

General Terms of Access to THL Biobank Materials

These General Terms of Access apply to the THL Biobank Material Transfer Agreement (“Agreement”) or any other agreement referring to or incorporating these General Terms. The Researcher and his/her affiliated institution as a Party to the Agreement shall ensure that any person dealing with the Material adheres to these Terms and the entire Agreement at all times.

Definitions defined in the Agreement apply in this document.

1. Permitted Use

Legitimate purposes for academic research and company research and development projects (R&D) are: (i) Promotion of population health, (ii) Identification of factors contributing to disease mechanisms, (iii) Prevention of diseases, (iv) Development of products and services promoting population health and welfare, and (v) Development of products and practices used in health care.

2. Payments

The current service price list is available at <https://thl.fi/en/web/thl-biobank/for-researchers/services-and-prices>. Unless otherwise agreed in writing, the payment term is 21 days from the date of invoice (30 days for foreign customers).

3. Shipment

Unless otherwise agreed in writing, THL Biobank will arrange transportation of Material and any related permissions. THL Biobank will not be liable for any loss of or damage to the Material during or after transport.

4. No warranty

THL Biobank provides the Material on an “as is” basis, without any representations and warranties, whether express or implied. THL Biobank samples are not routinely tested for any biohazards and should be handled with appropriate safety measures. Data derived from the biobank samples is not validated or equivalent to clinical data and for that reason the biobank data should be used for research purposes only. If the biobank data is utilized in a recall study, it should be confirmed.

5. Obligation to Share Results

To enrich biobank collections, the Recipient will provide THL Biobank with sample specific results from analysis of any biological material if requested. Results are to be provided within twelve (12) months after the conclusion of the Project at latest or before the date set forth in the Agreement. Results will be provided in well documented format and in such format that enables THL Biobank to link the results with its existing data and samples.

6. Obligation to Make Results Public

The research results derived by using the Material shall be published whether positive, negative or inconclusive without a delay and within 12 months from the completion of the Project or before the date set in forth in the IA. The published information should enable the objective evaluation of the study design, methods and results. The publication should be sent to THL Biobank 14 days prior to submission for potential comments. THL Biobank will inform about the research results on its website after the article has been published. For R&D projects the publication forum will be agreed separately for each project.

While encouraging wide and open dissemination, the Recipient is not allowed to decide upon disclosure of the individual level Material or individual level research project results in Open Access portals, such as public databases or Open Access Journals. Instead, they shall agree with THL Biobank as how to make it feasible.

7. Biological samples and Data on Completion of the Project

On completion of the Project or termination of the Agreement, the Recipient must return any remaining usable samples to THL Biobank, if requested to do so. Unusable samples must be destroyed and THL Biobank must be notified of it (admin.biobank@thl.fi). All electronic copies of the data held by the Recipient must be deleted.

8. Privacy and Data Protection

The Recipient may not use the Material for any other purpose than described in the Application. The Recipient must not grant access, show or in any way make Material available to any other party without a prior written approval of THL Biobank. THL Biobank provides the Material without personal identifiers unless otherwise agreed in writing in exceptional circumstances in accordance with the Biobank Act. The Recipient agrees that it has no intent, no need, and no right to identify any persons based on the Material and it will not attempt to do so in any circumstances. THL Biobank Data Protection Annex for Data Controller will apply to any processing of personal data.

9. Confidentiality

Each Party will for five years after the end of the Project keep confidential the other Party's non-public commercial, technical, and scientific information it obtained under the Agreement for the purposes of the Project. This obligation will not apply to the extent the information: (a) was already known to the receiving Party at the time of disclosure, (b) is in or becomes into the public domain through no fault of the receiving Party, (c) is lawfully received by the receiving Party from a third party without using the disclosing Party's information, (e) is required to be disclosed to comply with mandatory law, provided that the disclosure, or (f) was authorised to be disclosed by the disclosing Party.

10. Acknowledgement of using THL Biobank

A suitable note of acknowledgement should be included in the publication/s, such as: "The samples/data used for the research were obtained from THL Biobank (*study number*). We thank all study participants for their generous participation to Finnish health research."

THL brand or logo or specific cohort names cannot be used without a specific agreement.

11. Ownership and Intellectual property

THL Biobank owns the Material, databases, individual level raw analyses and assay data, and generic improvements and inventions related to THL Biobank's laboratory, sample and information handling methods and procedures.

THL Biobank does not claim ownership to new intellectual property invented or developed solely by the Recipient when using the Material. Actions to protect Recipients' intellectual property rights (eg. patent application) based on the use of THL Biobank's Material must not limit THL's or THL Biobank's activities, excluding time needed to withhold publication of results.

The Recipient covenants not to assert its intellectual property rights arisen from the Project and Material against THL Biobank, its owners or successors, in any court or administrative agency. This covenant applies only to THL's own activities, research and development.

12. Term and Termination

The Agreement applies for the duration of the Project, including the publication of results, or as set forth in the Agreement in writing. Agreement terminates (i) with 30 days' notice for curable material breach not cured within 30 days, and (ii) immediately for material breach that cannot be cured. The terms that by nature should reasonably be deemed to survive shall survive, including without being limited to the terms on ownership, intellectual property, non-assert, confidentiality and privacy, due care and returning Material, sharing and publishing results, disclaimers, limitation of liability, applicable law and jurisdiction.

13. Consent withdrawal

The sample donor has a right to withdraw from THL Biobank. In such a case, THL Biobank will inform the Recipient to exclude his/her material from the project, if feasible taking into account the nature and phase of the project and other relevant circumstances.

14. Limitation of liability

Parties shall not be liable towards the other party for indirect damages. Liability for direct damages is limited to the value of the agreement and at the maximum 10.000 euros, whichever is greater. The limitations shall not apply to gross negligence or intentional misconduct of the other Party or a breach of mandatory data protection legislation.

15. Law and jurisdiction

Finnish laws shall apply. Any controversy or claim arising out of or in relation to the Agreement that cannot be amicably solved within 60 days from the first written notice of the Party shall be finally settled by arbitration in accordance with the rules of the Arbitration institution of the Finnish Chamber of Commerce. The place of arbitration is Helsinki and the language is English, unless otherwise agreed.

Controversies or claims arising out of or in relation to Finnish public sector collaboration shall be brought into Helsinki District Court, unless otherwise agreed.

16. Export and Import Control and Sanctions

Each Party shall comply with sanctions, export control and import control laws and regulations adopted by the United Nations, the European Union, the United Kingdom and the United States (hereinafter Trade Regulations).

If the fulfilment of THL Biobank's obligations under the Agreement requires an authorization due to Trade Regulations and such authorization is not granted or THL Biobank's performance is otherwise prohibited or delayed due to Trade Regulations, THL Biobank shall be free from its contractual obligations with this regard. THL Biobank also has the right to prolong the agreed schedule of the Project in case the delay is due to complying with Trade Regulations. THL Biobank shall not be required to perform any activities that would be prohibited under Trade Regulations or that would expose THL Biobank to the risk of becoming subject to sanctions under Trade Regulations.

The Recipient shall be responsible for obtaining any authorisation required under Trade Regulations for any use, export, re-export, import and/or transfer of the Material, Confidential Information or goods supplied to the Recipient by THL Biobank. The Recipient shall be solely responsible for any damages or costs caused by its failure to obtain such authorization.