Estonian Research Council

Guidelines for Completing Your Ethics Self-Assessment for Grant Application

January 2023

These guidelines are designed to help you think about the ethical issues of your project and to describe these issues in your application. Whether one or more (or even none) of these regulated ethical aspects apply to the planned research project depends on the research field or the specifics of the project.

NB! If it is impossible to submit the relevant documents together with the application, then it is necessary to keep these documents on file and submit them later on when requested by the Estonian Research Council, or before the start of the experiments.

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If your project has no ethics issues described in this table and all the answers are “NO”, then you have to comment on only that in the ETIS application form.

1. HUMANS

This section refers to any research involving human participants in research, regardless of its nature or topic.

Examples: collection of biological samples, personal data, medical interventions, interviews, observations, tracking, processing of personal data, including secondary use of personal data provided for other purposes, e.g., other research projects, officially collected information, social media sites, etc.

When personal information is being processed, data storage, protection, and other relevant issues have to be explained in the data management plan. The data management plan has to be submitted to the Estonian Research Council after the grant contract has been signed.

You must obtain all relevant authorisations from the specific ethics committee and submit them to the Estonian Research Council before the beginning of the experiments.

1. HUMANS		YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file
Does your research involve human participants?				Confirm that the informed consent has been or will be obtained in advance.	1) Informed consent forms + information sheets 2) Copies of ethics approvals (if required)
If YES:	Are theyvolunteers, including medical or other students?			1) Description of the recruitment, inclusion, and exclusion criteria. 2) Description of the informed consent procedures.	1) Informed consent forms + information sheets 2) Copies of ethics approvals (if required)
If YES:	Are they vulnerable individuals or groups?			1) Explain the type of vulnerability. 2) Describe the recruitment, inclusion, and exclusion criteria as well as the informed consent procedures demonstrating appropriate efforts to ensure fully informed understanding of the implications of participation.	1) Informed consent forms + information sheets 2) Copies of ethics approvals

If YES:	Are they children and/or minors?			1) Give details of the age range and explain how children are informed about the research. 2) Describe the procedures for obtaining parental consent. 3) Describe the procedures for ensuring the welfare of the children or other minors. 4) Describe why there is a need for involving children and/or minors.	1) Informed consent forms + information sheets 2) Copies of ethics approvals
If YES:	Are they patients?			1) Describe what disease/condition /disability they have. 2) Describe the recruitment, inclusion, and exclusion criteria as well as the informed consent procedures. 3) Describe your policy on incidental findings and informing the participants about that.	1) Informed consent forms + information sheets 2) Copies of ethics approvals
If YES:	Are there other persons who are unable to give informed consent?			1) Describe the procedures for obtaining the approval from the guardian or legal representative. 2) Describe which steps will be taken to ensure that the participants are not subjected to any form of coercion.	1) Informed consent forms + information sheets 2) Copies of ethics approvals
Does your research involve interventions on the study participants?					
If YES:	Does it involve invasive techniques? (e.g., the collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, etc.)			1) Provide the risk assessment for each technique and describe the accompanying risks in general.	1) Informed consent forms + information sheets 2) Copies of ethics approvals

If YES:	Does it involve collection of biological samples?			1) Describe what type of samples will be collected. 2) Describe your procedures for collecting biological samples.	1) Informed consent forms + information sheets 2) Copies of ethics approvals

Background document
Declaration of Helsinki
Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine
EU Regulation 536/2014 of clinical trials on medicinal products for human use
EU Regulation 745/2017 on medical devices
EU Regulation 746/2017 on in vitro diagnostic medical devices

2. PERSONAL DATA

This section concerns research which involves the processing of personal data, regardless of the method used (e.g., interviews, questionnaires, direct online retrieval, etc.). Personal data means any information relating to an identified or identifiable natural person. If such data will be used, please ensure that the usage complies with the Estonian Personal Data Protection Act and the European General Data Protection Regulation (GDPR).

