Eesti Teadusagentuur
Estonian Research Council

Guidelines for Completing Ethics Self-Assessment for Grant Application

2024

These guidelines are designed to help you think about the ethical issues of your project and to help identify potential ethical issues or issues that should be addressed more specifically in the application. In addition, the guidance sets out possible documents that should be kept during the project and submitted to the funder, if necessary. The guide has been drawn up across scientific fields, but depending on the field or specific nature of the research planned, some projects may have a connection with several topics of scientific ethics, some with none. This guide is mainly based on the Horizon Europe guidance document.

Research Ethics Checklist: the application form includes a list of topics of research ethics, in which the applicant must assess the relevance of the topic to the planned project. Completion of the checklist helps to identify ethical issues that need to be addressed in more detail in the application.

If „NO“ is checked, then the subject or issue doesn’t need to be further explained in the application form.

If "YES" is checked, then the relevant ethical aspects or topics should be further explained in the application form, including the description of how ethical risks are mitigated.

Ethics Self-assessment: in case "YES" response, the applicant must assess the ethical risks that may arise from the project. This guide presents additional questions that may help to assess ethical issues. The application form should include: (1) a description of the activities or the situation where ethical issues or risks may arise; (2) a description of the activities or measures planned to address ethical issues or mitigate ethical risks; (3) a mention of the relevant documents (consents, approvals, permits, contracts, etc.) that are necessary for carrying out the planned research.

The guidelines lists possible documents that the Estonian Research Council may request from the applicant during the project. In some cases, the obligation to submit a document arises from the conditions and procedure of the respective grant, such as the submission of the approval of an ethics committee or the submission of a data management plan. However, if any of the documents specified in this guide are not covered by the conditions of the grant, these documents should be preserved during the project, as the Estonian Research Council may ask for them while auditing the grant.

Table of contents

1. Humans

This section refers to any research involving human participants in research, regardless of its nature or topic. Human participants could be involved in the study can occur in a wide variety of research activities. For example, collection of biological samples, medical research and procedures, interviews, focus groups, observations, monitoring, surveys, standardized tests, experiments and all other methods where data are collected from a person through intervention or interaction.

This section also concerns secondary studies using existing personal data or biological material from a person, since such use must normally be subject to informed consent. If the data or biological material is anonymised, it should be clarified who and how has anonymised the data.

This section deals only with general issues related to the inclusion of people in the study, such as vulnerability, information, voluntarity or possible interventions. When people are included in the study, most likely personal data about them will be collected, which should be addressed in section 2. In addition, depending on the study and its field, other topics covered by the guide may prove to be relevant.

General guidelines

Respect for human autonomy: involving people in research must be voluntary. Voluntary participation assumes that participants are not influenced in making their decisions and that they understand how the study could affect them. Voluntary participation in the study is usually ensured by informed consent, which usually has to be written.

Fair distribution of burdens and benefits: the principles of beneficience and non-maleficience must be respected when people are involved in research. The potential harm, risk and burden to humans should be foreseen when planning the research. It is important to take into account that the study or its results may also affect people and social groups who do not participate directly in the study.

Protecting rights and interests of the participants: throughout the study, participants' interests must be taken into account and their well-being guaranteed. The obligations of confidentiality or anonymity promised to the participants must also be respected. The potential impact of a research study or its results on human rights and well-being should be taken into account when planning the study. It should also be borne in mind that, in some cases, people's rights may be undermined by the subsequent misuse of the scientific results.

Independent ethical evaluation: in some cases, human research should be reviewed by an ethics committee before the beginning of the study. In this case, the ethical aspects of the planned study will be further evaluated. However, it is important that the ethical aspects of human participation in the study are considered even if the study does not require the approval of the Ethics Committee.

Checklist

1. HUMANS	YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
Does your research project involve human participants?			General information relevant for all the subsequent cases: 1) Describe the criteria for recruitment, inclusion and exclusion of subjects.	Documents required in all subsequent cases: 1) Informed consent forms and information sheets. 2) Approval of the ethics committee.

