**ANEXO V FORMULARIO DE ASPECTOS ÉTICOS**

# Ethical Issue Form

|  |  |
| --- | --- |
| Name and Surname |  |
| Email |  |
| Title of the project |  |

Please complete the Ethical Issue Table below, even if you believe that there are no ethical issues. Consider that ethical issues arise in many research areas. Apart from the obvious, the medical field, research protocols, e.g. in social sciences, might involve the voluntary participation of research subjects and the collection of data that might be considered as personal. You must protect your volunteers and also protect yourself (and your researcher colleagues). IMPORTANT: All ethical issues raised by a proposed project (ticked Yes-boxes) must be described in the second section, the ethics self-assessment. You should explain how the raised ethical issues will be addressed, so as to conform with national and HORIZON 2020 ethical principles.

Detailed information is provided in the EU grants guideline “How to complete your ethics Self-Assessment”: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment\_en.pdf

# Ethical Issue Table

Please fill in the ethical issue table by ticking either the *Yes*-box or the *No*-box for each question. Please note that if you answer *Yes* to any of the questions below, you are requested to provide additional information.

|  |  |  |
| --- | --- | --- |
|  | YES | NO |
| 1. Human Embryonic Stem Cells and Human Embryos |
| Does this activity involve Human Embryonic Stem Cells (hESCs)? |   [ ]  |   [ ]  |
| Does this activity involve the use of human embryos? |  [ ]  |  [ ]  |
| 2. Humans |
| Does this activity involve human participants?  |   [ ]  |   [ ]  |
| Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants? |  [ ]  |  [ ]  |
| 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) |  [ ]  |  [ ]  |
| 3. Human Cells / Tissues (not covered by section 1) |
| Does this activity involve the use of human cells or tissues? |   [ ]  |   [ ]  |
| 4. Personal Data |
| Does this activity involve processing of personal data? |   [ ]  |   [ ]  |
| Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)? |  [ ]  |  [ ]  |
| Is it planned to export personal data from the EU to non-EU countries? |  [ ]  |  [ ]  |
| 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? |   [ ]  |   [ ]  |
| Does this activity involve the processing of personal data related to criminal convictions or offences? |   [ ]  |   [ ]  |
| 5. Animals |
| Does this activity involve animals? |   [ ]  |   [ ]  |
| 6. Non-EU Countries |
| Will some of the activities be carried out in non-EU countries? |   [ ]  |   [ ]  |
| In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? |   [ ]  |   [ ]  |
| 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.)? |   [ ]  |   [ ]  |
| 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? |   [ ]  |   [ ]  |
| Does this activity involve low and/or lower middle income countries, (if yes, detail the benefitsharing actions planned in the self-assessment) |   [ ]  |   [ ]  |
| Could the situation in the country put the individuals taking part in the activity at risk? |   [ ]  |   [ ]  |
| 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) ? |   [ ]  |   [ ]  |
| Does this activity deal with endangered fauna and/or flora / protected areas? |   [ ]  |   [ ]  |
| 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) ? |   [ ]  |   [ ]  |
| 8. Artificial Intelligence |
| Does this activity involve the development, deployment and/or use of Artificial Intelligence based systems? |   [ ]  |   [ ]  |
| 9. Other Ethics Issues |
| Are there any other ethics issues that should be taken into consideration? |   [ ]  |   [ ]  |

# Ethics Self-Assessment

If your answer was *Yes* to one or more questions in the Ethical Issue Table (above), you **must** elaborate how you plan to cope with this/these issue(s). Please note down in the following field atfirst the **number of the question(s)** you ticked in the Ethical Issue Table and then provide **information on how you address the mentioned ethical issue**. In addition, you can (if applicable)refer to the corresponding page of your research proposal.

(describe ethical issues)