***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)
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| **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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