ETHICS SELF-ASSESSMENT

NOTE: Guidance notes are indicated in grey background. Delete all guidance notes before submitting your project proposal

Ethics checklist *(No page limit)*

Compliance with the relevant ethics provisions is essential from the beginning to the end of the project and is an integral part of research funded by the European Union within Horizon Europe.

1. Applicants submitting proposals for funding for the rePLANT programme should demonstrate proactively that they are aware of, and will comply with, ethical principles and applicable International, European and national law. Key sources of EU and international law are the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Another important source is the UN Convention on the Rights of Persons with Disabilities (UN CRPD).

Main ethical principles:

- Respecting human dignity and integrity
- Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)
- Protecting vulnerable persons
- Ensuring privacy and confidentiality
- Promoting justice and inclusiveness
- Minimising harm and maximising benefit
- Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries
- Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research
- Respecting and protecting the environment and future generations

Please be aware that it is the applicants' responsibility to identify any potential ethical issue, to handle the ethical aspects of the proposal and to detail how these aspects will be addressed.

All eligible proposals will be subject to an evaluation including the evaluation of Ethics. When submitting a proposal to rePLANT, all applicants are required to complete an Ethics Checklist (section 4.1) Applicants who flag ethical issues in section 3.1 have to complete also a more in depth Ethics Self-Assessment in section 3.2.

Answer YES/NO to **each question** in the table below, and indicate the corresponding page(s) of your Project Proposal that include information about the research activities that raise Ethical Issues. **Do not delete any lines of the table.**

1. HUMAN EMBRYOS/FOETUSES		PAGE
Does your research involve Human Embryonic Stem Cells (hESCs)?	YES / NO	
Does your research involve the use of human embryos?	YES / NO	
Does your research involve the use of human foetal tissues / cells?	YES / NO	
2. HUMANS		
Does your research involve physical interventions on the study participants?	YES / NO	
Does your research involve human participants?	YES / NO	
3. HUMAN CELLS / TISSUES		

Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, i.e. section 1)?	YES / NO	
4. PERSONAL DATA		
Does your research involve personal data collection and/or processing?	YES / NO	
Does your research involve further processing of previously collected personal data (secondary use)?	YES / NO	
5. ANIMALS		
Does your research involve animals?	YES / NO	
6. THIRD COUNTRIES		
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?	YES / NO	
Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	YES / NO	
Do you plan to import any material - including personal data - from non-EU countries into the EU?	YES / NO	
Do you plan to export any material - including personal data - from the EU to non-EU countries?	YES / NO	
In case your research involves low and/or lower middle income countries, are any benefits-sharing actions planned?	YES / NO	
Could the situation in the country put the individuals taking part in the research at risk?	YES / NO	
7. ENVIRONMENT & HEALTH and SAFETY		
Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	YES / NO	
Does your research deal with endangered fauna and/or flora and/or protected areas?	YES / NO	
Does your research involve the use of elements that may cause harm to humans, including research staff?	YES / NO	
8. ARTIFICIAL INTELLIGENCE		
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?	YES / NO	
Could the AI based system/technique potentially stigmatise or discriminate against people (e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority?	YES / NO	
Does the AI system/technique interact, replace or influence human decision-making processes (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)?	YES / NO	
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) and/or environmental impacts either through intended applications or plausible alternative uses?	YES / NO	
9. OTHER ETHICS ISSUES		
Are there any other ethics issues that should be taken into consideration? Please specify:	YES / NO	
[specify here]		
10. MISUSE		
Does your research have the potential for misuse of research results for unethical purposes?	YES / NO	

Ethics Self-Assessment

Provide information about the ethics issues concerning your proposed project (as indicated in above).

Specifically: Explain in detail how you intend to address the ethical issues flagged:

Delete those sections (1-11) that do not apply.

1. HUMAN EMBRYOS/FOETUSES

1.1 Does your research involve Human Embryonic Stem Cells (hESCs)? **If Yes,**

1.1.1 Are they previously established cells lines? **If Yes:**

- What is the origin and line of cells?
- Give details of the licensing and control measures by the competent authorities of the Member States involved

1.1.2 Does your research involve the use of human embryos? **If Yes,**

- What is the origin of embryos?
- Give details of the recruitment, inclusion and exclusion criteria and informed consent procedures.
- Confirm that informed consent has been obtained.

1.1.3 Does your research involve the use of human foetal tissues / cells? **If Yes,**

- What is the origin of human foetal tissues/cells?
- Give details of the informed consent procedures.
- Confirm that informed consent has been obtained.