The GDPR distinguishes special categories of personal data (like health or genetic data) which are more sensitive and therefore processing of such data need to follow additional requirements (GDPR art 9, also § 6 of Estonian Personal Data Protection Act). In addition, the Estonian Data Protection Inspectorate distinguishes a third category of data – sensitive personal data – which are not special categories, but which nonetheless have greater impact on the privacy of persons (like social welfare data, personal correspondece and communication, location data, personal data of children, data on criminal convictions and offences).

If personal information is gathered and stored, data collection, storage, protection, and other relevant aspects have to be explained in detail in the data management plan, which has to be submitted to the Estonian Research Council after the grant contract has been signed.

You must obtain all relevant authorisations from the specific ethics committee and/or from the Estonian Data Protection Inspectorate[1] and submit them to the Estonian Research Council before the beginning of the experiments.

2. PERSONAL DATA		YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file
Does your research involve processing of personal data?				1) Describe how informed consent will be obtained (if relevant). 2) Explain why are the processed data relevant and limited to the purposes of the project (by taking the "data minimisation" principle into account). 3) Describe the anonymisation /pseudonymisation techniques or justify why the research data will not be anonymised/pseudonymised. 4) Describe transfers of personal data, including the recipients of said data and whether data is transferred abroad. 5) Describe the security measures implemented to protect personal data.	1) Informed consent forms + information sheets used (if relevant) 2) Copies of ethics approvals (if relevant)
If YES:	**Does it involve the processing of special categories of personal data** (e.g., genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?			1) Describe which special categories of personal data will be processed and why is it neccessary. 2) Describe why the research objectives cannot be reached by processing anonymised/ pseudonymised data (if applicable).	1) Informed consent forms + information sheets used (if relevant) 2) Copies of ethics approvals (if relevant)

[1] If there is no ethics committee in the scientific area, including any analyses and studies by executive power which are carried out for the purposes of policy development, the compliance with the requirements shall be verified by the Estonian Data Protection Inspectorate. With regard to any personal data retained at the National Archives, the National Archives shall have the rights of the ethics committee.

If YES:	**Does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of and/or sensitive data, intrusive methods of data processing** *(such as tracking, surveillance, audio and video recording, geolocation tracking, etc.)*, **or any other data processing operation that may result in high risk to the rights and freedoms of the research participants**?			1) Describe the methods used for tracking, surveillance, or observation of participants. 2) Describe the methods used for profiling participants. 3) Describe the relevant risks to the rights and interests of data subjects, and which measures are implented to manage these risks. Describe how the participants are informed of their rights and the potential risks that data processing may bring. 4) Desribe the procedures for informing the research participants about profiling as well as its possible consequences and the protection measures.	1) Informed consent forms + information sheets used (if relevant) 2) Copies of ethics approvals (if relevant) 3) Data Protection Impact Assessment (if relevant)
Does your research involve further processing of previously collected personal data?				1) Describe the database (registries, repositories) used or of the source of the data. 2) Describe how the participants are informed of their rights and the potential risks that data processing may bring. 3) Explain how is all of the processed data relevant and limited to the purposes of the project (by taking the "data minimisation" principle into account). 4) Explain why the research data will not be anonymised pseudonymised (if relevant).	1) Permission by the owner/manager of the data sets (if applicable) 2) Copies of ethics approvals (if applicable) 3) Informed consent forms + information sheets + other consent documents (if applicable)
Does your research involve publicly available data?				1) Confirm that the data used in the project is publicly available (e.g., open data registries or repositories) and can be freely used for the project.	The permission by the owner/manager of the data sets (e.g., open data registries or repositories, if applicable).

Is personal data going to be exported to a non-EU country or imported from a third country to Estonia?			1) Describe what types of personal data will be exported or imported. 2) Describe how the rights of the research participants will be safeguarded.	1) Relevant data transfer documentation, 2) Permission from the Estonian Data Protection Inspectorate (if relevant)

Background documents

Estonian Personal Data Protection Act

European General Data Protection Regulation

Ethics and Data Protection Dynamic Desicion Tree

Adequacy decisions of the European Commission on the level of data protection in third countries

3. HUMAN EMBRYOS AND/OR FOETUSES

This section covers research on human embryos, foetuses, and human embryonic stem cells (hESC).