				2) Describe the procedure for obtaining informed consent.	
If YES	**Does the research involve potentially vulnerable individuals or groups?**			1) Explain the vulnerability of persons. 2) Describe how it is ensured that persons understand the risks associated with participation in the study. 3) Explain the need for the inclusion of vulnerable persons in the study and the impact of participation in the study. 4) Describe the measures taken to protect the well-being and interests of vulnerable persons.	
	Does the research involve minors?			1) Explain the age of minors, how age-appropriate information is provided and the voluntary participation of minors in the study is ensured. 2) Explain the procedure for requesting informed consent from a parent or guardian. 3) Describe how the protection of the well-being and interests of minors is ensured during the study. 4) Explain why minors are included in the study.	1) Information sheets given to the minors.
	Does the research involve patients?			1) Details on the disease, condition or disability. 2) Describe the incidental findings policy.	
	Does the research involve persons unable to give informed consent?			1) Details on the procedures for obtaining consent from the guardian/legal representative. 2) Procedures to ensure participants are not subject to any form of coercion and undue inducement.	1) Informed consent forms and information sheets
Does the research involve interventions on the participants?				1) Describe the intervetions.	
If YES	**Does the research involve invaseive techniques?** (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)			1) Risk assessment for each technique and overall.	

	Does the research involve collection of biological samples?			1) Details on the type of samples to be collected. 2) Procedure for the collection of biological samples. 3) Describe what is done with the samples after the end of the study.	
Does the research project involve conducting a clinical study?				1) Details on the medical products that are being used and risk assessment. 2) Details on the disease, condition or disability of the participants. 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 4) Details on the incidental findings policy.	1) Authorisation of the Estonian State Agency of Medicines.

Taustadokumendid

World Medical Association (WMA) Declaration of Helsinki

Convention on Human Rights and Biomedicine (Oviedo Convention)

Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

Regulation (EU) 2017/745 on medical devices

Regulation (EU) 2017/746 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 (IKS) 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). Additional restrictions apply to processing of special categories of personal data (see GDPR Article 9 and IKS § 6 (4)).

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).

The **data management plan** should describe the collection, storage, protection and other important aspects of processing personal data. The data management plan must be submitted to the Estonian Research Council after the grant contract has been signed.

The approval from the Ethics Committee or the Estonian Data Protection Inspectorate[1] must be obtained before the studies and submitted to the Estonian Research Council.

Checklist

2. PERSONAL DATA	YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
Does your research involve processing of personal data?			General information relevant for all the subsequent cases: 1) Describe how informed consent will be obtained (if relevant). 2) Explain why the processed data are relevant and limited to the purposes of the project (by taking the "data minimisation" principle into account). 3) Describe the anonymisation or pseudonymisation techniques or justify why the research data will not be anonymised or pseudonymised. 4) Describe transfers of personal data, including the recipients of said data and whether data is transferred abroad.	Documents required in all subsequent cases: 1) Informed consent forms and information sheets. 2) Data management plan.

[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.

				5) Describe the security measures implemented to protect personal data.	
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.	1) Approval of the ethics committee or the authorisation of the Estonian Data Protection Inspectorate (if relevant)
	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. 4) Describe how the welfare and rights of the participants are protected. 5) Desribe the procedures for informing the research participants about the intended processing, the possible consequences and their rights.	1) Data Protection Impact Assessment (DPIA) or the written statement of the controller on the necessity of carrying out the DPIA (if relevant)
Does your research involve further processing of previously collected personal data?				1) Details on the databases or sources used for the data (registries, repositories). 2) Describe what is done with the personal data. 3) Explain how the data subjects are informed of their rights and potential risks that the processing of the data may entail. 4) Explain why the data processed are relevant and necessary (based on the principle of minimising data). 5) Explain whether and to what extent it is planned to pseudonymise or anonymise personal data.	1) Confirmation that there is an appropriate legal basis for the planned processing. 2) A contract or other confirmation entered into with the controller or possessor of the data in order to obtain the necessary information. 3) Consent forms and information sheets (if relevant). 4) Approval of the Ethics Committee or authorisation of the Data Protection Inspectorate (if required).