2. HUMANS

2.1 Does your research involve physical interventions on the study participants? **If Yes,**

2.1.1 Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)? **If Yes,**

- Detail risk assessment for each technique and overall.

2.1.2 Does it involve collection of biological samples? **If Yes,**

- What type of samples will be collected?
- What are your procedures for collecting biological samples?

2.2 Does your research involve human participants? **If Yes**

2.2.1 Are they volunteers for social or human sciences research? **If Yes,**

- Give details of the recruitment, inclusion and exclusion criteria and informed consent procedures.

2.2.2 Are they persons unable to give informed consent (including children/minors)? **If Yes,**

- Give details of the procedures for obtaining approval from the guardian/legal representative and the agreement of the children or other minors.
- What steps will you take to ensure that participants are not subjected to any form of coercion?

2.2.3 Are they vulnerable individuals or groups? **If Yes,**

- Give details of the type of vulnerability.
- Give details of the recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.

2.2.4 Are they children/minors? **If Yes,**

- Give details of the age range.

- What are your assent procedures and parental consent for children and other minors?
- What steps will you take to ensure the welfare of the child or other minor?
- What justification is there for involving minors?

2.2.5 Are they patients? **If Yes,**

- What disease/condition/disability do they have?
- Give details of the recruitment, inclusion and exclusion criteria and informed consent procedures.
- What is your policy on incidental findings?

3. HUMAN CELLS / TISSUES

3.1 Does your research involve human cells or tissues (other than from Human Embryos/Foetuses)? **If Yes,**

3.1.1 Are they available commercially? **If Yes,**

- Give details of the provider (company or other).

3.1.2 Are they obtained within this project? **If Yes,**

- Give details of the source of the material, the amount to be collected and the procedure for collection.
- Give details of the duration of storage and what you will do with the material at the end of the research.
- Confirm that informed consent has been obtained.

3.1.3 Are they obtained from another project, laboratory or institution? **If Yes,**

- What is country where the material is stored?
- Give details of the legislation under which material is stored.
- How long will the material be stored and what will you do with it at the end of the research project?
- Give name of the laboratory/institution.
- In which country the laboratory/institution is located?
- Confirm that material is fully anonymised or that consent for secondary use has been obtained.

3.1.4 Are they obtained from a biobank? **If Yes,**

- What is the name of the biobank?
- In which country the biobank is located?
- Give details of the legislation under which material is stored.
- Confirm that material is fully anonymised or that consent for secondary use has been obtained.

4. PERSONAL DATA

4.1 Does your research involve personal data collection and/or processing? **If Yes,**

- Give details of the technical and organisational measures to safeguard the rights of the research participants. For instance: For organisations that must appoint a DPO under the GDPR: Involvement of the data protection officer (DPO) and disclosure of the contact details to the research participants. For all other organisations: Details of the data protection policy for the project (i.e. project-specific, not general).
- Give details of the informed consent procedures.

- Give details of the security measures to prevent unauthorised access to personal data.
- How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)?
- Give details of the anonymisation /pseudonymisation techniques.
- Give justification of why research data will not be anonymised/ pseudonymised (if relevant).
- Give details of the data transfers (type of data transferred and country to which it is transferred – for both EU and non-EU countries).

4.1.1 Does it involve the processing of special categories of personal data (e.g. genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.)? **If Yes,**

- Give justification for the processing of special categories of personal data.
- Why can the research objectives not be reached by processing anonymised/ pseudonymised data (if applicable)?

4.1.2 Does it involve processing of genetic, biometric or health data? **If Yes,**

- Confirm that you will obtain a declaration confirming compliance with the laws of the country where the data was collected.

4.1.3 Does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of 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? **If Yes,**

- Give details of the methods used for tracking, surveillance or observation of participants.
- Give details of the methods used for profiling.
- Describe risk assessment for the data processing activities.
- How will harm be prevented and the rights of the research participants safeguarded? Explain.
- Give details on the procedures for informing the research participants about profiling, and its possible consequences and the protection measures.

4.2 Does your research involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)? **If Yes**,

- Give details of the database used or of the source of the data.
- Give details of the data processing operations.
- How will the rights of the research participants be safeguarded? Explain.
- How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)?
- Give justification of why the research data will not be anonymised/ pseudonymised (if relevant).

4.3 Does your research involve publicly available data? **If Yes,**

- Confirm that the data used in the project is publicly available and can be freely used for the project.

4.4 Is it planned to export personal data from the EU to non-EU countries? **If Yes,**

- Details of the types of personal data to be exported.
- How will the rights of the research participants be safeguarded?

4.5 Is it planned to import personal data from non-EU countries into the EU? **If Yes,**

- Details of the types of personal data to be imported.

