***Ethics Statement***

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| **1. HUMAN EMBRYOS/FOETUSES** | **YES** | **NO** | **If YES - Information to**  **be provided in the proposal** | **If YES – Useful documents to**  **be provided** |
| **Does your research involve Human Embryonic Stem Cells (hESCs)?**  *P.N.*  *If they will be directly derived from embryos within this project, the activity will not be eligible for funding.*  *\* Six conditions*   1. cells were NOT derived from embryos specially created for research or by somatic cell nuclear transfer; 2. the project uses existing cultured cell lines only; 3. cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilization; 4. informed consent has been obtained for using donated embryos for the derivation of the cell lines; 5. personal data and privacy of donors of embryos for the derivation of the cells are protected according to the data protection rules applicable for the donors and in the EU; 6. NO financial inducements were provided for the donation of embryos used for derivation of the cell lines. |  |  | **If they are previously established cells lines**   * Origin and line of cells * Details on licensing and control measures by the competent authorities of the Member States involved * Declaration confirming that the 6 specific conditions **\*** for activities involving human embryonic stem cells are met   **If they are the cell lines registered in the European registry for human embryonic stem cell lines**  Same information as above | **If they are previously established cells lines**   * Copies of ethics approval * Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry ([www.hpscreg.eu](http://www.hpscreg.eu))   **If they are the cell lines registered in the European registry for human embryonic stem cell lines**  Same documents as above |
| **Does your research involve the use of human embryos?**  *P.N.*  *If the activity will lead to their destruction, the activity will not be eligible for funding.* |  |  | * Origin of embryos * Details of the recruitment, inclusion and exclusion criteria   and informed consent procedures   * Confirmation that informed consent has been obtained | * Copies of ethics approval * Informed consent forms and information sheets |

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| **2. HUMANS** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Does your research involve human participants?**  **\***P.N.  If children/minors are involved:   * Details on assent procedures and parental consent for children and other minors   If other persons unable to give informed consent are involved:   * Details on the procedures for obtaining consent from the guardian/legal representative * Procedures to ensure participants are not subject to any form of coercion and undue inducement |  |  | * Details on recruitment, inclusion and exclusion criteria, informed consent procedures **\*** plus:   **If they are volunteers**   * Details on unexpected findings policy   **If they are healthy volunteers for medical studies**   * Details on incidental findings policy   **If they are patients for medical studies**   * Details on the disease/condition/disability * Details on incidental findings policy   **If they are potentially vulnerable individuals or groups**   * Details on the type of vulnerability * Procedures to ensure participants are not subject to any form of coercion and undue inducement   **If they are children/minors**   * Details on the age range * Procedures to ensure the welfare of the child or other minors * Justification for involving children/minors | * Copies of ethics approvals * Informed consent forms and information sheets |
| **Does your research involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?** |  |  | **If it involves invasive techniques:**   * Risk assessment for each technique and overall   **If it involves collection of**  **biological samples:**   * Details on the type of samples to be collected * Procedure for the collection of biological samples | **If it involves invasive techniques:**   * Copies of ethics approvals |
| **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 so, is it a clinical trial or low-intervention clinical trial?** |  |  | * Details on the medical products that are being used and risk assessment * Details on the disease/condition /disability of the participants * Details of the recruitment, inclusion and exclusion criteria and informed consent procedures * Details on the incidental findings policy | * Registration in the EU database (when applicable) * Copy of authorisation/ethics approval to conduct clinical trial * Copy of the insurance and liability details |

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| **3. HUMAN CELLS / TISSUES** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Does your activity involve the use of human cells or tissues (other than those covered by section 1)?** |  |  | **If they are human embryonic or foetal cells or tissues:**   * Origin of human foetal tissues/cells * Details on informed consent procedures * Confirmation that the informed consent has been obtained * If applicable, details on the induced human pluripotent cell lines   **If they are available commercially:**   * Details on cell types and provider (company or other)   **If they are obtained within this project:**   * Details on cell types including the source of the material, the amount to be collected and the procedure for collection * Details on the duration of storage and what will be done with the material at the end of the activity * Confirmation that informed consent has been obtained   **If they are obtained from another project, laboratory or institution:**   * Details on cell types * Country where the material is stored * Details of the legislation under which material is stored * Details on the duration of storage and what will you do with it at the end of the project? * Name of the laboratory/institution. * Country where the laboratory/institution is located * Confirm that material is fully anonymised or that consent for secondary use has been obtained   **If they are obtained from a biobank:**   * Details on cell types * Details on the biobank * Details of the legislation under which material is stored * Confirmation that material is fully anonymised or that consent for secondary use has been obtained | **If they are human embryonic or foetal cells or tissues:**   * Copies of ethics approvals * Informed consent forms and information Sheet * If applicable, registration certificates of the cell lines and project from the hPSCre   **If they are available commercially:**   * Copies of import licences (if relevant)   **If they are obtained within this project:**   * Copies of ethics approvals (if relevant) * Informed consent forms and information sheets   **If they are obtained from another project, laboratory or institution:**   * Authorisation by primary owner of cells/tissues (including references to ethics approvals) * Copies of import licences (if relevant) * Statement from the primary laboratory/institution that informed consent has been obtained   **If they are obtained from a biobank:**   * Copies of import licences (if relevant) * Statement of biobank that informed consent has been obtained |

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| **4. PERSONAL DATA** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Does your research involve personal data collection and/or processing (inc. secondary use)?** |  |  | **If your activity involves processing of personal data**   * Details of the technical and organisational measures to safeguard the rights and freedoms of the participants/data subjects. These may include:   - Project specific data  - protection policy and/or the contact details of the data protection officer (these must be provided to the participants)  - The security measures to prevent unauthorised access to personal data  - Anonymisation/ pseudonymisation techniques   * Details of the informed consent procedures with regard to the data processing (if relevant) * Explanation as to how all of the processed data is relevant and limited to the purposes of the project (‘data minimisation’ principle) * Justification of why personal data will not be anonymised/ pseudonymised (if relevant) * Details of the data transfers (type of data transferred and country to which data are transferred)   **If it involves the processing of special categories of personal data (e.g. sexual lifestyle, ethnicity etc.):**   * Justification for the processing of special categories of personal data (if relevant) * Justification to why the project objectives cannot be reached by processing anonymised/pseudonymised data (if applicable)   **If it involves 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.)**   * Details of the methods used for tracking, surveillance or observation of participants * Details of the methods used for profiling * Assessment of the ethics risks related to the data processing operations * Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded and harm will be prevented * Explanation as to how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded   **If your activity involves further processing of previously collected**  **personal data (secondary use):**   * Details of the database used or of the source of the data * Details of the data processing operations * Explanation as to how the rights of the participants/data subjects will be safeguarded. * Explanation as to how all of the processed data is relevant and limited to the purposes of the project (‘data minimisation’ principle) * Justification of why the data will not be anonymised/ pseudonymised (if relevant) | **If your activity involves processing of personal data**   * Informed consent forms and information Sheets (if relevant) * Data management plan (if relevant) * Data protection impact assessment (if relevant)   **If it involves processing of genetic, biometric or health data:**   * Declaration confirming compliance with the laws of the country where the data were collected   **If it involves 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.)**   * Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR. (if relevant)   **If your activity involves further processing of previously collected**  **personal data (secondary use):**   * Confirmation that the data controller has a lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects * Permission by the owner/manager of the data sets (e.g. social media databases) (if applicable) * Informed Consent Forms + Information Sheets + other consent documents (if applicable) |
| **Are data transfer activities planned (export from the EU to non-EU countries / import from non-EU countries into the EU or from a non-EU country to another non-EU country)?** |  |  | **If it is planned to export personal data from the EU to non-EU countries**   * Details of the types of personal data and countries involved * Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded   **If it is planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country**   * Details of the types of personal data and countries involved | **If it is planned to export personal data from the EU to non-EU countries**   * Confirmation that data transfers will be made in accordance with Chapter V of the General Data Protection Regulation 2016/679   **If it is planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country**   * Confirmation of compliance with the laws of the country in which the data was collected |
| **Does your activity involve the processing of personal data related to criminal convictions or offences?** |  |  | * Details on the personal data to be processed and the legal basis for the processing * Risk assessment for the data processing operations * Explanation as to how harm will be prevented and the rights of the participants/data subjects will be safeguarded | * Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR (if relevant) |