Is personal data going to be transferred to or from a non-EU country?			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) Authorisation 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 embryo, embryonic stem cells and foetuses

This chapter specifies the issues that should be addressed in the application form when research uses human embryos, foetuses or human embryonic stem cells.

The use of embryonic stem cells must adhere to the following requirements:

- cells were NOT derived from embryos specially created for research or by somatic cell nuclear transfer
- the project uses existing cultured cell lines only
- cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilisation
- informed consent has been obtained for using donated embryos for the derivation of the cell lines
- personal data and privacy of donors are protected according to the data protection rules applicable for the donors and in the EU
- NO financial inducements were provided for the donation of embryos used for derivation of the cell lines.

The Estonian Research Council does not fund research which is not allowed based on § 35 or is not in compliance with § 32 and 33 of the Artificial Insemination and Embryo Protection Act.

Checklist

3. HUMAN EMBRYO, EMBRYONIC STEM CELLS AND FOETUSES		YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
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 and other relevant conditions. 3) Declaration confirming that the 6 specific conditions for activities involving human embryonic stem cells are met. 4) Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry (hPSCreg).	1) Approvals of ethics committees.
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.	1) Approvals of ethics committees. 2) Informed consent forms and information sheets.

			NB! Use of embryos for research purposes must follow the § 32 of the Artificial Insemination and Embryo Protection Act.	
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. 3) Confirm that the informed consent has been obtained.	1) Approvals of ethics committees. 2) Informed consent forms and information sheets.

Background documents
Regulation (Eu) 2021/695 Of The European Parliament And Of The Council
Artificial Insemination and Embryo Protection Act
European Human Pluripotent Stem Cell Registry (hPSCreg)

4. Human cells and tissues

This chapter specifies the issues that should be addressed in the application form when research uses human cells or tissues other than human embryonic stem cells, fetal or embryonic cells or tissues (see Chapter 3).

Cells and tissues necessary for research can be obtained: 1) from commercial sources; 2) as part of this project; 3) from another project, laboratory or institution; 4) from a biobank.

Checklist

4. HUMAN CELLS AND TISSUES		YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
Does your research involve human cells or tissues?				General information relevant for all the subsequent cases: 1) Describe the details of the cells or tissue types. 2) Explain the origin of the material. 3) Explain how long the material is stored and what is done with it after the completion of the research. 4) Confirmation that the donors have provided informed consent.	Documents required in all subsequent cases: 1) The informed consent forms and information sheets of donors. 2) Approval of the ethics committee. 3) Other documents that assure that the cells or tissues have been obtained lawfully.
If YES	Are they available commercially?			1) Details on cell types and provider (company or other).	1) Copies of import licences (if relevant).
	Are they obtained within this 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.	1) The informed consent forms and information sheets.
	Are they obtained from another project, laboratory, institution or biopank?			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) Confirmation by the owner of the material that the desired cells or tissues can be shared with the project and the necessary consents have been obtained. 2) Confirmation of the owner of the material that the sharing has the necessary approval of the ethics committee (if required). 3) A copy of the use licences (if required).

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

5. Animals

Use of animals in research must follow the 3 R principle (replacement, reduction, refinement), i.e. replacing animal experiment with other methods, the reduction of the number of experimental animals and the refinement of the experiment in order to reduce suffering, harm and pain to animals.

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.

Checklist

5. ANIMALS	YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
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. 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

Documents and references

Animal Protection Act

Nature Conservation Act

National Committee for Research Ethics in Science and Technology of Norway (2019) Ethical Guidelines for the Use of Animals in Research

6. Genetic resources and associated traditional knowledge

This chapter explains the ethical issues that arise when research uses genetic resources that are subject to access regulations and that fall under the Nagoya Protocol and the European Union Regulation 511/2014 which regulate the fair and equitable sharing of benefits that arise from the utilisation of such resources. Genetic resources are any material of plant, animal, microbial or other origin containing functional units of heredity that have an actual or potential value. In addition, the Nagoya Protocol covers the use of traditional knowledge related to such genetic resources.

