

ETHICS APPRAISAL PROCEDURE

ETHICS ISSUES TABLE

This table should be completed as an essential part of your proposal. Please go through the table and indicate which elements concern your proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any of the questions,

- indicate in the adjacent box at which page in your full proposal further information relating to that ethics issue can be found, and

- provide additional information on that ethics issue in the Ethics Self-Assessment section.

For more information on each of the ethics issues and how to address them, including detailed legal references, see the guidelines »How to Complete your Ethics Self-Assessment«.

1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS			PAGE
Does this activity involve Human Embryonic Stem Cells (hESCs)?		<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
If YES:	Will they be directly derived from embryos within this project?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
	Are they previously established cells lines?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
Does this activity involve the use of human embryos?		<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
If YES:	Will the activity lead to their destruction?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
2. HUMANS			PAGE
Does this activity involve human participants?		<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
If YES:	Are they volunteers for non medical studies (e.g. social or human sciences research)?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
	Are they healthy volunteers for medical studies?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
	Are they patients for medical studies?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
	Are they potentially vulnerable individuals or groups?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
	Are they children/minors?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
	Are they other persons unable to give informed consent?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?		<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
If YES:	Does it involve invasive techniques?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
	Does it involve collection of biological samples?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)		<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>
If YES:	Is it a clinical trial?	<input type="radio"/> YES <input type="radio"/> NO	<input type="text"/>



	Is it a low-intervention clinical trial?	<input type="radio"/> YES <input type="radio"/> NO		
3. HUMAN CELLS / TISSUES (not covered by section 1)			PAGE	
	Does this activity involve the use of human cells or tissues?	<input type="radio"/> YES <input type="radio"/> NO		
If YES :	Are they human embryonic or foetal cells or tissues?	<input type="radio"/> YES <input type="radio"/> NO		
	Are they available commercially?	<input type="radio"/> YES <input type="radio"/> NO		
	Are they obtained within this project?	<input type="radio"/> YES <input type="radio"/> NO		
	Are they obtained from another project, laboratory or institution?	<input type="radio"/> YES <input type="radio"/> NO		
	Are they obtained from biobank?	<input type="radio"/> YES <input type="radio"/> NO		
4. PERSONAL DATA			PAGE	
	Does this activity involve processing of personal data?	<input type="radio"/> YES <input type="radio"/> NO		
If YES :	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)?	<input type="radio"/> YES <input type="radio"/> NO		
	Does it involve processing of genetic, biometric or health data?	<input type="radio"/> YES <input type="radio"/> NO		
	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.)?	<input type="radio"/> YES <input type="radio"/> NO		
	Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	<input type="radio"/> YES <input type="radio"/> NO		
	Is it planned to export personal data from the EU to non-EU countries?	<input type="radio"/> YES <input type="radio"/> NO		
If YES :	Specify the type of personal data and countries involved:	<input type="radio"/> YES <input type="radio"/> NO		
	<div style="border: 1px solid black; height: 100px; width: 100%;"></div>			
	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?	<input type="radio"/> YES <input type="radio"/> NO		



If YES :	Specify the type of personal data and countries involved:	
Does this activity involve the processing of personal data related to criminal convictions or offences?	<input type="radio"/> YES <input type="radio"/> NO	
5. ANIMALS		PAGE
Does this activity involve animals?	<input type="radio"/> YES <input type="radio"/> NO	
If YES :	Are they vertebrates?	<input type="radio"/> YES <input type="radio"/> NO
	Are they non-human primates (NHP)?	<input type="radio"/> YES <input type="radio"/> NO
	Are they genetically modified?	<input type="radio"/> YES <input type="radio"/> NO
	Are they cloned farm animals?	<input type="radio"/> YES <input type="radio"/> NO
	Are they endangered species?	<input type="radio"/> YES <input type="radio"/> NO
6. NON-EU COUNTRIES		PAGE
Will some of the activities be carried out in non-EU countries?	<input type="radio"/> YES <input type="radio"/> NO	
If YES :	Specify the countries:	
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?	<input type="radio"/> YES <input type="radio"/> NO	
If YES :	Specify the countries:	
Is it planned 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.)?	<input type="radio"/> YES <input type="radio"/> NO	
Is it planned to import any material from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.	<input type="radio"/> YES <input type="radio"/> NO	



If YES :	Specify material and countries involved:	
Is it planned to export any material from the EU to non-EU countries?	<input type="radio"/> YES <input type="radio"/> NO	
If YES :	Specify material and countries involved:	
Does this activity involves low and/or lower-middle income countries? (if yes, detail the benefit sharing actions planned in the self-assessment).	<input type="radio"/> YES <input type="radio"/> NO	
Could the situation in the country put the individuals taking part in the activity at risk?	<input type="radio"/> YES <input type="radio"/> NO	
7. ENVIRONMENT, HEALTH and SAFETY		PAGE
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)?	<input type="radio"/> YES <input type="radio"/> NO	
Does this activity deal with endangered fauna and/or flora / protected areas?	<input type="radio"/> YES <input type="radio"/> NO	
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing them (during the implementation of the activity or further to the use of the results, as a possible impact)?	<input type="radio"/> YES <input type="radio"/> NO	
8. ARTIFICIAL INTELLIGENCE		PAGE
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	<input type="radio"/> YES <input type="radio"/> NO	
9. OTHER ETHICS ISSUES		PAGE
Are there any other ethics issues that should be taken into consideration?	<input type="radio"/> YES <input type="radio"/> NO	
Please specify: (Maximum number of characters allowed: 1000)		

ETHICS SELF-ASSESSMENT

If you have entered any YES in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines "How to Complete your Ethics Self-Assessment" and complete the table below.

ETHICAL DIMENSION OF THE OBJECTIVES, METHODOLOGY AND LIKELY IMPACT

Explain in detail the identified issues 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, stigmatization of particular social groups, political or financial adverse consequences, misuse, etc.)

COMPLIANCE WITH ETHICAL PRINCIPLES AND RELEVANT LEGISLATIONS

Describe how the issue(s) identified in the ethics issues table will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for activities performed in a non-EU country, they should also be allowed in at least one EU Member State.