V. 3.1 / 8.10.2018

These are the General Terms of access to THL Biobank resources.

Please note that THL Biobank retains the right to modify the contents of this document at any time. Version numbers and dates are in use. The valid version relating to each agreement shall be determined by the version in force at the time of applying and approving these terms.

Individual exemptions to these Terms can be negotiated and shall be listed in the Implementation Agreement.

General Terms of Access to THL Biobank Resources

THL Biobank is a publicly funded and registered biobank governed under Finnish law. It serves the official duties of the National Institute for Health and Welfare (THL).

THL Biobank owns its samples and all data related to samples and sample donors or derived from samples (later referred to as Material). It may grant access to the **Material** for research projects that are of high scientific quality and impact, and that correspond with the following research areas of the THL Biobank:

- Promotion of population health
- Identification of factors contributing to disease mechanisms
- Prevention of diseases
- Development of products promoting population health and welfare
- Development of products and practices used in health care

The whole research team of the applicant (the applicant is later referred to as Researcher) must abide by these Terms. The Researcher and his/her affiliated institution as a Party to the Implementation Agreement shall ensure that any person dealing with the Material adheres to these Terms and the entire Agreement at all times.

Application process

Only the principal investigator or main Researcher of the project, affiliated to a certain institute, can apply for THL Biobank's Materials.

If the sample collections are new to the Researcher, it is recommended first to contact THL Biobank (biopankki@thl.fi) to informally discuss the feasibility of the proposed project.

In the electronic application form the information required includes:

- Name, affiliation and title of the applying Researcher
- Description of the research group including full list of the researchers involved in the project, their affiliations and roles in the project
- Research plan and timetable, ethical aspects of the project
- Description of requested samples and data
- Short public description of the project to be published on THL Biobank's website
- Data management plan for using THL Biobank's material (a separate form to be filled out by the Researcher, available in THL Biobank's web pages)

The Researcher should allow 3 weeks for the initial application review process. THL Biobank shall treat the application and research plan as strictly confidential. However, the provided public description of the

project will be published on THL Biobank's website after the access has been granted and the project has officially started.

The Implementation Agreement (IA) will be concluded between THL Biobank and the institutes or organisations involved in the project, not with individual persons. The agreement party receiving Material from THL Biobank is later referred to as Recipient. The Implementation Agreement must be signed by an official signee of the institute of the Recipient before any access to the Material is allowed. Signatures can be executed electronically; a scan of a signed agreement is acceptable.

The IA covers, among other issues, the intended use of the samples and/or data, timetable for the project, terms of collaboration, and timetable for submitting the research results to the biobank. In addition, the IA includes THL Biobank's data safety and data processing instructions.

The Recipient may use the Material only for the specified research project. The Recipient must notify THL Biobank of changes in the project, including changes in the research group. Such changes are recorded in the amendments to the Agreement. THL Biobank decides whether the changes require a new application.

THL Biobank may, without compromising confidentiality, propose collaboration to research groups that have similar research plans.

Criteria for approval of a research project

THL Biobank approves research projects that correspond to THL Biobank's research areas and are of high quality, high impact and ethically conducted. The research group shall include reputable researchers with an established scientific record. The research project should comply with the following criteria:

- The project is clear, specifically defined, and limited in scope.
- The analysis plan is scientifically compelling and coherent.
- The requested samples and sample amounts are available in the biobank.
- The Material requested is available for sharing (e.g. the processing of samples, the storing of data and the basic analysis -of the samples and/or data has been completed).
- The project proposal does not fully overlap with on-going projects using the same datasets/samples.
- The requested data and analysis plan does not compromise the integrity and rights of the sample donors, privacy in particular.
- The requested Material does not endanger the process to protect immaterial rights.

Use of national registry data

Any access to national register-based data requires project specific approval by the relevant registry officials. THL Biobank cannot give any guarantee of the approval of the applications, nor of the time period needed for the processing of the applications at the registries. Based on evaluation of the research, the registry authorities may approve or decline access to the respective registry data. Recipients must be prepared to meet additional requirements that the authorities may lay down, such as:

- separate organisation and researcher specific confidentiality commitments,
- payments of applicable registry fees and
- supporting documents, such as detailed research plan, ethical approval for the project or data safety procedures within the institute.

The terms and conditions of the Implementation Agreement supplement the terms and conditions of the commitments to be made with the registry authorities.

Material usage and data security

Collaboration with the research team involved in the initial collection of Material may be beneficial for optimal interpretation of Material. Terms for possible collaboration will be agreed upon separately for each research project.

THL Biobank will regularly provide information on its website concerning research themes or projects that use its Material. For that purpose, the Researcher must provide a short abstract to be published in the application.

The Recipient must submit progress reports to THL Biobank at 12 month intervals during the active project period. A reminder about the progress report will be sent by e-mail to the Recipient.

