

**OCHSNER CLINIC FOUNDATION
RESEARCH INFORMED CONSENT**

**Prospective, Observational Study of Donor and Recipient Factors Which May
Influence Preservation Injury in Liver Transplant Recipients****Sponsor's Protocol # Cohen 10-01**
Sponsor name: Ari Cohen, MD**IRB # 2010.179.A**

Principal Investigator: Ari Cohen, MD**Sub-Investigators: Humberto Bohorquez, MD****David Bruce, MD****Ian Carmody, MD****George Loss, MD, PhD****Nigel Girgrah, MD****Shobha Joshi, MD****Natalie Bzowej, MD, PhD****John Seal, MD****Emily Ahmed, MD**

Are you in any other research studies? Yes _____ No _____
please initial your response

You have been invited to participate in a research study. The doctors and staff at Ochsner study the nature of disease and attempt to improve methods of diagnosis and treatment. This is called clinical research. Understanding this study's risks and benefits will allow you to make an informed judgment about whether to be part of it. This process is called informed consent.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

PURPOSE

You have been asked to participate in this study because you will receive a liver transplant. Your new liver will come from a donor. The donor's blood in the liver will be replaced by a cold storage solution of special chemicals and nutrients. This preserves the liver until it can be connected in you. Currently, some donor livers are not transplanted. We think these organs may be injured during the storage period when

there is no blood flow. We are studying liver injury during the period when there is no blood flow. The purpose of this study to help determine which livers may have problems during the period without blood flow.

LENGTH OF STUDY AND NUMBER OF PARTICIPANTS

Your active participation in this research study will be for 1 day. Ochsner will be the only site and about 500 subjects will be enrolled.

PROCEDURE

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

A total of 3 blood samples will be collected from a vein. Each will be about 2 teaspoons of blood. They will be collected at the start of your transplant, 5 minutes after your new liver is connected and at the end of your transplant operation.

During your transplant operation, we always take a biopsy of your new liver for routine testing. We would like to take an additional liver biopsy for our research.

Routine medical information will be collected from your chart. This includes current information about your age, race, sex, height, weight, your diagnosis, and MELD score at transplant. Clinical data pertaining to your transplant and post-transplant hospital stay will be collected. Clinical data pertaining to your post-transplant follow-up care will also be collected.

RISKS

General / Unforeseeable

The greatest risk to you is the release of information from your health records. Your personal information such as name, address and telephone number will be kept private. The chance that this information will be given to someone else is very small. You will be identified by a code.

Whenever blood is drawn, there is a small risk of slight pain, bruising, the possibility of infection, or bleeding from the site. A qualified person will be drawing the blood samples to make sure that the risk of drawing blood will be small.

The additional biopsy will not add any additional risks beyond those that are existing due to the transplant surgery.

POTENTIAL BENEFITS

You may not receive direct personal or health benefit from taking part in this study. However, the information gained from your participation in this study may be used to

help others in the future.

COSTS

There is no cost to you for participation in this study.

PAYMENT FOR PARTICIPATION AND/OR REIMBURSEMENT OF EXPENSES

There is no payment for participation in this study.

ALTERNATIVE METHODS/TREATMENTS

You do not have to participate in this study. If you do not join, your care at Ochsner will not be affected. Your transplant will proceed as planned if you decline the study.

STUDY RELATED QUESTIONS AND COMPENSATION FOR INJURY

If you have any questions concerning your participation in this study or if at any time you feel you have experienced a research-related injury or a reaction to a study drug, contact:

Dr. Ari Cohen at Ochsner Clinic Foundation
Address: 1514 Jefferson Highway
New Orleans, LA 70121
Phone: 504-842-3925 or 1-800-928-6247

In the event of research-related injury from the research procedures or drugs or device, medical treatment and hospitalization, if necessary for injuries or illness, is available. This medical treatment and/or hospitalization is not free of charge.

QUESTIONS ABOUT YOUR RIGHTS

If you have questions about your rights as a research subject, you may contact:

Ochsner Clinic Foundation Institutional Review Board
1514 Jefferson Highway
New Orleans, LA 70121
Telephone: 1-504-842-3535

The Institutional Review Board is a group of people who perform independent review of research for human subject protection.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THE RESEARCH

Participation in this study is voluntary. You may decide not to participate in this study or

you may withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled at this site. If you withdraw, no further medical information will be collected about you for the study.

CONFIDENTIALITY

Your identity and your personal records will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Confidentiality will be maintained during and after your participation in this study.

HIPAA AUTHORIZATION TO RELEASE INFORMATION FOR RESEARCH

If you volunteer to take part in this research study, you have the right to know that others may know your identity. Study information may identify you in the following ways.

- Name
- Address
- Telephone number
- Other details about you

This study includes a number of researchers, businesses and government agencies. They may use your health information and share it with others. We want you to know who may use this information and how they may use it.

We also want to tell you about your rights concerning the use of your personal information before you agree to take part in the study.

Who may use and give out information about you?

The Investigator (study doctor) and research staff will have information about your health that tells us your identity. They may give this information to others during and after the study.

Who may see this information?

The study sponsor also may see your health information and know your identity.

“Sponsor” includes any people or companies working for or with the sponsor or owned by the sponsor. They all have the right to see information about you during and after the study.

The following people, agencies and businesses may get information from us that shows who you are.

- Doctors and healthcare professionals taking part in the study
- Ochsner Clinic Foundation Research & Compliance Offices
- Ochsner Clinic Foundation Institutional Review Board (IRB)

What information may be used and shared?

If you decide to be in this study, medical information that identifies you and relates to your participation will be created. This may include the following types of medical information.

- Information obtained from the procedures used to find out whether you are eligible to take part in this study. This may include physical examinations, blood and urine tests, x-rays and other procedures or tests, and any other information that you may release to us, including information about your health history.
- Information obtained in the course of the study including information about your response to any study treatments you receive, information related to study visits and phone calls, physical examinations, blood and urine tests, x-rays and other tests or procedures that may be performed, and other medical information relating to your participation in this study.

Why will this information be used and/or shared?

Information about you and your health, that might identify you, may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by the Ochsner Institutional Review Board.

The Ochsner Research & Compliance Offices may review this research in their oversight and auditing roles.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this authorization (permission) will never expire (end) unless you revoke (cancel) it in writing.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If

you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information that might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Your personal information may be disclosed if required by law. Your records for this study may be sent by facsimile transmission (FAX machine) or over the Internet. It is possible that your records could be sent to the wrong person.

How long is my information kept?

Ochsner Clinic Foundation policy requires that all files related to a research study are stored for ten (10) years after the research study has been closed at the Ochsner site.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have been informed about this study's purpose, procedures, possible benefits and risks, and the use and disclosure of my health care information from this research. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above. By signing this consent form I have not waived any of the legal rights that I otherwise would have as a subject in a research study.

CONSENT SIGNATURE

Patient Signature	Printed Name	Date
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Signature of Legally Authorized Representative (when applicable)	Printed Name	Date
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Authority of Subject's Legally Authorized Representative or Relationship to Subject

Person Obtaining Consent - Signature	Printed Name	Date
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----- Use the following only if applicable -----

If this consent form is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to participate in the research study.

Signature of Impartial Witness	Printed Name	Date
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Note: This signature block cannot be used for translations into another language. A translated consent form, with the translation approved by the IRB, is necessary for enrolling subjects who do not speak English.