

International Living Donor Liver Transplant Registry

LDLTregistry.org

Informed Consent form for the International Living Donor Liver Transplant Registry – LDLTregistry.org

This **Informed Consent Form** is for men and women who attend the [*please add the name of your clinic here*] and who we are invited to participate in the International Living Donor Liver Transplant Registry - LDLTregistry.org.

The international **Chief Investigators** of LDLTregistry.org are: Professors Mohamed Rela, from Chennai, India; Elizabeth Pomfret, from Aurora, CO, USA; Hiroto Egawa, from Tokyo, Japan; and Ki-Hun Kim, from Seoul, Korea. The local Principal Investigator at [*please add here the Name of the Clinic, Hospital / University*] is [*please add here the Name of Principal Investigator*].

[*please add here the Logo of your Clinic / Institution in colour and high resolution*]

This **Informed Consent Form** has two parts:

- A. Information Sheet** (to share information about the Registry with you)
- B. Certificate of Consent** (for signatures if you agree to take part)

You will be given a copy of the full **Informed Consent Form**.

To proceed with the Information Sheet (PART A), please go to the next page.

International Living Donor Liver Transplant Registry

LDLRegistry.org

PART A: Information Sheet

Introduction

We have developed a worldwide Registry that seeks to assess the complication rates of donors and recipients undergoing living donor liver transplantation. Audits and **registries** are a way to find out if healthcare is being provided in line with standards and lets care providers and patients know where there could be improvements. The aim is to allow quality improvement to take place where it will be most helpful and will improve outcomes (e.g. complication rates) for patients.

We are going to give you information and invite you to be part of this Registry. You do not have to decide today whether or not you will participate in it. Before you decide, you can talk to anyone you feel comfortable with about this Registry. There may be some words that you do not understand. Please ask your doctor to stop as he/she goes through the information and will take time to explain. If you have any questions later, you can ask the doctor or the staff.

Purpose of the Registry

Living donor liver transplantation was introduced in the early 90's to overcome an increasing shortage of available organs for transplantation. Living donor liver transplantation remains the main source of livers for liver transplantation in Asian countries, however, reports on donor morbidity have hampered the uptake of the procedure in Western countries. Outcome data are available from developed countries, but outcomes in developing countries remain unknown. There is a need to collect data from all parts of the world, to create a single database and allow meaningful comparisons, as well as standardization of the procedure, across the globe.

The purpose of LDLRegistry.org is to improve the practice of living donor liver transplantation by sharing of information and innovation worldwide.

Participant selection

We are inviting all donors and recipients undergoing living donor liver transplantation to participate in the International Living Donor Liver Transplant Registry - LDLRegistry.org.

Voluntary Participation

Your participation in this Registry is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this Registry, you will be offered the treatment that is routinely offered in this clinic/hospital. You may change your mind later and stop participating even if you agreed earlier.

Information on the International Living Donor Liver Transplant Registry

Several risk factors, such as age, type of disease and medical history and different types of treatments will be associated with complication for both the donor and the recipient in a statistical analysis. This way we may provide a verified record of the true complication rates as well as what could be causing them. As LDLRegistry.org is a Registry, this will not influence the type of treatment that you are offered, thus there will be no health risks involved if you agree to participate.

International Living Donor Liver Transplant Registry

LDLTregistry.org

Duration

The **International Living Donor Liver Transplant Registry** - LDLTregistry.org will take start in 2023 with an enrolment period of at least 10 years.

Benefits

If you participate in LDLTregistry.org, there will be no direct health benefit for you but your participation is very likely to help us improve the practice of living donor liver transplantation and hence future generations are likely to benefit from it.

Reimbursements

You will not be given any money or gifts if you agree to participate in LDLTregistry.org.

Confidentiality

We will not be sharing the identity of those participating in the registry. The information that we collect from LDLTregistry.org will be kept strictly confidential. Information about you that will be collected will be put away and no-one but the local doctors will be able to see it. Any information about you will have a number on it instead of your name, date of birth, date of operation, or any other personal identifier. Only the local doctors will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the local Principal Investigator (*[please add here the Name of Principal Investigator]*) at our clinic (*[please add here the Name of the Clinic, Hospital / University]*).

Sharing the Results

The knowledge that we get from doing this clinical audit will be presented in conferences and published in scientific journals in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in LDLTregistry.org if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the Registry at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way. It is your choice and all of your rights will still be respected.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: (*[please add here the Name of Principal Investigator, the address, telephone number and email address]*).

Accreditation

This Information Sheet was written by the Founders of LDLTregistry.org and it complies with the guidelines provided by the World Health Organisation Research Ethics Review Committee (WHO ERC), Avenue Appia 20, CH-1211 Geneva, Switzerland.

[http://www.who.int/ethics/review-committee/informed_consent/en/].

International Living Donor Liver Transplant Registry

LDLTregistry.org

PART B: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant _____

Signature of Participant _____

Date _____
Day/month/year

Statement by the doctor taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of doctor/person taking the consent _____

Signature of doctor /person taking the consent _____

Date _____
Day/month/year