The Recipient shall comply with Finnish law, and if applicable, any local laws or IRB/ethics committee opinion. The Recipient may not use the Material for any other purpose than described in the application, or share it with any other party without a written approval of THL Biobank. The Recipient shall notify THL Biobank of any access requests from the local authorities.

While encouraging wide and open dissemination, the Recipient is not allowed to decide upon disclosure of the Material or 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.

Secure data access, such as passwords, firewalls, etc., must be in place to ensure that the data are kept secure. THL Biobank data users should access the provided dataset using a network drive set up by the organisation where they work and a computer provided and maintained by their organisation. The use of personal computers to access or analyse the Material is prohibited. Detailed instructions for data safety are provided in a separate document, which is an essential part of the IA. In addition, THL Biobank instructions for data processing form an integral part of the IA.

The data provided is pseudonymised for research projects and do not contain any individual identifiers such as names, addresses, contact information or attributes enabling identification. Additionally, extra restrictions have been applied to the data released to external data users:

(1) Sample donors are identified using a secondary ID that will be different for each THL Biobank resource sharing project.

(2) All datasets will be stripped off specific variables that can create a risk of sample donor identification (such as complete date of birth and death), which could potentially enable the identification of subjects.

However, given the nature of the data, it is virtually impossible to prevent the identification of specific individuals were one so minded. Therefore, it will be the responsibility of the data users to ensure that no sample donor's identity is disclosed under any circumstances. THL Biobank resource users must also preserve the confidentiality of the data in outputs and publications. It is forbidden to match or attempt to match individual records to any other data outside the project.

Publications and acknowledgement of using THL Biobank

The Finnish Biobank Act prescribes that the research results derived by using the Material shall be published whether positive, negative or inconclusive. Thus, the Recipient should aim to publish the research results based on THL Biobank's Material in peer-reviewed scientific journals without a delay and within 12 months from the completion of the Project or before the date set in forth in the IA.

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. We thank all study participants for their***

generous participation at THL Biobank, and (a) specific cohort(s) as defined in IA." If a BRIF-ID has been assigned to the sample collection, this should be mentioned in the Methods section of the publication. Recipient must update THL Biobank's contact person/s on the progress of the project, and send a copy of all material planned for publication 30 days prior to submission for potential comments. THL Biobank will inform about the research results on its website after the article has been published.

Completion of project and returning of research results

On completion of the research project, 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). The data provided by THL Biobank must not be used anymore. All electronic copies of the data held by the Recipient must be deleted with the exception of copies needed for backing up work, unless there is a justified ground to act differently.

THL Biobank pursues FAIR data principles (findable, accessible, interoperable, reusable), and aims to make analysis and results available for the research community via application procedure. To meet this goal, the Recipient must provide THL Biobank with all data resulting from assays and analyses on the Material well documented and in such format that enables THL Biobank to link them with its existing data and samples after the completion of the project.

THL Biobank may freely use and grant access rights to for further research via the standard biobank application process, at a date agreed upon with the original research group.

Appeal process

In case the application was not approved, the Researcher is welcome to make the appropriate changes and submit a new application. The revised application should identify how THL Biobank's concerns have been addressed. The Researcher can also appeal the decision of THL Biobank in the administrative court of Helsinki, or make a complaint to the National Supervisory Authority for Welfare and Health (Valvira).

Payment

The cost for accessing THL Biobank's Materials depends on what is being accessed, calculated as a simple reimbursement of THL Biobank's internal costs plus any third party costs incurred by THL Biobank. This includes charges for administration, sample extraction, sample handling and shipment, sample assays, any re-contacting costs, and data extraction and preparation costs. In addition, a fixed access fee of 1000€ is invoiced for each new project application and an access fee of 200-1000€ is invoiced for each amendment to an approved project, dependent on the nature of the amendment. THL Biobank retains the right to change its service prices. The current service price list is available at https://thl.fi/en/web/thl-biobank/for-researchers/services-and-prices.

Sample donor's statutory right to withdraw

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.

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.

Ownership and Intellectual property

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

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

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, exluding 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.

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.

Law and jurisdiction

Finnish laws shall apply. Any controversy or claim arising out of or in relation to this 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.

The entire agreement

The entire Material Transfer Agreement between THL Biobank and the organisations granted access to the Material is composed of the following:

- Application, as submitted in the last approved format,
- THL Biobank's decision of grant with possible special conditions,
- Implementation Agreement, containing deviations, exemptions, and special conditions,
- THL Biobank's Data Safety and Data Processing Instructions,
- when applicable, EU model clauses between THL Biobank and Recipient and
- Terms of Access (this document).

Potential consortium or other collaboration agreement between parties shall be part of the entire agreement, and will be registered in the Implementation Agreement. The parties shall agree in the Implementation Agreement on which terms take presedence, if the terms in the above documents conflict with other agreements between parties.