Human genetic resources fall outside the scope of the Nagoya Protocol.

Pathogenic organisms that pose a risk to human, animal or plant health are generally covered by the Nagoya Protocol, except for material covered by the WHO Pandemic Influenza Preparedness Framework (PIP) that falls outside the scope of the Regulation.

Before submitting an application, it is necessary to determine whether the research activities are subject to the Nagoya Protocol: whether the genetic resources or the traditional knowledge associated with them originate from a country that is party to the Nagoya Protocol and that has adopted laws, regulations or regulatory requirements on access and benefit sharing. If the Nagoya Protocol applies to research, the user of genetic resources must submit a due diligence declaration in the European Union declaration environment DECLARE.

Due diligence declaration must be submitted after the Estonian Research Council has made the first instalment and the user has received all the genetic resources used for this research and/or traditional knowledge related to genetic resources, but not later than together with the final report.

Checklist

6. GENETIC RESOURSES AND ASSOCIATED TRADITIONAL KNOWLEDGE	YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
Does the research use genetic resources or traditional knowledge related to such resources?			1) Explain which genetic materials are used and how. 2) Explain whether the Nagoya Protocol applies to the planned use of genetic material.	1) Declaration of duty of care (in the DECLARE environment). 2) A certificate of compliance, national permit or other document certifying access. 3) a revenue distribution agreement or agreement (if relevant).

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. Non-EU countries

This chapter deals with possible issues that should be addressed when project activities take place outside the European Union. This concerns, in particular, situations where:

- 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.

In such a case, it is important to take into account that the laws and standards of Estonia and the European Union do not apply and that research (particularly in developing countries) may, for example, raise the following ethical concerns:

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

The issue of non-EU countries is also important in the context of the processing of personal data covered by Chapter 2. It also has a link to Chapter 6 on the collection of genetic resources and associated traditional knowledge from third countries.

Checklist

7. NON-EU COUNTRIES	YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
Is part of the research being carried out in a country outside the European Union?			1) Details on the third countries. 2) Describe planned activities. 3) Potential risks associated with operating in a non-EU country. 4) Confirmation that all activities carried out outside the EU are permitted in Estonia or the European Union.	1) Approval of the local ethics committee (if relevant)
Is it planned to use local resources?			1) Details on the type of local resources to be used. 2) Details on additional regulation for use of the relevant resources in that country.	1) Approval of the local ethics committee (if relevant) 2) Documents confriming the lawful use of local resources (if required).
Are low- or lower-middle income countries involved in the research?			1) Details on countries and planned activities. 2) Explain whether and how it is planned to share the benefits of research. 3) Explain whether and how local circumstances and needs have been taken into account. 4) Explain whether and how it is planned to contribute to the development of local capabilities and competences.	

Is it planned to export any material from the EU to non-EU countries?			1) Details on materials and countries.	1) Copies of export licences/ Material Transfer Agreement (MTA).
Could the situation in the country put the individuals taking part in the activity at risk?			1) Details on potential risks. 1) Details of the safety measures you intend to take, including training for staff and insurance cover.	1) Insurance coverage (if relevant)

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.

Checklist

8. ENVIRONMENT, HEALTH AND SAFETY	YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
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 for the transfer of GMOs into the environment (if required)
Does your research deal with endangered fauna and flora or protected areas?			1) Details on species or protected areas.	1) Approval of an ethics commitee or other authorisations (if required) 2) a permit to move on the territory of a protected natural object (if relevant)
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. Artificial Intelligence

This chapter specifies the issues that should be addressed if the project uses or develops AI systems. Since AI systems cover a wide range of technologies, applications and tools, it is difficult to provide more detailed guidance on how to address potential threats or ethical issues. The general principles of responsible AI use should be followed while conducting research.

