

APPLICATION TO THE ACADEMIC ETHICS COMMITTEE

FOR ETHICAL EVALUATION OF A RESEARCH AND DEVELOPMENT (R&D) PROJECT

1. R&D project title: Enter the project title
2. Main purpose / brief description of the R&D project (up to 1000 characters) Briefly describe the purpose and provide an overview of the project
3. Reasons for asking for an ethical evaluation of the R&D project (up to 1000 characters) NB! The Committee does not assess compliance of projects related to studies on humans and animals with the principles of research ethics. These applications shall be processed and approved by: the Research Ethics Committee of the National Institute for Health Development; the Estonian Committee on Bioethics and Human Research; the Research Ethics Committee of the University of Tartu; the Project Authorisation Committee for Animal Experiments – contact details . Please tell which issues of the project should be assessed and why (e.g. the financier's requirement or required due to the activities, etc.) Be sure to include information about previous evaluation (including received evaluation) or simultaneous evaluation in other commissions (including other countries) of this same study/project.
4. First and last name and contact details of the project manager/applicant
First name: Last name: Structural unit: Position: Phone: E-mail: must be an address ending with@taltech.ee
5. Project financier (source of funding)
6. Project duration - from to

7. Project activities that may involve ethical risks (up to 1000 characters or attach a file marked 7_1 or 7_2, etc.). To map the risks, we recommend using the guidelines of the Estonian Research Council for completing your ethics self-assessment, see here . See also Good Scientific Practice .	
8. Description of the sample and/or data. Participant information sheets and consent forms, poll, questionnaire and test forms shall be <u>annexed</u> to the application and marked in accordance with the sub-clauses, e.g. 8_4, etc. <i>NB! Polling or interviewing</i>	
1) Please describe the sampling methodology. Who recruits the study participants and from among whom and how are they recruited? <i>E.g. random sample, students, etc.</i>	
2) Please indicate the size of the sample(s)	
3) How is the privacy of the study participants ensured? Please explain the methodology (anonymisation, pseudonymisation, etc.)	
4) Does the study involve vulnerable target groups or minors? If YES, please elaborate, how is informed consent obtained from the study participants (incl. parental consent in case of minors). The consent form must be submitted in Annex 8_4	
9. Conflict of interests	
How do you mitigate the potential risk that project results can be used for personal gain? Please explain how a potential conflict of interests is avoided.	
10. The intellectual property generated and the university's rights arising from the research (see the university's legislation)	
Please describe how intellectual property rights are defined in the project?	
11. Safety in conducting research	
Please describe how safety compliance is ensured in the project and how the participants are informed of the existing instructions? Please include <u>links</u> to relevant instructions and safety requirements.	

12. Use and misuse of research results See the Good Scientific Practice , the European Code of Conduct for Research Integrity	
1) Please confirm that the research results have been obtained and are used in accordance with the requirements of research ethics, including publication requirements.	
2) Explain, if necessary, the additional ethical risks that may arise from factors such as the involvement of military partners, new developments in neurobiology, genetic engineering, nanotechnology, human-machine interaction, the creation of androids and cyborgs, etc.	
13. Fill out in case a database is created in the course of the study or the study is based on data from a database. (See scientific data management, data management plan)	
1) Name of the database	
2) Purpose of the processing of personal data	Dropdown menu options (separate file at the end)
3) List of variables and period for which data are collected (in Annex 13_3, if necessary)	
14. Description of personal data protection measures, including data storage, security and deletion, including the date of deletion of data and/or the code key (up to 1800 characters, 1 page), see also the university's legislation).	
1) Are personal data collected and/or are previously collected personal data analysed in the study?	If YES,
a) explain from which database (register, data collection) or source the data are obtained;	
b) explain how the subjects are informed of their rights and potential risks that data processing may entail;	
c) explain why all the data processed are relevant and adequate (based on the principle of data minimization);	
d) explain why it is not possible to study the subjects so that the data obtained would be anonymous or pseudonymous (if applicable);	
2) Are publicly available data analysed in the study?	If YES, please explain that the data are publicly available (public data registers and databases) and can be used freely in research.

3) Are data that are not publicly available collected and/or analysed in the study? If YES, please explain how the data are obtained, whether and how the data are anonymised / pseudonymised?	
4) Describe the methods of storage, preservation, security and deletion of the collected data, including the date of data and/or code key deletion	
5) Will the data be disclosed to third parties? If YES, please explain to whom and which data will be exported or imported? How will the rights of the study subjects be protected?	
6) Will personal data be exported to a third country or imported from another country to Estonia? If YES, please elaborate which personal data will be exported or imported and how the rights of the subjects will be protected.	

Dropdown menu in clause 13_2 of the questionnaire of the application:

1. Processing of personal data is lawful if:
 - a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;
 - b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
 - c) processing is necessary for compliance with a legal obligation to which the controller is subject;
 - d) processing is necessary in order to protect the vital interests of the data subject or of another natural person;
 - e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
 - f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.