**​Data Sharing Agreement**

## **This data sharing agreement is made on**

## [State the date the agreement is signed]

## **Between:**

[Give the full name of your organization signing this agreement] (“Provider”)

**AND**

Klinik Hirslanden (Kappelistrasse 7, 8002 Zürich, Switzerland | LDLTregistry.org Headquarters (“Recipient”)

***WHEREAS***

* Provider and Recipient seek to collaborate on LDLTregistry.org International Audit, as further described (the “Study”);
* the Parties desire to transfer to each other for the advancement of clinical research certain de-identified scientific data;

## **Purpose and objectives of the information sharing**

The International Living Donor Liver Transplant (LDLT) Registry | LDLTregistry.org is a multidisciplinary collaborative of international physicians to study the outcomes of Living Donor Liver Transplantation (LDLT). The goal of LDLTregistry.org is to improve the practice of LDLT by sharing of research and innovation.

## **Controller and Processor**

The Recipient will act as sole controller and processor of data in this registry.

## **Data items and confidentiality**

Fully anonymized data of donor and recipient pre-, peri-operative characteristics, and postoperative outcomes are collected by the provider. The provider certifies that the Study Data shall be provided in a coded de-identified fashion. Under no circumstances shall Provider provide Recipient with the name, address, social security number, or any other identifier or protected health information (collectively, “PHI”) which would permit Recipient to identify the research subjects from whom such Study Data was collected. Detailed items of collected data are subsummized in the attached Case Report Forms (CRF). There will be no surgeon, or center related data reporting, all data will be fully anonymized. All data collected, processed, and stored for the purpose of the LDLTregistry.org project will remain confidential and comply with Good Clinical Practice (GCP) for research guidelines and the principles of the Revised Federal Act on Data Protection (FADP) (CH).

## **Transparency**

The registry protocol is available at LDLTregistry.org along with patient information leaflets. All analyses and results will be published in peer reviewed journals with open access. All involved with LDLTregistry.org will receive PubMed cited group authorship. Social media and email communication will be used for communication and dissemination of information.

## **Data sharing**

Data submitted are anonymized prior to submission to the LDLTregistry.org data entry system in compliance with Article 45 of the GDPR. Access to the data entry system will be protected by username and password during the registration process for individual local investigators. All electronic data transfer between participating centers and the coordinating centers will be encrypted using SSL/TLS protocol (HTTPS). The LDLTregistry.org platform is protected by additional web security software that monitors, identified and mitigates threats, prevents attacks, accelerates website performance and meets international compliance standards. The study Chief Investigators and Founders will act as the custodians of the data. The data however belong to all collaborators. The scientific and management committees together will decide after the publication of the main report about requests from LDLTregistry.org members regarding secondary analyses and will consider all such requests based on quality and the validity of the proposed project and decide by majority decision.

**Accuracy of the data being shared and rectification of shared data**

Each participating center will identify an additional Auditor (data monitor) at their institution. Auditors will be assigned to monitor the adherence to the registry protocol as well as auditing the quality of data collection of the participating centers on a regular basis. Auditors should be healthcare professionals not directly involved in LDLT. Data that has been submitted by the provider requiring rectification due to inaccuracy (held in good faith), must be corrected by the provider. Detailed information regarding the affected data must be shared from the provider with the recipient.

## **Retention and disposal of information**

## Data will be retained for 20 years by the recipient. Once maximum data retention time has been reached, the information is deleted permanently by the recipient. In case of prolonged need of data storage, justification is sent to the provider by the recipient. Recipient agrees that upon termination of this Agreement, Recipient shall, at its expense, (a) return or destroy all Study Data received from Provider and (b) retain no copies of such Study Data for further research purposes. Recipient may retain one archival copy solely for determination of compliance with this Agreement.

## **Ownership of study results**

## Recipient shall own the technical results generated as a result of the use of the Study Data pursuant to this Agreement. Recipient hereby grants to Provider a non-exclusive, sub-licensable, worldwide, perpetual, royalty-free license to the results generated from the Study Data pursuant to this Agreement for non-profit academic, educational, and research purposes.

## **Breach management**

Main types of breach include inappropriate or accidental disclosure by the provider. In occurrence of such a breach, the recipient must be informed immediately. In occurrence of data loss by the recipient the provider is informed by the recipient and a review of data systems is triggered.

## **Points of contact**

## The provider offers a point of contact for the recipient. If the point of contact changes, it is the responsibility of the provider to update the recipient of the new point of contact. The Governance point of contact of the recipient is Dr Christian Eugen Oberkofler at Hirslanden, Zurich, Switzerland.

## **Commencement of agreement**

## The date of the commencement of the DSA is either the date of the first patient enrolled in the registry or the date of signature of the agreement, whichever comes first.

## **Review Period**

The DSA is review periodically (every 12 months) by the recipient to ensure it remains current and fit for purpose. Change in legislation or a party deciding to leave the agreement triggers a review outside the regular review period.

## **Variation**

The recipient remains the right to change the DSA. Prior to changes of the DSA, the provider is informed in written form.

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## **Term and Termination**

The Agreement shall remain effective from the time point defined above and expire on the earliest of the following dates: (a) on completion of the Study; or b) on thirty days written notice from one party to the other. This Agreement may be terminated by either Party, for any reason, upon thirty (30) days’ advance written notice to the other Party. This Agreement may be terminated immediately upon mutual written agreement signed by the authorized representatives of both Parties.

**Signatories**

[Add your signature here]

[Add your Full Name here]

[Give the full name of your organization signing this agreement]

**AND**

 [Christian Eugen Oberkofler Signature here]

PD Dr. med. univ. Christian Eugen Oberkofler.

LDLTregistry.org Headquarters

Klinik Hirslanden, Kappelistrasse 7, 8002 Zürich, Switzerland.

Email: christian.oberkofler@vivevis.ch

Tel: +41442810090

**Appendix A**

The data would include the demographic, preoperative, intraoperative, and postoperative variables for each donor as well as recipient specified in the Case Report Form attached to this DSA.