

Part B3 - Ethics Issues Table

Ethics & security

Ethics Issues Table

1. Human Embryonic Stem Cells and Human Embryos		
Does this activity involve Human Embryonic Stem Cells (hESCs)?	☐ Yes	☐ No
Does this activity involve the use of human embryos?	☐ Yes	☐ No
2. Humans		
Does this activity involve human participants?	☐ Yes	☐ No
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	☐ Yes	☐ No
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)	☐ Yes	☐ No
3. Human Cells / Tissues (not covered by section 1)		
Does this activity involve the use of human cells or tissues?	☐ Yes	☐ No
4. Personal Data		
Does this activity involve processing of personal data?	☐ Yes	☐ No
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	☐ Yes	☐ No
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved	☐ Yes	☐ No
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? Specify the type of personal data and countries involved	☐ Yes	☐ No
Does this activity involve the processing of personal data related to criminal convictions or offences?	☐ Yes	☐ No
5. Animals		
Does this activity involve animals?	☐ Yes	☐ No
6. Non-EU Countries		
Will some of the activities be carried out in non-EU countries?	☐ Yes	☐ No
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?	☐ Yes	☐ No
It is planned to use local resources (e.g. animal and/or human tissue samples, genetic material,	☐ Yes	☐ No

live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?		
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? For data imports, see section 4	☐ Yes	☐ No
Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4.	☐ Yes	☐ No
Does this activity involve low and/or lower middle income countries , (if yes, detail the benefit sharing actions planned in the self-assessment)	☐ Yes	☐ No
Could the situation in the country put the individuals taking part in the activity at risk?	☐ Yes	☐ No
7. Environment, Health and Safety		
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
Does this activity deal with endangered fauna and/or flora / protected areas?	☐ Yes	☐ No
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
8. Artificial Intelligence		
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).	☐ Yes	☐ No
9. Other Ethics Issues		
Are there any other ethics issues that should be taken into consideration?	☐ Yes	☐ No

I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment as described in the guidelines [How to Complete your Ethics Self-Assessment](#).

Ethics Self-Assessment

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, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)

(max 5000 characters)

Compliance with ethical principles and relevant legislations

Describe how the issue(s) identified in the ethics issues table above 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.

(max 5000 characters)

Security issues table

1. EU Classified Information (EUCI) ¹		
Does this activity involve information and/or materials requiring protection against unauthorised disclosure (EUCI)?	☐ Yes	☐ No
Does this activity involve non-EU countries which need to have access to EUCI?	☐ Yes	☐ No
2. Misuse		
Does this activity have the potential for misuse of results?	☐ Yes	☐ No
3. Other Security Issues		

¹ According to the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information, "European Union classified information (EUCI) means any information or material designated by an EU security classification, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union or of one or more of the Member States".

Classified background information is information that is already classified by a country and/or international organisation and/or the EU and is going to be used by the project. In this case, the project must have in advance the authorisation from the originator of the classified information, which is the entity (EU institution, EU Member State, third state or international organisation) under whose authority the classified information has been generated.

EU classified foreground information is information (documents/deliverables/materials) planned to be generated by the project and that needs to be protected from unauthorised disclosure. The originator of the EUCI generated by the project is the European Commission.

Does this activity involve information and/or materials subject to national security restrictions? If yes, please specify: (Maximum number of characters allowed: 1000)	☐ Yes	☐ No
Are there any other security issues that should be taken into consideration? If yes, please specify: (Maximum number of characters allowed: 1000)		

Security self-assessment

Please specify: (Maximum number of characters allowed: 5000)
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