AuSpire Program – Ethics self-assessment form

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| Instructions  Applicants must submit an ethics self-assessment for each position applied to, along with the proposed research challenge.  The ethics form below is adapted from the guidelines provided by the European Commission. For further information on how to complete this form, please refer to <https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf>  Read carefully the questions in the table below and mark ‘Yes’ or ‘No’ in the columns on the right. If you have answered ‘Yes’, provide additional information in the appropriate box.  Please submit the final version of the document in **PDF format.** Please ensure you have deleted the guidance notes and this table of instructions before submission. |

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| **Applicant name** |  |
| **Position reference** |  |
| **Project proposed title** |  |

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| **1. Human Embryonic Stem Cells and Human Embryos** | **Yes** | **No** |
| Does this activity involve Human Embryonic Stem Cells (hESCs)? | ¨ | ¨ |
| Does this activity involve the use of human embryos? | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered 'Yes']* | | |
| **2. Humans** | **Yes** | **No** |
| 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](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536))? (Using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products.) | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered 'Yes']* | | |
| **3. Human Cells/Tissues (not covered by Section 1)** | **Yes** | **No** |
| Does this activity involve the use of human cells or tissues? | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered 'Yes']* | | |
| **4. Personal Data** | **Yes** | **No** |
| Does this activity involve processing of personal data? | ¨ | ¨ |
| Does this activity involve further processing of previously collected personal data (including use of pre-existing datasets or sources, merging existing datasets)? | ¨ | ¨ |
| 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? | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered 'Yes']* | | |
| **5. Animals** | **Yes** | **No** |
| Does this activity involve animals? | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered 'Yes']* | | |
| **6. Non-EU Countries** | **Yes** | **No** |
| Will some of the activities be carried out in non-EU countries? | ¨ | ¨ |
| 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.) | ¨ | ¨ |
| Could the situation in the country put the individuals taking part in the activity at risk? | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered 'Yes']* | | |
| **7. Environment, Health and Safety** | **Yes** | **No** |
| 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.) | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered 'Yes']* | | |
| **8. Artificial Intelligence** | **Yes** | **No** |
| Does this activity involve the development, deployment and/or use of Artificial Intelligence? (If yes, detail in the self-assessment whether this could raise ethical concerns related to human rights and values and detail how this will be addressed.) | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered 'Yes’]* | | |
| **9. Other Ethics Issues** | **Yes** | **No** |
| Are there any other ethics issues that should be taken into consideration? | ¨ | ¨ |
| *[Please provide here additional information on the questions you have answered ‘Yes’]* | | |