**Cover letter**

............................. (dd mmmm yyyy)

**To the item “Grant of permission for preservation and studying of tissue samples of the Estonian Biobank outside the territory of Estonia” on the agenda of the University of Tartu Senate meeting of ... (dd mmmm yyyy). The Estonian Biobank submits the request pursuant to subsection 18 (4) of the Human Genes Research Act.**

The Estonian Biobank (hereinafter the EstBB) would like to release the tissue samples of ......... (**number of gene donors**) gene donors to ....................... (**countries to which the samples will be released**) within the scope of the project “........................ (**name of project**)”. Approval No. ..... (e.g. 1.1-12/1923) for the implementation of the project has been received from the Estonian Bioethics and Human Research Council (EBIN) on ................ (e.g. 12 April 2022).

1. The principal investigator of the project is ........................ (**name of the principal investigator**), ..................................... (**title of the principal investigator**, e.g. Professor, Head of the Statistical Genetics Research Group) at ............................... (**name of the institution and country of location of the principal investigator**, e.g. Heidelberg University Hospital (Federal Republic of Germany)).
2. The project will last from .................. to .................. (e.g. from 1 May 2022 to 30 April 2027).
3. The project will be funded from .............. (**source of funding**, e.g. grant of the EU’s research and innovation funding programme Horizon 2020), the period of which is ............ (e.g. 2019–2025).
4. Objective of the project

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1. ............. (name and quantity of tissue sample, e.g. 400 microlitres of plasma and 600 nanograms of DNA) per each gene donor of the ........... (**number of gene donors whose tissue samples are to be released,** e.g. up to 60 gene donors) donors will be released to ..................... (**name of institution to which the tissue samples will be released,** i.e. the Heidelberg University Hospital) for analysis.

(Please note: All institutions to which the tissue samples will move during the project must be listed. For example, if the main cooperation partner in Germany plans to send the tissue samples for analysis to another institution, either in Germany or in another country, such recipients must also be indicated.)

1. Contact details of the representative of the recipient of the tissue samples:

……………………………………. (**title, first name and surname)**

......................... (**name of institution**)

 …………………………………… (**full address: street, house no,**

…………………………………… **postcode, city,**

……………………………………… **country**)

telephone: .........................

e-mail: ………………………….

(Please note: The data must match the data in the EBIN’s application and may be written in a foreign language if the recipient of the tissue samples is from abroad.)

1. Reason for sending tissue samples abroad and applied safeguards

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(Below is an example of a previous application that needs to be adapted to the specific project. Please note! The text must be in line with the EBIN’s application and, where necessary, the contract to be entered into.

*Pursuant to subsection 18 (4) of the* [*Human Genes Research Act*](https://www.riigiteataja.ee/akt/72581?leiaKehtiv) *(hereinafter the HGRA), the EstBB may also preserve and study tissue samples for research outside the territory of the Republic of Estonia if good reasons therefor become evident and if the tissue sample is issued in non-personalised form and the controller ensures effective control over the tissue samples and that the tissue samples cannot be used in a manner prohibited by legislation. The good reason in this case is the need described in point 4 of the application to analyse tissue samples obtained from several cohorts (including the EstBB) and the subsequent association analysis of data by the same methods at centres having the respective competency.*

*The cooperation described in the application will help achieve innovative research results, which will make it possible to identify biomarkers for a more personal assessment of the risk of gallbladder cancer.*

*The tissue samples will be released in non-personalised form and the contract to be entered into with the recipient of the tissue samples will determine the use of the tissue samples and excludes the use of the tissue samples in a manner prohibited by legislation.*

*Pseudonymisation will be applied as a safeguard within the meaning of Article 89(1) of the* [*General Data Protection Regulation (2016/679) of the European Union*](https://eur-lex.europa.eu/legal-content/ET/TXT/PDF/?uri=CELEX:32016R0679&from=EN) *pursuant to the HGRA. The tissue samples and information on the disease group of the gene donor who donated the sample are provided in pseudonymised form, so the data obtained from the analysis are also pseudonymised and anonymised for the Heidelberg University Hospital. The Heidelberg University Hospital does not have the option to deidentify the data.*

*The tissue samples and the data will be processed within the European Economic Area and pseudonymised tissue samples and data will not be sent to third countries*.)

1. Characterisation of the final processor of the tissue samples and the conditions to be met by the final processor in relation to the processing of tissue samples

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(Below is an example of a previous application that needs to be adapted to the specific project. Please note! The text must be in line with the EBIN’s application and, where necessary, the contract to be entered into.

*The research will be carried out in cooperation with Leiden University, which will invoice the University of Tartu for the consumables of analysing the tissue samples. This is the best pharmacogenetics and long-read sequencing laboratory in Europe with a long history of developing and evaluating the application of long-read sequencing for pharmacogenetic analyses. The partner has a certificate of accreditation (issued by the Dutch Accreditation Council RvA) to prove compliance with the requirements of the General Data Protection Regulation.*

*An overview of the safety requirements applied in the Netherlands is available in Dutch on the agency's website. The processing conditions are laid down in a contract for the release of samples between the final processor and the EstBB, under which the EstBB will batch the samples and release them to the end user. Under the terms of the release contract, the end-user’s contractual obligation at the end of the research is to*

* *send the results of the analyses carried out during the project to the EstBB;*
* *return or destroy leftover tissue samples. The principal investigator will decide on the need to return the samples on the basis of whether the quantity of the DNA left over after the analyses is big enough for use in future research.*

Annexes to the cover letter

1. EBIN’s application and decision
2. Decision of the UT Institute of Genomics

Kind regards,

Professor Andres Metspalu

Director of the Estonian Genome Centre