TOGAS Ethics Self-assessment form

Please note: The instructions (highlighted in grey) must be deleted from the submitted ethics form.

The TOGAS Ethics Self-Assessment form is largely based on the Horizon Europe Ethics Self-Assessment guidelines, adapted for the TOGAS call.
You must answer all questions in the below Ethics Issue Table with a 'Yes' or 'No'** and provide a **confirmation for the Ethics declaration.
***If you answer 'Yes' to any of the questions, you need to conduct an ethics 'self- assessment'** and explain how you will address those ethical aspects in the **ethics self-assessment boxes** below.*
The ethics self- assessment consists of two parts:

- *The ethical dimension of the objectives, methodology and likely impact*
- *The compliance with ethical principles and relevant legislations*

For more detailed information on how to complete the ethics self-assessment please consult the Ethics chapter in the TOGAS Guide for Applicants and the Horizon Europe guideline on How to complete your ethics self-assessment. If you have any questions regarding the completion of this form, please contact the TOGAS helpsdesk (togas@uantwerpen.be, with ethics in the subject).

The TOGAS Ethics self-assessment form should be saved in this format: 'Family name_Ethics.pdf'.

Ethics Issues Table

Section			Guidance notes
1.Human Embryonic Stem Cells and Human Embryos			
1.1 Does this activity involve Human Embryonic Stem Cells (hESCs)?	Yes	No	Activities that involve hESCs directly derived from embryos are ineligible for funding. If the hESCs you will use are previously established cells lines and/or registered in the European registry for human embryonic cells lines, you must provide information about the origin and line of cells, the licensing and control measures of the countries involved and declare that you have met the specific conditions for involving human embryonic stem cells
1.2 Does this activity involve the use of human embryos?	Yes	No	Your Ethics-Self Assessment should include details about the origin of the embryos, the recruitment, inclusion and exclusion criteria and informed consent procedures and confirmation that informed consent has been obtained. Activities that involve the destruction of human embryos are ineligible for funding.
2. Human Cells/Tissues (not covered by section 1)			
2.1 Does this activity involve the use of human cells or tissues? **If yes**, answer questions 2.2 to 2.6 below. **If no**, move on to question 3.1	Yes	No	Your Ethics-Self Assessment Project should include details of how you will keep track of the origin of the cells and tissues you use, produce and collect and confirmation that you will obtain the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells or tissues and free and fully-informed consent of the donors

2.2 Are they human embryonic or foetal cells or tissues	Yes	No	
2.3 Are they available commercially?	Yes	No	
2.4 Are they obtained within this project?	Yes	No	
2.5 Are they obtained from another project, laboratory or institution?	Yes	No	
2.6 Are they obtained from a biobank?	Yes	No	
3. Humans			
3.1 Does this activity involve human participants? **If yes**, answer questions 3.2 to 3.7 below. **If no**, move on to question 3.8	Yes	No	Concerning all research or study participants, persons concerned by the project activities, etc., regardless of its nature or topic.
3.2 Is their participation voluntary?	Yes	No	Your Ethics-Self Assessment should include details on the recruitment, inclusion and exclusion criteria and informed consent procedures and details on unexpected findings policy
3.3 Are they healthy volunteers for medical studies?	Yes	No	Your Ethics-Self Assessment should include details on the recruitment, inclusion and exclusion criteria and informed consent procedures and details on unexpected findings policy
3.4 Are they patients for medical studies?	Yes	No	Provide details on the impairment/disease/condition/disability of the patients.
3.5 Are they potentially vulnerable individuals or groups?	Yes	No	Your Ethics-Self Assessment should include details on the type of vulnerability, which can be highly contextual. Also describe the procedures in place to ensure participants are not to be subjected to any form of coercion and undue inducement.
3.6 Are they children/minors?	Yes	No	Your Ethics-Self Assessment should include thorough reasoning on why the involvement of children is necessary, on the age range of the minors and on how consent from parents/legal guardians will be obtained.
3.7 Are there other persons unable to give informed consent?	Yes	No	Other persons unable to give consent include certain elderly populations, persons judged as lacking mental capacity
3.8 Does this activity involve interventions (physical also including imaging technology, behavioural treatments etc.) on the study participants? **If yes**, answer questions 3.9 and 3.10. **If no**, move on to question 3.11	Yes	No	Your Ethics-Self Assessment should provide information on the ethical implications of the chosen methodology, a risk assessment, and a detailed explanation on how you will minimise harm.
3.9 Does it involve invasive techniques e.g., collection of human cells or tissue, surgical or medical interventions,	Yes	No	Include a risk assessment for each technique and for the overall project or procedures.

