

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: FUNCTIONAL ASSESSMENT IN LIVER TRANSPLANT CANDIDATES

This is a medical research study. Your study doctor, Dr. Jennifer C. Lai, from the UCSF Division of Gastroenterology/Hepatology, or other key study personnel will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are undergoing Phase 1 liver transplant evaluation at UCSF or you are currently on the liver transplant waiting list.

Why is this study being done?

The purpose of this study is to learn more about the effects of functional status (also known as “frailty”) in liver transplant patients and their outcomes both before and after liver transplant.

How many people will take part in this study?

About 3200 people will take part in this study.

What will happen if I take part in this research study?

If you agree to be in this study:

- 1) You will be asked to answer questions regarding your functional status and level of resilience.
- 2) You will be asked to perform several physical tests to assess your functional status. For example, you will be asked to stand up from a chair several times in a row, do a grip strength test, balance with your feet together, and walk at your normal pace 4 meters down the hall. If you cannot perform any or all of these tasks, you may refuse to perform them.
- 3) Your medical chart will be reviewed by the study personnel. Information that will be collected includes demographic information (e.g., age, gender, race), laboratory data, liver transplant listing date, etiology of liver disease, and your transplant outcomes.
- 4) You will be assessed for the presence of hepatic encephalopathy, which is a term used to describe the state of confusion associated with end-stage liver

disease. This will be assessed using the numbers connection test, where you will be asked to connect a sequence of numbers on a piece of paper using a pen.

Study location: All study procedures will be done at the UCSF Liver Transplant Clinics or the UCSF Moffitt-Long Hospital.

How long will I be in the study?

You will be asked to perform the physical tests during each clinic visit while you are on the liver transplant waiting list and for about 1 year after your liver transplant. You may also be asked to undergo testing upon admission for your liver transplant. Your medical record will be reviewed before and after your liver transplant to determine your outcome on the liver transplant waiting list and/or after transplant.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What risks can I expect from being in the study?

- **Physical injury from performing measures of functional status:** The tests of functional status involve basic activities that you would normally do throughout the day, so the risk of injury is minimal. These tests will be administered only by trained study personnel who will be ready to assist you in case of instability. However, there is the possibility of injury from performing one of the measures of basic functional status. For example, you may slip and fall while walking down the hall to test your walking speed. If you do not feel safe to perform any of these measures, you may refuse to perform that specific test.
- For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help doctors learn more about the relationship between functional status and liver transplant waiting list outcomes, and it is hoped that this information will help in the treatment of future patients on the liver transplant waiting list.

What other choices do I have if I do not take part in this study?

You do not have to participate in this study. If you decide not to be in this study, you will not lose any of your regular benefits, and you will still receive medical care from UCSF. There will be no benefits or repercussions to your liver transplant listing status based on your agreement or refusal to participation in this study.

Who is sponsoring this study?

This study is being funded by the National Institutes of Health, the American Federation for Aging Research, the American College of Gastroenterology, the UCSF Older Americans Independence Center, and the UCSF Research Allocation Program.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Representatives of the University of California

Some of your research test results may be provided to your UCSF liver doctor or may be included in your medical record. Your doctor may use this information to make decisions about how to provide you with better clinical care. Hospital regulations require that all health care providers treat information in medical records confidentially.

What are the costs of taking part in this study?

You or your insurance will not be charged for any of the tests of functional status.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

You may be offered your choice of a 1 hour parking voucher and/or a \$5 gift card to either Starbucks or Target.

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

It is important that you tell your study doctor, Dr. Jennifer C. Lai, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at 415-476-6422.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor, Dr. Jennifer C. Lai, at 415-476-6422.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent