**ComFuturo iAGE (IV Edition) Call**

**Ethics Self-Assessment Form**

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| **1\_HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS** | **YES/NO** |
| **Does your activity involve Human Embryonic Stem Cells (hESCs)?** |  |  |
| If**YES:** | Will they be directly derived from embryos within this project? |  |  |
| Are they previously established cells lines?Are the cell lines registered in the European registry for human embryonic stem cell lines? |  |  |
| **Does your activity involve the use of human embryos?** |  |  |
| If**YES:** | Will the activity lead to their destruction? |  |  |
| **Does your activity involve the use of other human embryonic or foetal tissues / cells?** |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **2\_HUMANS** | **YES/NO** |
| **Does your activity involve human participants?** |  |  |
| If**YES:** | Are they volunteers? |  |  |
| Are they healthy volunteers for medical studies? |  |  |
| Are they patients for medical studies? |  |  |
| Are they potentially vulnerable individuals or groups? |  |  |
| Are they children/minors? |  |  |
| Are there other persons unable to give informed consent? |  |  |
| **Does your activity involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?** |  |  |
| If**YES:** | Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)? |  |  |
| Does it involve collection of biological samples? |  |  |
| **Does your activity involve conducting a clinical study as defined by the Clinical Trial Regulation 536/2014 (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)?** |  |  |
| If**YES:** | Is it a clinical trial? |  |  |
| Is it a low-intervention clinical trial? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **3\_HUMAN CELLS / TISSUES** | **YES/NO** |
| **Does your activity involve the use of human cells or tissues?** |  |  |
| If**YES:** | Are they human embryonic or foetal cells or tissues? |  |  |
| Are they available commercially? |  |  |
| Are they obtained within this project? |  |  |
| Are they obtained from another project, laboratory or institution? |  |  |
| Are they obtained from a biobank? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **4\_PROTECTION OF PERSONAL DATA** | **YES/NO** |
| **Does your activity involve processing of personal data?** |  |  |
| If**YES:** | Does it involve the processing of special categories of personal data (e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)? |  |  |
| If**YES:** | 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 your activity involve further processing of previously collected personal data** (including use of pre-existing data sets or sources, merging existing data sets**)?** |  |  |
| **Is it planned to export personal data (data transfer) from the EU to non-EU countries?***Specify the type of personal data and countries involved:* |  |  |
|  |
| **Is it planned to import personal data (data transfer) 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 your activity involve the processing of personal data related to criminal convictions or offences?** |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **5\_ANIMALS** | **YES/NO** |
| **Does your activity involve animals?** |  |  |
| If**YES:** | Are they vertebrates? |  |  |
| Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)? |  |  |
| Are they genetically modified? |  |  |
| Are they cloned farm animals? |  |  |
| Are they an endangered species? |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **6\_THIRD COUNTRIES** | **YES/NO** |
| **Will some of the activities be carried out in non-EU countries?***Specify the countries:* |  |  |
|  |
| **In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?***Specify the countries:* |  |  |
|  |
|  **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 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 imports, see section 4** |  |  |
|  **Does this activity involve low and/or lower middle income countries** |  |  |
|  **Could the situation in the country put the individuals taking part in the activity at risk?** |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **7\_ENVIRONMENT, HEALTH AND SAFETY** | **YES/NO** |
| **Does this activity involve the use of substances or processes (or technologies) 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 (or technologies) 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, or the deployment of the technology as a possible impact**)?** |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **8\_ARTIFICIAL INTELLIGENCE** | **YES/NO** |
| **Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?** |  |  |
| **Could the AI based system/technique potentially stigmatise or discriminate against people (**e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority**)?** |  |  |
| **Does the AI system/technique interact, replace or influence human decision-making processes (**e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions**)?** |  |  |
| **Does the AI system/technique have the potential to lead to negative social (**e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance**) and/or environmental impacts either through intended applications or plausible alternative uses?** |  |  |
| **Does this activity involve the use of AI in a weapon system?** |  |  |
| If**YES:** | Is it possible to establish which specific function/functions are automated/autonomous in the weapon system? |  |  |
| If the weapon system has AI-enabled functions, could these functions render the weapon system indiscriminate? |  |  |
| Does the design include the possibility of an autonomous mode for self- protection? If yes, can the system reliably distinguish between targets (threats) and non-targets? |  |  |
| If**YES:** | Can the system reliably distinguish between targets (threats) and non-targets? |  |  |
| **Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above (**e.g., subliminal, covert or deceptive AI, AI that is used to stimulate addictive behaviours, life- like humanoid robots, etc.**)?** |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **9\_OTHER ETHICS ISSUES** | **YES/NO** |
| **Are there any other ethics issues that should be taken into consideration?***Please specify:* |  |  |
|  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **10\_CROSSCUTTING ISSUE: POTENTIAL MISUSE OF RESULTS** |  |
| **Does your research have activities that involve or generate materials, methods, technologies or knowledge that could be misused for unethical purposes?** |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **11\_DUAL USE** | **YES/NO** |
| **Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?** |  |  |
| I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |
| **12\_EXCLUSIVE FOCUS ON CIVIL APPLICATIONS** | **YES/NO** |
| **Could your research raise concerns regarding the exclusive focus on civil applications?** |  |  |
| I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL |  |  |