

THE IKP-STUTTGART LIVER COHORT (IKP-LIVER-NGS) STUDY GROUP

DATA ACCESS AGREEMENT

This agreement governs the terms on which access will be granted to the data generated by the IKP-LIVER-NGS Study Group.

In signing this agreement, You are agreeing to be bound by the terms and conditions of access set out in this agreement.

For the sake of clarity, the terms of access set out in this agreement apply both to the User and the User's Institution (as defined below). User Institution and User are referred to within the agreement as "You" and "Your" shall be construed accordingly.

Definitions:

IKP-LIVER-NGS Study Group means the Dr. Margarete Fischer-Bosch Institute of Clinical Pharmacology (IKP) Stuttgart liver cohort study group, a group of investigators collaborating on the topic of next-generation sequencing of ADME genes in the IKP human liver cohort.

Data means all and any human genetic and epigenetic data as well as study related data obtained from the IKP-LIVER-NGS Study Group.

Data Subject means a person, who has been informed of the purpose for which the Data is held and has given his/her informed consent thereto.

User means a researcher whose User Institution has previously completed this Data Access Agreement and has received acknowledgement of its acceptance.

Publications means, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

User Institution means the organisation at which the User is employed, affiliated or enrolled.

Terms and Conditions:

In signing this Agreement:

1. You agree to use the Data only for the advancement of medical research, according to the consent obtained from sample donors.
2. You agree not to use the data or any part thereof for the creation of products for sale or for any commercial purpose.
3. You agree to preserve, at all times, the confidentiality of information and Data pertaining to Data Subjects. In particular, You undertake not to use, or attempt to use the Data to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.
4. You agree not to attempt to link the data provided under this agreement to other information or archive data available for the data sets provided, even if access to that data has been formally granted to You, or it is freely available without restriction, without specific permission being sought from the relevant access committees.
5. You agree not to transfer or disclose the Data, in whole or part, or any identifiable material derived from the Data, to others, except as necessary for data/safety monitoring or programme management. Should You wish to share the Data with a collaborator outwith the same Institution, the third party must make a separate application for access to the Data.

6. You agree to use the data for the approved purpose and project described in Your application; use of the data for a new purpose or project will require a new application and approval.
7. You accept that Data will be reissued from time to time, with suitable versioning. If the reissue is at the request of sample donors and/or other ethical scrutiny, You will destroy earlier versions of the Data.
8. You agree to abide by the terms outlined in the IKP-LIVER-NGS Study Group 'Publications Policy' as set out in Schedule 1.
9. You agree to acknowledge in any work based in whole or part on the Data, the published paper from which the Data derives, the version of the data, and the role of the IKP-LIVER-NGS Study Group and the relevant primary collectors and their funders. Suitable wording is provided in the Publications Policy given in Schedule 1.
10. You accept that the IKP-LIVER-NGS Study Group, the original data creators, depositors or copyright holders, or the funders of the Data or any part of the Data supplied: a) bear no legal responsibility for the accuracy or comprehensiveness of the Data; and b) accept no liability for indirect, consequential, or incidental, damages or losses arising from use of the Data, or from the unavailability of, or break in access to, the Data for whatever reason.
11. You understand and acknowledge that the Data is protected by copyright and other intellectual property rights, and that duplication, except as reasonably required to carry out Your research with the Data, or sale of all or part of the Data on any media is not permitted.
12. You recognise that nothing in this agreement shall operate to transfer to the User Institution any intellectual property rights relating to the Data. The User Institution has the right to develop intellectual property based on comparisons with their own data.
13. You accept that this agreement will terminate immediately upon any breach of this agreement by You and You will be required to destroy any Data held.
14. You accept that it may be necessary for the IKP-LIVER-NGS Study Group or its appointed agent to alter the terms of this agreement from time to time in order to address new concerns. In this event, the IKP-LIVER-NGS Study Group or its appointed agent will contact You to inform You of any changes and You agree that Your continued use of the Data shall be dependent on the parties entering into a new version of the Agreement.
15. You agree that You will submit a report to the Data Access Committee for the IKP-LIVER-NGS Study Group, if requested, on completion of the agreed purpose. The Data Access Committee for the IKP-LIVER-NGS Study Group agrees to treat the report and all information, data, results, and conclusions contained within such report as confidential information belonging to the User Institution.
16. You accept that the Data is protected by and subject to international laws, and that You are responsible for ensuring compliance with any such applicable law. The Data Access Committee for the IKP-LIVER-NGS Study Group reserves the right to request and inspect data security and management documentation to ensure the adequacy of data protection measures in countries that have no national laws comparable to that which pertain in the EEA.

SCHEDULE 1

Publications Policy

The primary purpose of the IKP-LIVER-NGS Study Group is to accelerate efforts to identify genomic and epigenomic factors influencing interindividual differences in gene expression, primarily among drug metabolizing enzymes and transporters, through implementation and analysis of large-scale omics data.

The IKP-LIVER-NGS Study Group anticipates that data generated from the project will be used by others, such as required in understanding liver pathophysiology, or in guiding selection of markers to map candidate genes involved in disease susceptibility, progression and therapeutic response.

Authors who use data from the project must acknowledge the IKP-LIVER-NGS Study Group using the following wording "*This study makes use of data generated by the IKP-LIVER-NGS Study Group. Funding for the project was provided in part by the Robert Bosch Stiftung, Stuttgart, Germany*" and cite the relevant primary IKP-LIVER-NGS Study Group publication:

Klein K, Tremmel R, Winter S, Fehr S, Battke F, Scheurenbrand T, Schaeffeler E, Biskup S, Schwab M, Zanger UM: A New Panel-Based Next-Generation Sequencing Method for ADME Genes Reveals Novel Associations of Common and Rare Variants With Expression in a Human Liver Cohort. *Front Genet.* 2019;10:7. doi: 10.3389/fgene.2019.00007.

Users should note that the IKP-LIVER-NGS Study Group bears no responsibility for the further analysis or interpretation of these data, over and above that published by the IKP-LIVER-NGS Study Group.

For and on behalf of User:

Name of Applicant(s):

Signature of Applicant(s): _____

Date:

For and on behalf of User Institution:

**Signature of Institutional or
Administrative Authority:** -----

Print name:

User Institution:

Date:

WHEN SUBMITTING THIS DOCUMENT, PLEASE INCLUDE ALL PAGES OF THE AGREEMENT WITH THIS SIGNATURE PAGE