

These are the General Terms to access Biobank of Eastern Finland's resources. Please note that the Biobank of Eastern Finland 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 Biobank of Eastern Finland's Resources

The Biobank of Eastern Finland is a publicly funded and registered biobank governed under Finnish law. It is owned by the North Savo Hospital District, the South Savo Social and Health Care Authority, Siun sote – the Joint Municipal Authority for North Karelia Social and Health services, the Eastern Savo Hospital District, and the University of Eastern Finland. The Biobank of Eastern Finland is affiliated and belongs to the corporate body of the North Savo Hospital District.

The Biobank of Eastern Finland owns its samples and data (hereunder 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 research area of the Biobank of Eastern Finland.

- 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 of the applicant's research team (hereunder referred to as Researcher) must abide by these Terms of Access at the time of applying for Biobank of Eastern Finland's Materials. The Researcher and his or her affiliation institution as a Party to this Agreement shall ensure that any person dealing with the Material adheres to these Terms and the entire Agreement at all times.

Application process

FINGENIOUS is a service portal for researchers in biobank studies. Registering with FINGENIOUS is the first step to conducting a biobank study with samples and/or data from one or several regional hospital biobanks in Finland.

FINGENIOUS offer direct services:

- Feasibility requests from biobank samples and data
- Direct communication with biobank research specialists
- Feasibility reports uploaded
- Access requests for biobank samples and data

The researcher, affiliated to a certain institute, is entitled to apply for the Biobank of Eastern Finland's Materials. The Researcher can contact the Biobank of Eastern Finland's Research Services (e-mail info@ita-suomenbiopankki.fi, telephone +358 44 717 9960 or +358 17 173 311) to discuss the feasibility of the proposed project.

The Researcher should allow three weeks for the application review process. The Biobank of Eastern Finland

shall treat the application and research plan as strictly confidential until it is published. However, the provided public description of the project will be published on the Biobank of Eastern Finland's website after access has been granted and the project has started, or as agreed with the Researcher.

The Implementation Agreement (IA) shall be concluded between the Biobank of Eastern Finland and the scientific institutes or organisations involved in the project, not with individual persons. The Researcher is required to sign the Implementation Agreement before any release of resources. Signatures may be executed electronically. Signed and scanned application forms are acceptable.

The IA covers, among other issues, the intended use of the samples and data, the timetable for the project, terms of collaboration, and the timetable for submitting the research results to the biobank.

The Researcher may use the Material only for the specified research project. The Researcher must notify the Biobank of Eastern Finland of any changes in the project, including changes in the research group. Such changes shall be recorded in the amendments to the Agreement. The Biobank of Eastern Finland will decide whether the changes require a new application.

The Biobank of Eastern Finland may, without compromising confidentiality, propose collaboration with research teams that have similar research plans.

Criteria for approval of a research project

The Biobank of Eastern Finland approves research projects that correspond to its research areas, are of high quality and high impact, and are ethically conducted. The Researcher and their collaborators shall be reputable researchers with an established scientific record. The research project should comply with the following criteria:

- The project is clear and specifically defined,
- The analysis plan is scientifically compelling and coherent,
- The scope of the project is limited to 1–3 publications, ideally published within the first three years of the project,
- 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/data has been completed),
- The project proposal does not overlap with ongoing projects using the same datasets/samples,
- The requested data and analysis plan do not compromise the confidentiality of sample donors,
- The requested Material does not endanger the process to protect immaterial rights.

Resource usage terms and data security

For optimal interpretation of the data, collaboration with researchers with deep knowledge related to the data is usually needed. Collaboration terms with the Biobank of Eastern Finland's researchers will be agreed upon separately for each research project.

The Biobank of Eastern Finland will regularly provide information on its website concerning research themes or projects that have been granted access to its resources, unless a period of non-disclosure has been agreed upon. For that purpose, the Researcher must provide a short progress report to Biobank of Eastern Finland at 12-month intervals during the active project period. A reminder about the progress report will be sent to the Researcher via e-mail.

The Researcher shall comply with Finnish laws, and if applicable, any local laws or IRB/ethics committee opinion. The Researcher may not use the Material for any other purposes than that described in the Application,

or share it with any other party without written approval from the Biobank of Eastern Finland. The Researcher shall notify the Biobank of Eastern Finland of any access requests from local authorities. Disciplinary provisions for Material usage against any other purposes than those described in the Application are given in Chapter 6, Section 43 of the Biobank Act (688/2012).

While encouraging wide and open dissemination, the Researcher and research team are 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, if there is a risk of identification of the sample donors. Instead, they shall agree with the Biobank of Eastern Finland as to how to make such sharing feasible.

Secure data access, such as passwords, firewalls, etc., must be in place to ensure that the data is kept secure. Biobank of Eastern Finland data users should access the provided dataset using a network drive set up by the organisation for whom they work, and they should avoid keeping datasets on their own PC/laptop, unless it is highly encrypted.

The data provided for research projects does not contain any individual identifiers such as names, addresses, contact information and the like, thus conforming to Chapter 3, Section 26 of the Biobank Act and Regulation (EU) 2016/679 of the European Parliament and of the Council (GDPR). 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 Biobank of Eastern Finland resource sharing project.

(2) All datasets will be stripped of specific variables (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. Biobank of Eastern Finland 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 not belonging to this project.

Publications

The Finnish Biobank Act prescribes that the research results derived from using the Material shall be published whether positive, negative or inconclusive. Thus, the research team should aim to publish the research results based on Biobank of Eastern Finland'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 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 the Biobank of Eastern Finland. We thank all study participants at the Biobank of Eastern Finland for their generous participation."* It is expected that the Biobank of Eastern Finland's named contact person/s will be updated on the progress of the project and will be informed about the planned publication prior to submission, for potential comments. The Biobank of Eastern Finland will provide information about research results after they are published on its website (www.ita-suomenbiopankki.fi).

Completion of project and return of research results

On completion of the research project, the research team must return any remaining usable samples to the Biobank of Eastern Finland, if requested to do so. Unusable samples must be destroyed and the Biobank of Eastern Finland must be notified of this. The data provided by the Biobank of Eastern Finland must not be

used any further. All electronic copies of the data held by the research team must be deleted, with the exception of copies needed for backing up work.

The research team should offer to the Biobank of Eastern Finland all research project results, such as assay and analysis data ("raw data"), supplied with the appropriate documentation. These research results will be available for other researchers.

Appeal process

If an application is not approved, the Researcher is welcome to make the appropriate changes and submit a new application. The revised application should identify how the Biobank of Eastern Finland's concerns have been addressed. The Researcher can also appeal the decision of the Biobank of Eastern Finland in the Administrative Court of Eastern Finland, or make a complaint to the National Supervisory Authority for Welfare and Health (Valvira).

Payment

The cost for accessing Biobank of Eastern Finland's Materials depends on what is being accessed, calculated as a simple cost recovery of Biobank of Eastern Finland's internal costs plus any third party costs incurred by the Biobank of Eastern Finland. This includes charges for administration, sample extraction, sample handling and shipment, sample assays, any costs incurred for contacting sample donors, data derivation and, for large data sets, extraction. These costs should be paid prior to the release of any data or samples.

Sample donor's statutory right to withdraw

The sample donor has a right to withdraw from the Biobank of Eastern Finland. In such cases, the Biobank of Eastern Finland will inform the Researcher to exclude the relevant Material from the project, taking into account the nature and phase of the project and other relevant circumstances.

The sample donor's statutory rights must not be compromised. Any person who intentionally or out of gross negligence compromises the protection of privacy of the donor and his or her rights, shall be subject to a fine for *the violation of provisions concerning biobanks*, unless a more severe penalty is provided elsewhere in law (Chapter 6 Section 43 of the Biobank Act (688/2012)).

No warranty

The Biobank of Eastern Finland provides the Material on an "as is" basis, without any representations and warranties, whether express or implied.

Ownership and intellectual property

The Material remains the property of the Biobank of Eastern Finland. It claims no ownership to new intellectual property invented or developed solely by or for the Researcher in connection with the project, except that the Biobank of Eastern Finland will own the raw analyses and assay data to the extent it performs the analyses and assays, and generic improvements and inventions related to Biobank of Eastern Finland's laboratory, sample and information handling methods and procedures.

Non-assertion

The Researcher agrees not to assert his or her intellectual property rights that arise from the Project and Material against the Biobank of Eastern Finland, its owners or successors, in any court or administrative agency. This applies only to the Biobank of Eastern Finland's own not-for-profit activities, research and development.

Limitation of liability

Each party 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 law 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 Kuopio 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 to Kuopio District Court, unless otherwise agreed.

The entire agreement

The entire Material Transfer Agreement between the Biobank of Eastern Finland and the Researcher is composed of the following:

- Application, as submitted in the last format
- Biobank of Eastern Finland's grant decision, with possible special conditions
- Schedule for samples and/or data
- Implementing agreement, containing deviations, exemptions and special conditions
- Schedule for payments
- Terms of Access (this document)

Any potential consortium or other collaboration agreement between parties shall be part of the entire agreement, and will be registered in the implementing agreement. The parties shall agree in the implementing agreement on which terms take precedence, if the terms in the above documents conflict with other agreements between parties.