5. ANIMALS

5.1 Does your research involve animals? **If Yes,**

- Give details of the species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used.
- Give justification of animal use (including the kind of animals to be used) and why alternatives cannot be used.

5.2 Are they vertebrates? **If Yes,**

5.2.1 Are they nonhuman primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)? **If Yes,**

- Why are NHPs the only research subjects suitable for achieving your scientific objectives?
- What is the purpose of the animal testing?
- Where do the animals come from?

5.2.2 Are they genetically modified? **If Yes,**

- Give details of the phenotype and any inherent suffering expected.
- What scientific justification is there for producing such animals? Give details.
- What measures will you take to minimise suffering in breeding, maintaining the colony and using the GM animals?

5.2.3 Are they cloned farm animals? **If Yes,**

- Give details of the phenotype and any inherent suffering expected.
- What scientific justification is there for producing such animals?
- What measures will you take to minimise suffering in breeding, maintaining the colony and using of the GM animals?

5.2.4 Are they an endangered species? **If Yes,**

- Why is there no alternative to using this species?
- What is the purpose of the research?

6. THIRD COUNTRIES

6.1 In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? **If Yes,**

- Describe risk-benefit analysis.
- What activities are carried out in non-EU countries?

6.2 Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)? **If Yes,**

- What type of local resources will be used and how exactly?

6.3 Do you plan to import any material from non-EU countries into the EU? **If Yes,**

- What type of materials will you import?
- Specify the materials and countries involved.

6.4 Do you plan to export any material from the EU to non-EU countries? **If Yes,**

- Give details of the type of materials to be exported.
- Specify the materials and countries involved.

6.5 Does your research involve low and/or lower middle income countries? **If Yes,**

6.5.1 Are any benefits-sharing actions planned? **If Yes,**

- Give details of the benefit sharing measures.
- Give details of the responsiveness to local research needs.
- Give details of the procedures to facilitate effective capacity building.

6.6 Could the situation in the country put the individuals taking part in the research at risk? **If Yes,**

- Give details of the safety measures you intend to take, including training for staff and insurance cover.

7. ENVIRONMENT & HEALTH and SAFETY

7.1 Does your research involve the use of elements that may cause harm to the environment, to animals or plants? **If Yes**,

- Describe risk-benefit analysis.
- Show how you apply the precautionary principle (if relevant).
- What safety measures will you take?

7.2 Does your research deal with endangered fauna and/or flora and/or protected areas? **If Yes,**

- Declare you will obtain specific authorisations (if required).

7.3 Does your research involve the use of elements that may cause harm to humans, including research staff? **If Yes,**

- Give details of the health and safety procedures.

8. ARTIFICIAL INTELLIGENCE

8.1. Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems? **If Yes,**

- Explanation as to how the participants and/or end-users will be informed about:

- their interaction with an AI system/technology (if relevant);
- the abilities, limitations, risks and benefits of the proposed AI system/technique;
- the manner in which decisions are taken and the logic behind them (if relevant).

- Detailed risk assessment accompanied by a risk mitigation plan (if relevant).
- Copies of ethics approvals (if relevant).
- Details on the measures taken to avoid bias in input data and algorithm design;
- Explanation as to how the respect to fundamental human rights and freedoms (e.g. human autonomy, privacy and data protection) will be ensured;
- Detailed explanation on the potential ethics risks and the risk mitigation measures.

8.2. Could the AI based system/technique potentially stigmatise or discriminate against people (e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a politicalgroup, or membership to a national minority)? **If Yes,**

- Detailed explanation of the measures set in place to avoid potential bias, discrimination and stigmatisation.

8.3. Does the AI system/technique interact, replace or influence human decision-making processes (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)? **If Yes,**

- Detailed explanation on how humans will maintain meaningful control over the most important aspects of the decision-making process;

- Explanation on how the presence/role of the AI will be made clear and explicit to the affected individuals.

8.4. 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) and/or environmental impacts either through intended applications or plausible alternative uses?

- Justification of the need for developing/using this particular technology.
- Assessment of the ethics risks and detailed description of the measures set in place to mitigate the potential negative impacts during the research, development, deployment and post-deployment phase.

9. OTHER ETHICS ISSUES

9.1 Are there any other ethics issues that should be taken into consideration? **If Yes,**

- Please specify any relevant information.

10. MISUSE

10.1 Does your research have the potential for misuse of research results? **If Yes,**

- Describe risk-assessment.
- Give details of the applicable legal requirements.
- Details of the measures to prevent misuse.

For more information about Ethics Self-Assessment, please see: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf