permission to use the specimens and information for new studies to prevent, diagnose, or treat disease, including genetic research. Your specimens and information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the biobank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my specimens and information about me used for future research studies.
_____ I do NOT consent to have my specimens and information about me used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

Taking part in this study will not involve added costs to you. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

What else do I have to do?

- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- If you think you have become pregnant, contact your research study doctor immediately.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to **Dr. Azzi at 718-952-6421**.

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information and specimens will be kept as long as they are useful for this research.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

Information about your participation in this study will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, the information will be available to all of your providers who participate in the EMR system. The purpose of this entry is to provide research information that has the potential to impact your medical care.

The only people who can see your research records are:

- the research team and staff who work with them
- the organization that funded the research
- organizations and institutions involved in this research
- groups that review research (the Einstein IRB, and the Office for Human Research Protections, and the US Food and Drug Administration)

These people, who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Being a HIV positive patient who will undergo organ transplantation, you may have one or more of the risks below regardless of the study, whether you will undergo organ transplant from HIV

negative donor which is the standard of care, or from the HIV positive donor which is the case in this study research. These risks are:

- A possible drug interaction may occur which can be quite severe and may lead to serious undesirable outcomes from unexpected changes in blood levels of drugs; these may include: increased rejection rate, increase viral level in the blood, and decrease in your T-cell count with possible progression to AIDS.
- Higher acute rejection rate
- Increased risks of venous thromboembolism (formation of one or more blood clots in your veins) in HIV Positive individuals.
- If you have a co-infection with HBV, HCV or both, transplantation adds additional risks, risk of developing Hepatocellular carcinoma (a liver cell cancer) is high
- There may be a possibility of change in the standard organ transplant treatment regimen or change in the doses of their medications which may lead to a possible undesirable outcome.
- You may need a life-long treatment for opportunistic infections (which are infections that occur more frequently and are more severe in individuals with weakened immune systems like in HIV positive).

An additional risk, that you may have from participation in this study, is a transmission of a medication resistance type of virus from the donor organ.

Blood Draw
Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless “black and blue” may develop. Very rarely, fainting may occur.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you or the embryo or fetus will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefit of taking part in this study, allowing the use of organ donors infected with HIV, is the potential for increasing the pool of available organ donors to you, and potentially shortening your wait time until transplantation. Your participation will generate new clinical knowledge and a better understanding of HIV-positive to HIV-positive organ transplantation.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not the individual named below participates. I know enough about the purpose, methods, risks and benefits of the research study to decide. I understand that I am not waiving any of his/her legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed Name of Surrogate (when applicable)	Signature of Surrogate (when applicable)	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time