

TEMPLATE*

DONOR CONSENT

Solid Organ Transplantation in HIV:
Multi-Site Study
HIVTR Version 3.0
August, 2006

[Kidney, Liver]



*Note: The Kidney and Liver consents have been combined in this template.
Sites should create separate consents for each organ.

Sections of the consent that are organ or site specific have been marked in [bold, brackets] and should be modified accordingly .

Consent to be a Research Subject
Solid Organ Transplantation in HIV: Multi-Site Study

Living Kidney or Liver Donation in a Research Study [and
Collection and Preservation of Blood Specimens from Organ Donors]

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Consent to be a Research Subject
Solid Organ Transplantation in HIV: Multi-Site Study

Living Kidney or Liver Donation in a Research Study [and
Collection and Preservation of Blood Specimens from Organ Donors]

PURPOSE AND BACKGROUND

A research study is being conducted to look at the safety of **[kidney, liver]** transplants and how well they work in persons living with HIV infection. The main questions being studied include 1) do post-transplant immunosuppressive medications (drugs that prevent the body from attacking the new **[kidney, liver]**) make HIV infection worse, 2) does HIV infection make the transplanted **[kidney, liver]** not work as well, and 3) how do antiretroviral medications (drugs used to treat HIV infection) and immunosuppressive medications interact with each other in the body.

People with HIV infection are at risk for **[kidney, liver]** disease for the same reasons that people without HIV infection get these diseases, and also because of HIV-related **[kidney, liver]** disease. Due to improvements in the treatment of HIV, HIV-infected patients may now be better candidates for a transplant. Up until recently, people with HIV infection have often not been offered a transplant because of concerns that the immunosuppressive medications might worsen the patient's HIV infection. This concern is a major focus of this study.

I am being asked to participate in this study because I am interested in donating either my kidney or a part of my liver for transplantation in an HIV-positive friend or relative who has enrolled in this study.

PROCEDURES

If I agree to participate in this study, I will not have any special tests or procedures different from what I would have if I wanted to donate my organ to someone who was not in this study except I will have approximately [Cluster 1: 3 tablespoons] [All other Clusters: 2 teaspoons] of blood drawn and shipped to laboratories participating in this study for research tests, or will be frozen and stored for future research studies. Samples will be stored with a coded number at a central storage bank or at participating laboratories. Only the study doctors will know who the samples belong to. Unused samples will be discarded after 5 years unless additional funding is available to continue storing them.

RISKS/DISCOMFORTS

There are risks associated with donating an organ that have been explained to me by the surgical team evaluating me for potential organ donation. These risks must be weighed against the potential benefits for the transplant recipient. In the case of

transplantation in people with HIV infection, the outcome has not been well studied. It is possible that the transplant recipient will not do as well as someone without HIV infection and that my donated organ may not survive as long as it would in someone who is HIV negative. There is no greater risk to me than usual, but I may not want to accept the usual risk to me given the unknown benefit to the transplant recipient. I can elect at any time not to donate my organ for this or any reason.

A. Blood drawing

Blood drawing may cause some discomfort, bleeding or bruising where the needle enters the skin, and rarely, fainting or infection may occur.

B. Confidentiality

No individual identities will be used in any reports or publications resulting from this study. If you agree to participate, a regular medical record will be created for you at the medical center.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

Understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

[The sites should include language such as the following if they intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures.] The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you/your child as a participant in the research project under the following circumstances. [The sites should state here the conditions under which voluntary disclosure would be made. If no voluntary disclosures will be made, the researchers should so state.]

Medical and research records may be reviewed by the United States agency sponsoring the research (the National Institute of Allergy and Infectious Diseases), including its representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring or analyzing the study. In addition, the U.S. Food and Drug Administration, or other health authorities may review your medical and research records for regulatory purposes.

TREATMENT AND COMPENSATION FOR INJURY

If I am injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by [xx] on a number of factors. The University does not normally provide any other form of compensation for injury. For further information I may call [xx] at [xxx] or write: [xx].

A. Benefits

There is no direct benefit to me from participation in this study.

B. Alternatives

The alternative to study participation is not to participate.

C. Cost

There are no costs to me for participating in this study.

D. Reimbursement

I will not be reimbursed.

QUESTIONS

I have discussed this study with [xx] and my questions have been answered. If I have further questions or I experience a study-related injury, I may call [xx] at [xx]. If I have any questions about my rights as a participant in a research study, I may contact [xx] at [xx].

CONSENT

I have been given a copy of this signed and dated consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. I may decline to participate or may withdraw at any point from this study without jeopardy to any present or future care I may require. I agree to participate in this study.

Subject's Signature

Date

Subject's Printed Name

Signature of Person Obtaining Consent

Date

I agree to have blood stored for possible future tests.

Yes

No

Subject's Initials