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| **5. SECURITY ISSUES** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Does the proposed research involve EUCI classified at the following level?**   * **TOP SECRET** * **SECRET** * **CONFIDENTIAL** * **RESTRICTED** |  |  | Details about the application of protective measures, techniques and materials designed to prevent or mitigate the risks of unauthorised access to EUCI |  |

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| **6. ARTIFICIAL INTELLIGENCE** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?** |  |  | * Explanation as to how the participants and/or end-users will be informed about:   + their interaction with an AI system/technology (if relevant);   + the abilities, limitations, risks and benefits of the proposed AI system/technique;   + the manner in which decisions are taken and the logic behind them (if relevant) * Details on the measures taken to   avoid bias in input data and algorithm design   * Explanation as to how the respect to fundamental human rights and freedoms (e.g. human autonomy, privacy and data protection) will be ensured * Detailed explanation on the potential ethics risks and the risk mitigation measures |  |
| **Could the AI based system/technique potentially stigmatise or discriminate against people (e.g. based on sex, race,**  **ethnic or social origin, age etc.)?** |  |  | * Detailed explanation of the measures set in place to avoid potential bias, discrimination and stigmatisation |  |
| **Does the AI system/technique interact, replace or influence human decision-making processes (e.g. issues affecting human life, health, well-being etc.)?** |  |  | * 1) Detailed explanation on how humans will maintain meaningful control over the most important aspects of the decision-making process * Explanation on how the presence/role of the AI will be made clear and explicit to the affected individuals | * Information sheets/Template Informed consent forms (if relevant) |
| **Does the AI system/technique have the potential to lead to negative social (e.g. on democracy, media, labour market, freedoms, educational choices etc.)?** |  |  | * Justification of the need for developing/using this particular technology * Assessment of the ethics risks and detailed description of the measures set in place to mitigate the potential negative impacts during the research, development, deployment and post-deployment phase | * For serious and/or complex cases: Algorithmic impact assessment/human right assessment. These must cover the development, deployment and post-deployment phases |
| **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 etc.)?** |  |  | * Detailed explanation on how the potential ethics issues will be addressed and the measures set in place to mitigate ethics risks | * Detailed risk assessment accompanied by a risk mitigation plan. These must cover the development, deployment and postdeployment phases |

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| **7. ANIMALS** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Does your research involve animals?** |  |  | * Details on the numbers of animals to be used, nature of the experiments, procedures and techniques to be used * Details on species and rationale for their use * Details on procedures to ensure animal welfare * Details on implementation of the 3Rs Principle   **If they are genetically modified**   * Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised * Details on species and rationale for their use * Details on procedures to ensureanimal welfare * Details on implementation of the 3Rs Principle   **If they are non-human primates (NHP) (e.g. monkeys, chimpanzees etc.)**  Same information as above plus:   * Justification on why NHPs are the only subjects suitable for achieving your scientific objectives * Details on the purpose of the animal testing * Details on the origin of the animals   **If they are cloned farm animals**  Same information as above  **If they are an endangered species**   * Justification on why there is no alternative to using this species * Details on the purpose of the activity | * Copies of all appropriate authorisations for the supply of animals and the project experiments * Copies of training certificates/ personal licences of the staff involved in animal experiments   **If they are genetically modified**  Same documents as above  **If they are non-human primates (NHP) (e.g. monkeys, chimpanzees etc.)**  Same documents as above plus:   * Personal history file of NHP (See art 31 of Directive 2010/63)   **If they are cloned farm animals**   * Copies of all appropriate authorisations for the supply of animals and the project experiments * Copies of training certificates/ personal licences of the staff involved in animal experiments * Copies of authorisations for cloning (if required)   **If they are an endangered species**   * Copies of authorisations for supply of endangered animal species (including CITES) and the project experiments * Copies of training certificates/ personal licences of the staff involved in animal experiments |

