

INNOCHEMBIO

Ethics self-assessment

The following form is based on the standard EU's Ethics issue table.

Please go through the table below and indicate which elements concern your proposal by answering Yes or No. If you answer Yes to any of the questions, provide additional information on that/those ethics issue(s) in the Ethics Self-Assessment section (2 tables at the end of the document, if possible, please section these by their corresponding topic number: 1-9). This is your initial assessment of the situation based on your understanding and your vision for the project. It is important for us that you have considered ethics aspects of the possible project and there might be a question regarding ethics issues during the interview.

If you are unfamiliar with these topics: 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](#)'. Please bear in mind: you do not need to describe a full ethics plan for the project (this will be done if you are selected with the help of your supervisors), just your initial assessment. **Please mark you answer with X.**

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

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.)?

☐ Yes ☐ No

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

Ethics Self-Assessment

If you have entered any issues 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 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 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 the activities performed in a non-EU country, they should also be allowed in at least one EU Member State.