**Informed Consent Form for Parents of Children Participating in the International Living Donor Liver Transplant Registry – LDLTregistry.org**

This Informed Consent Form is for parents of children who attend the [*please add the name of your clinic here*] and who 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; and Hiroto Egawa, from Tokyo, Japan. 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 color 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 let your child 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.**

**PART A: Information Sheet**

**Introduction**

We have created a global database that aims to capture the number of complications experienced by donors and recipients who undergo a liver transplant from a living donor. Audits and registries help us determine if healthcare providers are meeting certain standards and allow us to identify areas where improvements can be made. The goal is to improve the quality of care and outcomes for patients by addressing any issues that arise, such as reducing complications.

We would like to provide you with information about this database and invite your child to participate in it. However, you don't have to decide right away. Take your time to discuss it with someone you trust before deciding. If there are any unfamiliar words or terms, don't hesitate to ask your child's doctor to pause and explain them to you. They will take the time to ensure you understand. If you have any questions later on, you can always ask your child's doctor or the healthcare staff.

**Purpose of the Registry**

Living donor liver transplantation was developed in the early 1990s as a solution to address the growing shortage of organs available for transplantation. In Asian countries, living donor liver transplantation continues to be the primary source of livers for transplantation. However, concerns about complications experienced by donors have limited the adoption of this procedure in Western countries. While some outcome data exist from developed countries, we still lack information about outcomes in developing countries.

To address this, it is important to gather data from all regions of the world and create a unified database. This will enable meaningful comparisons and promote global standardization of the procedure. By collecting data from diverse locations, we can better understand the effectiveness and safety of living donor liver transplantation worldwide.

The purpose of LDLTregistry.org is to improve the practice of living donor liver transplantation by sharing 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 - LDLTregistry.org.

**Voluntary Participation**

Your child's involvement in this registry is completely voluntary. The decision to participate or not is entirely up to you as their parent. Regardless of your choice, the services your child receives at this clinic will continue as usual, and nothing will change in that regard. If you decide not to let your child take part in this registry, they will still be offered the standard treatment provided by this clinic or hospital. It's important to know that you have the freedom to change your mind at any time and withdraw your child from participating, even if you had initially agreed to be part of the registry.

**Information on the International Living Donor Liver Transplant Registry for Parents of Children**

In several statistical analyses, we will examine various risk factors such as age, type of disease, medical history, and different treatment approaches specific to children. By doing so, we aim to establish a reliable record of the actual rates of complications in pediatric living donor liver transplantation and identify potential causes behind them.

It's important to note that participating in the LDLTregistry.org as a registry will not impact the type of treatment offered to your child. Therefore, agreeing to let your child participate does not pose any additional health risks to them.

**Duration**

The International Living Donor Liver Transplant Registry - LDLTregistry.org will start on September 1st, 2023, with an enrollment period of at least 10 years.

**Benefits**

If your child participates in LDLTregistry.org, there will be no direct health benefit for them, but their participation is very likely to help us improve the practice of living donor liver transplantation in children. As a result, future generations of children are likely to benefit from these improvements.

**Reimbursements**

You will not receive any money or gifts if you agree to let your child participate in LDLTregistry.org.

**Confidentiality**

We will not share the identity of those participating in the registry. The information we collect from LDLTregistry.org will be kept strictly confidential. Any information about your child that will be collected will be stored securely, and only the local doctors involved in the registry will have access to it. Your child's information will be anonymized and identified by a unique number instead of their name, date of birth, or any other personal identifier. Only the local doctors will know the corresponding number, and we will ensure that this information is securely locked away. 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 information obtained from this registry will be shared through conferences and published in scientific journals. This allows other individuals who are interested in this research to learn from our findings. By disseminating this knowledge, we contribute to the broader medical community and promote the advancement of understanding in the field of pediatric living donor liver transplantation.

**Right to Refuse or Withdraw**

You are not obligated to let your child take part in LDLTregistry.org if you do not wish to do so, and refusing to participate will not affect your child's treatment at this clinic in any way. Your child will still receive all the benefits they would otherwise have at this clinic. You may stop your child's participation in the Registry at any time without losing any of their rights as a patient here. Your child's treatment at this clinic will not be affected in any way. It is your choice as a parent, and all of your child's 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 complies with the guidelines provided by the World Health Organization Research Ethics Review Committee (WHO ERC), Avenue Appia 20, CH-1211 Geneva, Switzerland.

[http://www.who.int/ethics/review-committee/informed\_consent/en/].

**PART B: Certificate of Consent**

I, as the parent/legal guardian of the participant, 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 hereby give consent on behalf of my child to participate voluntarily as a participant in this research.

Name of Participant (Child) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent/Legal Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Day/month/year

**Statement by the doctor / person taking consent**

I, the undersigned doctor/person taking the consent, confirm that the participant's parent/legal guardian was given an opportunity to ask questions about the study, and all the questions asked 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's parent/legal guardian.

Print Name of doctor/person taking the consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of doctor/person taking the consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Day/month/year