The applicant is responsible for the possible use of artificial intelligence and must carefully consider the potential ethical aspects while planning the research and continously assess and monitor the identified risks throughout the project. To support the researchers, the European Commission has created a guide: "Ethics By Design and Ethics of Use Approaches for Artificial Intelligence" (2021). According to the guide, the general ethical principles of using artificial intelligence are:

1. **Respect for Human Agency and Human Rights:** people should be able to decide and act on their own. Any use of artificial intelligence must support and respect human autonomy and dignity. The fundamental rights of people must also be taken into account.
2. **Privacy and Data Governance:** the use of artificial intelligence must take into account people's right to privacy and data protection requirements. This, in turn, requires thorough data management policies, especially when it comes to the use of personal data.
3. **Fairness:** equal rights and opportunities for people must be provided. The use of artificial intelligence must avoid biased, unequal treatment of people and the creation of unjustified advantages or obstacles.
4. **Individual, Social and Environmental Well-being:** the use of artificial intelligence systems should increase well-being and avoid harming individiuals, society and the environment.
5. **Transparency:** the purposes, methods and inputs of the AI system should be knowable and understandable to all parties.
6. **Accountability and Oversight:** humans should be able to understand, supervise and control the development and operation of the AI system. Artificial intelligence system developers and administrators must take responsibility for the function and consequences of these applications.

In addition, the legal regulation related to artificial intelligence is in development and the preparations are ongoing for the European Union Artificial Intelligence Act, which regulates the use of artificial intelligence systems according to their degree of risk. The Act prohibits certain forms of use of AI with unacceptable risk:

1. Subliminal influence of human behaviour that is likely to manipulate persons to cause harm to themselves or others.
2. Exploiting any vulnerability of persons to influence their behaviour, as a result of which persons may cause harm to themselves or others.
3. Social scores of people based on their behaviour, characteristics or personal characteristics.
4. Real-time biometric remote human detection (e.g. facial recognition), except for narrowly defined security needs.

In addition, the proposed Act defines a number of uses for high-risk uses, in which case additional obligations have to be taken into account. The proposed Artificial Intelligence Act focuses on the use

and development of an AI System. Therefore, it is especially relevant for applied research aimed at developing solutions or applications using artificial intelligence.

Checklist

9. ARTIFICIAL INTELLIGENCE		YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
Does the research involve the use or development of AI systems or methods?				1) Explanation as to how the participants and/or end-users will be informed about the use of AI. 2) Details on the measures taken to avoid bias in input data and algorithm design; 3) Explanation as to how the respect to fundamental human rights and freedoms (e.g. human autonomy, privacy and data protection) will be ensured; 4) Detailed explanation on the potential ethics risks and the risk mitigation measures.	1) Risk assessment (if relevant) 2) Approval of ethics committee (if relevant).
If YES	Could the AI based system/technique potentially stigmatise or discriminate against people?			1) Detailed explanation of the measures set in place to avoid potential bias, discrimination and stigmatisation.	
	Does the AI system/technique have the potential to lead to negative social (*e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance*) or environemental impacts?			1) Justification of the need for developing/using this particular technology. 2) Assessment of the ethics risks and detailed description of the measures set in place to mitigate the potential negative impacts.	1) Impact Assessment (if relevant)
	Does the AI system/technique interact, replace or influence human decision-making processes?			1) Explanation on how humans will maintain meaningful control over the most important aspects of the decision-making process. 2) Explanation on how the presence/role of the AI will be made clear and explicit to the affected individuals.	1) Information sheets and informed consent forms (if relevant)

Useful documents

European Commission. (2021) Ethics By Design and Ethics of Use Approaches for Artificial Intelligence

European Commission. (2020) Assessment List for Trustworthy Artificial Intelligence (ALTAI)

Materials of European AI Alliance: https://futurium.ec.europa.eu/en/european-ai-alliance/document

H2020 SIENNA project collection of AI and robotics related codes and guidelines: https://www.sienna-project.eu/robotics/codes-and-guidelines/

10. Potential misuse of research results

This chapter 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.

The following questions could be used to identify potential for misuse:

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, research on potentially polarising issues etc.

Checklist

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

11. 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.).

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).

11. OTHER ETHICAL ISSUES	YES	NO	Information to be provided in the application form in ETIS	Documents to be kept on file and provided on request
Are there any other ethics issues that should be taken into consideration? Please specify.			1) Details on potential ethical issues.	