Annex 5

Ethics Statement

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) **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?			• Origin of embryos	• Copies of ethics approval

P.N. *If the activity will lead to their destruction, the activity will not be eligible for funding.*			• Details of the recruitment, inclusion and exclusion criteria and informed consent procedures • Confirmation that informed consent has been obtained	• Informed consent forms and information sheets

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	• Copies of ethics approvals • Informed consent forms and information sheets

			• 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	
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)?			**<u>If they are human embryonic or foetal cells or tissues:</u>** • 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 **<u>If they are available commercially:</u>** • Details on cell types and provider (company or other) **<u>If they are obtained within this project:</u>** • 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 **<u>If they are obtained from another project, laboratory or institution:</u>**	**<u>If they are human embryonic or foetal cells or tissues:</u>** • Copies of ethics approvals • Informed consent forms and information Sheet • If applicable, registration certificates of the cell lines and project from the hPSCre **<u>If they are available commercially:</u>** • Copies of import licences (if relevant) **<u>If they are obtained within this project:</u>** • Copies of ethics approvals (if relevant) • Informed consent forms and information sheets

			• 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 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

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**	**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)	• Informed consent forms and information Sheets (if relevant) • Data management plan (if relevant) • Data protection impact assessment (if relevant)

			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	**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)

			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 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**	**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 **<u>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</u>** • Details of the types of personal data and countries involved	• Confirmation that data transfers will be made in accordance with Chapter V of the General Data Protection Regulation 2016/679 **<u>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</u>** • 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)

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	

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 ensure animal 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	• 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)

			• Details on the origin of the animals **<u>If they are cloned farm animals</u>** Same information as above **<u>If they are an endangered species</u>** • Justification on why there is no alternative to using this species • Details on the purpose of the activity	**<u>If they are cloned farm animals</u>** • 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) **<u>If they are an endangered species</u>** • 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

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)

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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

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

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

Holographic or digital signature