The Estonian Research Council does not fund research which is not allowed based on §35 or is not in compliance with §32 of the Artificial Insemination and Embryo Protection Act.

3. HUMAN EMBRYOS AND/OR FOETUSES		YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file
Does your research involve the use of human embryonic stem cells?					
If YES:	Are they previously established cell lines?			1) Describe the origin and line of cells. 2) Provide information about the licensing (conditions).	1) Copies of ethics approvals. 2) Declaration that the human embryonic or pluripotent stem cell lines used in the project are registered in the European Human Embryonic Stem Cell Registry. 3) Declaration confirming that the 6 following specific conditions for research activities involving human embryonic stem cells are met:

					1) *the cells have NOT been derived from embryos specially created for research or by somatic cell nuclear transfer;* 2) *the project uses existing cultured cell lines only;* 3) *the cell lines have been derived from supernumerary non-implanted embryos resulting from in vitro fertilisation;* 4) *informed consent has been obtained for using donated embryos for the derivation of the cell lines;* 5) *personal data and privacy of the donors of the embryos for the derivation of the cells are protected;* 6) *NO financial inducements were provided for the donation of embryos used for the derivation of the cell lines.*
Does your research involve the use of human embryos?				1) Explain the origin of the embryos. 2) Describe the recruitment, inclusion, and exclusion criteria as well as the informed consent procedures. 3) Confirm that the informed consent has been obtained. **NB! For research purpose only these embryos can be used, which justify the §32 of the Artificial Insemination and Embryo Protection Act.**	1) Copies of ethics approvals 2) Informed consent forms + information sheets
Does your research involve the use of human foetal tissues and/or cells?				1) Describe the origin of the human foetal tissues and/or cells. 2) Describe the details of the informed consent procedures.	1) Copies of ethics approvals 2) Informed consent forms + information sheets

			3) Confirm that the informed consent has been obtained.	

Background documents
Regulation (Eu) 2021/695 Of The European Parliament And Of The Council
Artificial Insemination and Embryo Protection Act

4. HUMAN CELLS AND/OR TISSUES

This section refers to research using, producing, or collecting human cells or tissues other than from human embryos and/or foetuses.

You may obtain cells or tissues:

- from commercial sources;
- as part of this research project;
- from another research project, laboratory, or institution;
- from a biobank.

4. HUMAN CELLS AND/OR TISSUES		YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file
Does your research involve human cells or tissues (other than from human embryos and/or foetuses, i.e., section 3)?				Describe the details of the cells or tissue types.	1) Copies of ethics approvals 2) Copies of authorisation, licensing for using, processing, or collecting the human cells or tissues (if required)
If YES	Are the cells and/or tissues available commercially?			Describe the details of the provider (company or other).	Copies of import licences (if relevant)

If YES	Will the cells and/or tissues be obtained during the project?			1) Describe the source of the material, the amount to be collected, and the procedure for collection. 2) Describe the duration of storage and what you will do with the material at the end of the research. 3) Confirm that the informed consent has been obtained.	1) Copies of ethics approvals 2) Informed consent forms + information sheets
If YES	Will the cells and/or tissues be obtained from another laboratory, project, institution, or biobank?			1) Give information about the name of the laboratory, institution, biobank, and country from which the material has been obtained. 2) Describe how long the material will be stored during the project and what you will do with it at the end of the research project. 3) Confirm that the material is fully anonymised and that the consent for secondary use has been obtained.	1) Copies of import licences (if relevant) 2) Statement of the laboratory, institution, biobank, or other provider that the informed consent has been obtained

Background Document
Procurement, Handling and Transplantation of Cells, Tissues and Organs Act

5. ANIMALS

When the research involves animals, it is important to implement the principles of replacement, reduction, and refinement.

Endangered species cannot be used, except for very important research purposes when it is impossible to use non-endangered species to achieve the objectives and if the animal experiments are in compliance with the Nature Conservation Act, and the animal experiments meet the objectives described in the Animal Protection Act.