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| **8. THIRD COUNTRIES** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?** |  |  | * Countries involved * Risk-benefit analysis * Details on activities are carried out in non-EU countries * Details on the materials and the countries involved | * Copies of ethics approvals and other authorisations or notifications (if required) * Confirmation that the activity could have been legally carried out in an EU country (for instance, an opinion from an appropriate ethics structure in an EU country) |
| **Do you plan 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.)?** |  |  | * Details on the type of local resources to be used and modalities for their use | * For human resources: copies of ethics approvals * For animals, plants, micro-organisms and associated traditional knowledge: documentation showing compliance with the UN Convention on Biological Diversity (e.g. access permit and benefit sharing agreement) |
| **Do you plan to import any material - other than data - from non-EU countries into the EU? (n/a for EDF)** |  |  | * Countries involved * Details on the type of materials to be imported | * Copies of import licences/Material Transfer Agreement (MTA) |
| **Do you plan to export any material - other than data - from the EU to non-EU countries? (n/a for EDF)** |  |  | * Countries involved * Details on the type of materials to be exported | * Copies of export licences/ Material Transfer Agreement (MTA) |
| **Could the situation in the country put the individuals taking part in the research at risk?** |  |  | * Details of the safety measures you intend to take, including training for staff and insurance cover | * Insurance coverage (if relevant) |
| **In case your research involves low and/or lower middle-income countries, are any benefits sharing actions planned?** |  |  | * Details on the benefit sharing measures * Details on the responsiveness to local needs * Details on the procedures to facilitate effective capacity building |  |

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| **9. ENVIRONMENT & HEALTH and SAFETY** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Does your research involve the use of substances or processes (or technologies) that may cause harm to the environment, to animals or plants?** |  |  | * Risk-benefit analysis * Show how you apply the precautionary principle (if relevant) * Details on safety measures to be implemented | * Safety classification of laboratory. * Copy of GMO and other authorisations (if required) |
| **Does your research deal with endangered fauna and/or flora and/or protected areas?** |  |  | * Details on endangered fauna and/or flora/protected areas | * Specific authorisations (if required) |
| **Does your research involve the use of substances or processes (or technologies) that may cause harm to humans, including those performing the activity?** |  |  | * Details of the health and safety procedures | * Safety classification of laboratory * Host Institution safety procedures |

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| **10. MISUSE** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Could the materials/methods/technologies and knowledge involved or generated harm humans, animals or the environment?** |  |  | * Details on additional safety measures | * Risk-assessment to prevent misuse * Copies of health and safety authorisations, and ethics approvals if relevant |
| **Does your research involve dual-use items, or other items for which an authorisation is required?** |  |  | * Details on dual-use items | * Copies of safety authorisations |
| **Could your research raise concerns regarding the exclusive focus on civil applications?** |  |  | * Any relevant information (e.g. direct military use, potential for terrorist abuse etc.) | * Any relevant document |
| **Could the materials/methods/technologies and knowledge involved or generated serve purposes other than those intended? If so, would such use be unethical?** |  |  | * Any relevant information (e.g. development of technologies that could curtail human rights and civil liberties, involvement of minority or vulnerable groups etc.) | * Any relevant document |

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| **11. OTHER ETHICS ISSUES** | **YES** | **NO** | **If YES - Information to**  **be provided** | **If YES - Documents to**  **be provided** |
| **Are there any other ethics issues that should be taken into consideration?** |  |  | * Any relevant information | * Any relevant document |

Date

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