ETHICS & SECURITY ASSESSMENT

***[Each sub-project must jointly fulfil and sign this document.]***

This Ethics Assessment consists of three tables: **A) Ehtics Issues Table, B) Ethics Self-Assessment and C). Security Issues Table**. All tables must be fullfilled and the document must be signed by all participating companies in the sub-project in to be considered eligible. The assessment will be screened by an independent Ethics Advisory Panel. Note that in the case of uncertainty or in the need for clarification, follow-up questions may be asked. It is the sub-projects responsiblity to be available and to answer questions to the best of their ability.

If you require more input on how to interpret and to complete this assessment, we kindly refer to the EU guide: [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)

# A) ETHICS ISSUES TABLE

|  |  |  |  |
| --- | --- | --- | --- |
| 1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS | | | |
| *Mark you answer with X* | **YES** | **NO** | **Comment** |
| Does this activity involve Human Embryonic Stem Cells (hESCs)? |  |  |  |
| Does this activity involve the use of human embryos? |  |  |  |
| 1. 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](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536) (EU 536/2014)? (using pharmaceuticals, biologicals, medtech, health tech/ICT, radiopharmaceuticals, or advanced therapy medicinal products) |  |  |  |
| 1. HUMAN CELLS/TISSUES (not covered by section 1) | | | |
| Does this activity involve the use of human cells or tissues? |  |  |  |
| 1. PERSONAL DATA | | | |
| Does this activity involve processing of personal data? |  |  |  |
| Does it involve the processing of special categories of personal data (e.g.: genetic, biometric and health data, sexual lifestyle, ethnicity, political opinion, religious or philosophical beliefs)? |  |  |  |
| Does it involve processing of genetic, biometric or health data? |  |  |  |
| 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.)? |  |  |  |
| 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? Specify the type of personal data and countries involved |  |  |  |
| 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 |  |  |  |
| Does this activity involve the processing of personal data related to criminal convictions or offences? |  |  |  |
| 1. ANIMALS | | | |
| Does this activity involve animals? |  |  |  |
| 1. 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? For data imports, see section 4. |  |  |  |
| Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4. |  |  |  |
| 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 section 10). |  |  |  |
| Could the situation in the country put the individuals taking part in the activity at risk? |  |  |  |
| 1. 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) ? |  |  |  |
| 1. 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). |  |  |  |
| 1. OTHER ETHICS ISSUES | | | |
| Are there any other ethics issues that should be taken into consideration? If yes, describe in the self-assessment. |  |  |  |

# B) ETHICS SELF-ASSESSMENT

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| Please describe the ethical dimension of the objectives, methodology and likely impact for the planned sub-project activities and products/services. |
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| Please describe the compliance with ethical principles and relevant legislations for the planned sub-project activities and products/services. |
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C) SECURITY ISSUES TABLE

|  |  |  |  |
| --- | --- | --- | --- |
| 1. EU CLASSIFIED INFORMATION (EUCI)[[1]](#footnote-2) | | | |
| Does this activity involve information and/or materials requiring protection against unauthorized disclosure (EUCI)? |  |  |  | |
| Does this activity involve non-EU countries? |  |  |  | |
| 1. MISUSE | | | | |
| Does this activity have the potential for misuse of results? |  |  |  | |
| 1. OTHER SECURITY ISSUES | | | | |
| Does this activity involve information and/or materials subject to national security restrictions? If yes, please specify below in comments section. (Maximum number of characters allowed: 1000) |  |  |  | |
| Are there any other security issues that should be taken into consideration? If yes, please specify below in comments section: (Maximum number of characters allowed: 1000) |  |  |  | |
| COMMENTS | | | | |
|  | | | | |

It is hereby confirmed that all ethics issues above have been taken into account and that, if any ethics issues apply, necessary precautions and actions are taken.

**Note that the sub-project may be subject to rejection from this procedure if any of the declarations or information provided as a condition for participating in this procedure prove to be false.**

**COMPANY X**

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| **Full name of signatory** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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**COMPANY Y**

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| **Full name of signatory** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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**COMPANY Z**

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| **Full name of signatory** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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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”. [↑](#footnote-ref-2)