Using experimental animals in research requires a project authorisation from The Agriculture and Food Board of Estonia. You must submit the authorization to the Estonian Research Council before the beginning of the animal experiments.

5. ANIMALS	YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file
Does your research involve animals?			1) Give information about the species and rationale for their use, nature of the experiments, procedures, and techniques to be used. 2) Describe why alternatives cannot be used. 3) If the research doesn't involve the procedure of using experimental animals, explain the potential impact of research activities on animals and which measures are implemented to ensure their welfare.	1) Copies of authorizations for use of experimental animals

Background documents
Animal Protection Act
Nature Conservation Act

6. GENETIC RESOURCES AND/OR ASSOCIATED TRADITIONAL KNOWLEDGE

This section concerns research involving the users of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their utilization, e.g., the compliance with the international EU 511/2014 regulation, e.g., the Nagoya Protocol.

NB! Human genetic resources are out of scope of the Nagoya Protocol regulation and are covered in Sections 1 and 2 of this document.

Pathogenic organisms that pose a threat to human, animal, or plant health are generally covered by the Nagoya Protocol, except for the WHO's Pandemic Influenza Preparedness (PIP) Framework, which is outside of the scope of the Nagoya Protocol.

Before submitting the application, please find out if your project necessitates compliance with the Nagoya Protocol.

A due diligence declaration is required only for genetic resources and/or traditional knowledge associated with genetic resources obtained from a Party to the Nagoya Protocol that has established relevant access and benefit-sharing legislation or regulatory requirements.

If the project necessitates compliance with the Nagoya Protocol, then the due diligence declaration has to declared in the EU database DECLARE. The due diligence declaration must be submitted to the Estonian Research Council after the first payment has been made by the Council and after all genetic resources and/or traditional knowledge used for the implementation of this project has been received, but no later than at the time of the final report.

6. GENETIC RESOURSES AND/OR ASSOCIATED TRADITIONAL KNOWLEDGE	YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file
Do you plan to use genetic resources (e.g., animal tissue samples, genetic material, live animals, materials of historical value, endangered fauna or flora samples, etc.) and/or associated traditional knowledge?			Decribe what type of genetic resources will be used and how exactly. **NB! When using genetic material from animals, plants, micro-organisms and/or associated traditional knowledge which are in compliance with Nagoya protocol, then the explanation should be added under the tab "Compliance with the Nagoya Protocol" in the ETIS application form. If the project needs the due diligence declaration, then tick the box "Does the project necessitate compliance with the Nagoya Protocol?"**	The documents demonstrating the compliance with the Nagoya Protocol: 1) due diligence declaration; 2) access permit; 3) benefit-sharing agreement. **The due diligence has to declared in the EU database DECLARE.** **NB! Due diligence declaration has to be declared only if the utilisation of the genetic resources in question is within the scope of the Regulation (EU) No 511/2014 of the European Parliament and of the Council.**

Background documents
Guidance document (2021/C 13/01) on the scope of application and core obligations of Regulation (EU) No 511/2014
EU regulation 511/2014 Nagoya Protocol on Access and Benefit Sharing

International Treaty on Plant Genetic Resources for Food and Agriculture
Nature Conservation Act
Explanation of Nagoya protocol in Estonian

7. LOW INCOME COUNTRIES

This is the case where countries with low and/or lower middle income are involved:

- research activities are conducted, partially or wholly, in such country;
- participants or resources come from such country;
- material is imported from or exported to such country.

Being outside the reach of Estonian and European laws and standards, such research can raise specific ethical issues (particularly in developing countries), such as:

- exploitation of research participants;
- exploitation of local resources;
- risks to researchers and staff;
- research that is prohibited in the EU.

7. LOW INCOME COUNTRIES	YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file
Is it planned to use local resources of low and/or lower middle income countries (e.g. animal and/or human tissue samples, genetic material other than covered in section 6)?			1) Describe what type of local resources will be used and how exactly.	Copies of ethics approvals and other authorisations.
In case your research involves low and/or lower middle income countries, are any benefit-sharing actions planned?			1) Describe the benefit-sharing measures. 2) Describe the responsiveness to local research needs.	Any relevant document

Could the situation in low and/or lower middle income country put the individuals taking part in the research at risk?			1) Describe the safety measures you intend to take, including training for staff and insurance cover.	Any relevant document

Background document
EU Global Code of Conduct for Research in resource-poor settings

8. ENVIRONMENT, HEALTH, AND SAFETY

The precautionary principle requires that where there is plausible scientific evidence for serious risks, you must prove that a new technology will not harm the environment.

The health and safety of all human participants in research – as subjects, investigators, or uninvolved third parties, must be a priority in all research studies.

8. ENVIRONMENT, HEALTH, and SAFETY	YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file
Does your research involve any activities or the use of elements that may cause harm to the environment, to animals, or plants (e.g., GMO plants, microorganisms, etc.)?			*1)* Risk-benefit analysis. *2)* What safety measures will you take?	1) Certificate of the safety classification of the laboratory for the contained use of genetically modified organisms (GMOs) 2) An emergency plan 3) Copy of the approval from a genetic technology committee for the transfer of GMOs into the environment (if required)
Does your research deal with endangered fauna and/or flora and/or protected areas?			*Please specify.*	1) Approval from the specific ethics commitee or other authorisations (if required)

Does your research involve the use of elements (toxic chemicals, explosives, radioactive material, etc.) that may cause harm to humans, including the research staff?			1) Details of the health and safety procedures.	1) Certificate of the safety classification of the laboratory

Background documents
Directive 2009/41/EC of The European Parliament and of The Council on the Contained Use of Genetically Modified Microorganisms
Release into Environment of Genetically Modified Organisms Act
Nature Conservation Act

9. POTENTIAL MISUSE OF RESEARCH RESULTS

This section concerns research involving or generating materials, methods, technologies, or knowledge that could be misused for unethical purposes. Although such research is usually carried out with benign intentions, it has the potential to harm humans, animals, or the environment.

Some questions that could be used to identify potential misuse are:

- Could the materials, methods, technologies, and knowledge involved or generated harm humans, animals, or the environment if they were modified or enhanced?
- What would happen if the materials, methods, technologies, and knowledge involved or generated ended up in the wrong hands?
- Could the materials/methods/technologies and knowledge involved or generated serve purposes other than those intended? If so, would such use be unethical?

Examples: biological, chemical, radiological, and nuclear security-sensitive materials and explosives, research with a potential impact on human rights, etc.

9. POTENTIAL MISUSE OF RESEARCH RESULTS	YES	NO	Information to be provided in the application form in ETIS	Documents to be provided/kept on file

Is it possible that the research results could be misused?			1) Describe the possible risks and describe the measures for managing said risks. 2) Describe the applicable legal requirements. 3) Describe the measures to prevent misuse.	1) Copies of authorisations (if required) 2) Copies of security clearances (if applicable) 3) Copies of ethics approvals (if applicable)

Background document
Guidance note of the EU – Potential misuse of research

10. OTHER ETHICAL ISSUES

Since the Estonian Research Council intends to support ground-breaking and innovative research, it may be that your research raises new ethical issues and concerns that are currently not (fully) covered by these guidelines (e.g., participation of military partners, new developments in the fields of neurobiology, genetic technology, nanotechnology, man-machine interaction, the creation of androids and cyborgs, etc.). This section should also be used to address the ethical and legal implications of using artificial intelligence.

If you know of any such other ethically relevant issues that apply to your project, describe them in this section and explain how you intend to address them. This allows you to alert the Estonian Research Council in time and get appropriate assistance for addressing them. It also avoids the problems you would have if such issues were discovered later (when assessing the project for the continuation of funding).

OTHER ETHICS ISSUES	YES	NO	Information to be provided in the application form in ETIS	Documents to be provided
Are there any other ethics issues that should be taken into consideration? Please specify.			Any relevant information.	Any relevant document