invasive studies on the brain etc?			
3.10 Does it involve collection of biological samples?	Yes	No	Provide details on the samples and the collection procedure.
3.11 Does it involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products). **If yes,** answer questions 3.12 and 3.13. **If no**, move on to question 4.1	Yes	No	'Clinical study' means any investigation in relation to humans intended: a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; b) to identify any adverse reactions to one or more medicinal products; or c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products; With the objective of ascertaining the safety and/or efficacy of those medicinal products.
3.12 Is it a clinical trial?	Yes	No	Your Ethics-Self Assessment should contain a risk assessment and details on the medical products that are being used, details on the impairment/disease/condition/disability of participants. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures and details on the incidental findings policy.
3.13 Is it a low intervention clinical trial?	Yes	No	Your Ethics-Self Assessment should contain a risk assessment and details on the medical products that are being used, details on the impairment/disease/condition/disability of participants. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures and details on the incidental findings policy.
4. Personal Data			
4.1 Does this activity involve processing or personal data? **If yes,** answer questions 4.2 and 4.3 . **If no**, move on to question 4.4	Yes	No	Your Ethics-Self Assessment should provide details on how and why these personal data are collected, include a project specific data protection policy, a potential data transfer plan and information on whether or not these personal data will be anonymised/pseudonymised.
4.2 Does it involve the processing of special categories of personal data (e.g.: sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)?	Yes	No	Your Ethics-Self Assessment should provide information on why the gathering of these special categories of personal data is justified and how these data will be processed.
4.3 Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	Yes	No	Your Ethics-Self Assessment should provide details of the methods used and a risk assessment of the ethics risks related to the processing of these data. Explain how the rights and freedoms of participants/data subjects will be safeguarded and how harm will be prevented. Elaborate on how data subjects will be informed about the possibility of profiling, its possible consequences, and how their fundamental rights will be safeguarded.
4.4 Does this activity involve further processing or previously collected personal data (including the use of pre-	Yes	No	Provide details on the source and processing of the data and how the rights of data subjects will be safeguarded.

existing data sets or sources, merging existing data sets?)			
4.5 Is it planned to export personal data from the EU to non-EU countries?	Yes	No	Your Ethics-Self Assessment should specify the type of personal data and countries involved
4.6 Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country?	Yes	No	Your Ethics-Self Assessment should specify the type of personal data and countries involved
4.7 Does this activity involve the processing of personal data relating to criminal convictions or offences?	Yes	No	Your Ethics-Self Assessment should provide details on the personal data that are being processed and the legal basis for this processing. Furthermore, provide a risk assessment for the processing and explain how harm will be prevented and the rights of subjects will be safeguarded.
5. Animals			
5.1 Does this activity involve animals? **If yes**, answer questions 5.2 to 5.6 below. **If no**, go to question 6	Yes	No	Provide details on the numbers of animals to be used, the nature of the experiments, procedures, and techniques to be used. Provide details on the species and a thorough justification for their use. Provide details on how animal welfare will be ensured and on how the 3Rs Principle will be implemented; Replace, Reduce, Refine.
5.2 Are they vertebrates?	Yes	No	
5.3 Are they non-human primates (NHP) e.g., monkeys, chimpanzees, gorillas etc	Yes	No	
5.4 Are they genetically modified?	Yes	No	Provide specific information on how the anticipated impact will be minimised
5.5 Are they cloned farm animals?	Yes	No	
5.6 Are they an endangered species?	Yes	No	Give thorough justification on why there is no alternative to using this species.
6. Countries			
6.1 Will some of the activities be carried out in non-EU (this includes the UK) countries?	Yes	No	Your application should provide information on the countries involved and details on the activities to be carried out. Also include a risk-benefit analysis. All activities must be legal in both EU Member States and non-EU countries
6.2 Where non-EU countries are involved, do the activities undertaken in these countries raise potential ethical issues?	Yes	No	Provide details on the materials and the countries involved.
6.3 Is it planned to use local resources?	Yes	No	For example, animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna, or flora samples, etc.
6.4 Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country?	Yes	No	Specify the material and the countries involved
6.5 Is it planned to export any material (other than data)	Yes	No	Specify the material and the countries involved

from the EU to non-EU countries?			
6.6 Does this activity involve low and/or middle-income countries	Yes	No	Your Ethics-Self Assessment should include details of the benefit-sharing actions planned
6.7 Could the situation in the country put the individuals taking part in the activity at risk?	Yes	No	Your Ethics-Self Assessment should provide details on the safety measures to be taken, including training for staff and insurance cover.
7. Environment, Health, and Safety			
7.1 Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?	Yes	No	Your Ethics-Self Assessment should provide details on safety measures to be implemented and on (if applicable) you will apply the precautionary principle.
7.2 Does this activity deal with endangered fauna and/or flora/protected areas?	Yes	No	More information can be found in The Habitats Directive.
7.3 Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, as a possible impact)?	Yes	No	Your Ethics-Self Assessment should provide details of the health and safety procedures.
8. Artificial Intelligence (AI)			
8.1 Does this activity involve the development, deployment and/or use of AI? **If yes**, answer questions 8.2 to 8.5. **If no**, go to question 9.	Yes	No	There are six general ethical principles that any AI system must preserve and protect: (i) respect for human agency, autonomy, dignity and freedom; (ii)privacy and data governance; (iii)fairness; (iv) individual, social and environmental well-being; (v)transparency; and (vi) accountability and oversight
8.2 Could the AI system/technique potentially stigmatise or discriminate against people?	Yes	No	Based on for example, sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership of a political group. Provide information on how you will avoid potential bias, discrimination, or stigmatisation.
8.3 Does the AI system/technique interact, replace, or influence human decision-making processes?	Yes	No	For example, issues affecting human life, health, wellbeing, or human rights or economic, social, or political decisions. Provide a detailed explanation on how humans will maintain meaningful control over the most important aspects of the decision-making process.
8.4 Does the AI system/technique have the potential to lead to negative social and/or environmental impacts either through	Yes	No	Negative social impacts include for example, on democracy, media, labour markets, freedoms, educational choices, and mass surveillance.

intended applications or through plausible alternative uses			
8.5 Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above?	Yes	No	Other ethical issues could include subliminal, covert, or deceptive AI, AI that is used to stimulate addictive behaviours, life-like humanoids/robots etc.
9. Dual-use and military applications			
9.1 Does your research have the potential for military applications?	Yes	No	Research intended to be used for a military application or with the aim to serve military purposes, cannot be funded. Projects involving the defence industry or military organisations are not automatically excluded from funding, however, their participation can be justified only if they are involved in research activities exclusively focused on civil applications
9.2 Does your research involve dual-use items or other items for which an authorisation is required?	Yes	No	Dual-use items have both a civic and military application. All dual use items can be found in Annex I of the European Regulation on export-control of dual use items. For the UK consult the following list: UK Strategic Expert Control Lists.
10. Misuse, security, and human rights			
10.1 Does your research have the potential for misuse of research results?	Yes	No	Can your research/research results be misused for unethical purposes? The main focus is on misuse for terrorist or criminal activities, or on applications that can be used to violate human rights or compromise the safety of people, animals or the environment. Reflect not only on your own intentions but on the possibility of the research results falling into 'the wrong hands'.
10.2 Might the activities lead to, or might the chosen partners be involved in, human rights violations?	Yes	No	Certain types of partners, activities and contexts may call for heightened vigilance. For example: - non-academic partners like the police, the army or other (public or private) security services; - companies in sectors with large-scale violations of workers'/residents' rights; - a governmental partner in a country with a poor reputation for human rights violations; - an academic institution closely associated with one of the above; - the use of dual-use/misuse sensitive materials, e.g., surveillance technologies.
10.3 Do you take security measures to prevent misuse?	Yes	No	Your Ethics-Self Assessment should provide information on how you will maximize damage control, safeguard fundamental rights, and implement the principle of due diligence on the careful handling of the research data.
11. Other Ethics Issues			
11.1 Are there any other ethics issues that should be taken into consideration?	Yes	No	New ethical issues might arise when working on highly innovative activities and new-emerging technologies, e.g., new developments in the fields of neurobiology, human-machine interaction, developments in nanotechnology, genetic enhancement, the creation of androids and cyborgs, etc.

☐ *"I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply (any Yes identified in the table above), I will complete the ethics self-assessment below, as described in the guidelines above and on How to complete your ethics self-assessment Horizon Europe guidelines."*

Ethics Self-Assessment

Please note: The instructions (highlighted in grey) must be deleted from your ethics-self-assessment

Ethical dimension of the objectives, methodology and likely impact
Explain in detail the identified ethical considerations in relation to: - *Objectives of the activities (e.g., study of vulnerable populations etc.)* - *Methodology (e.g., clinical trials, involvement of children, protection of personal data, etc.)* - *The potential impact of the activities (e.g., environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)*
Compliance with ethical principles and relevant legislations
Describe how the identified ethical considerations will be addressed to adhere to the ethical principles and what will be done to ensure that the activities are complaint with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out.