**ANEXO II. ASPECTOS ÉTICOS**

4 - Ethics & security

Ethics Issues Table

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| 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](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536) [(EU 536/2014)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536> | [ ]  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, 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?  | [ ]  Yes [ ]  No |
| Does this activity involve [low and/or lower middle income countries,](https://datahelpdesk.worldbank.org/knowledgebase/articles/906519) (if yes, detail the benefit sharing actions planned in the self-assessment)<https://datahelpdesk.worldbank.org/knowledgebase/articles/906519> | [ ]  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](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf)

<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf>