Co-funded by the European Union

This project is co-funded by the European Union as part of the Horizon Europe programme, Marie Sklodowska-Curie Actions call COFUND 2023 and under the Grant Agreement N°101179124.

Ethics & Security:

Please go through the table and indicate which elements are relevant to your proposal by answering Yes or No. For more information on each of the ethics issues and how to address them, including detailed legal references, please consult the guidelines 'How to Complete your Ethics Self-Assessment'.

Title of the thesis project:	
La Rochelle University Research Unit:	**Partner university:**
Name of the LRUniv supervisor:	**Name of the co-supervisor:**

1. Human Embryonic Stem Cells and Human Embryos	**Yes/No**
Does your activity involve Human Embryonic Stem Cells (hESCs)?	
Does your activity involve the use of human embryos?	
Does your activity involve the use of other human embryonic or foetal tissues / cells?	

2. Humans		**Yes/No**	**Information to be provided in the proposal**	**Documents to be kept on file and provided on request**
Does your activity involve human participants?			Please provide information in one of the subcategories below.	
If **YES**:	Are they volunteers?		1) Details on recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on unexpected findings policy.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they healthy volunteers for medical studies?		1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on incidental findings policy.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.
	Are they patients for medical studies?		1) Details on the disease/condition /disability. 2) Details on the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Details on incidental findings policy.	1) Copies of ethics approvals. 2) Informed consent. forms and information sheets.
	Are they potentially vulnerable individuals or groups?		1) Details on the type of vulnerability. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Procedures to ensure participants are not subject to any form of coercion and undue inducement.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they children/minors?		1) Details on the age range. 2) Details on assent procedures and parental consent for children and other minors. 3) Procedures to ensure the welfare of the child or other minors. 4) Justification for involving children/minors.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are there other persons unable to give informed consent?		1) Details on the procedures for obtaining consent from the guardian/ legal representative. 2) Procedures to ensure participants are not subject to any form of coercion and undue inducement.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.

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.)*?		1) Risk assessment for each technique and overall.	1) Copies of ethics approvals.
	Does it involve collection of biological samples?		1) Details on the type of samples to be collected. 2) Procedure for the collection of biological samples.	1) 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 **YES**:	Is it a clinical trial?		1) Details on the medical products that are being used and risk assessment. 2) Details on the disease/condition /disability of the participants. 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 4) Details on the incidental findings policy.	1) Registration in the EU database (when applicable). 2) Copy of authorisation/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.
	Is it a low-intervention clinical trial?		1) Details on the medical products that are being used and risk assessment. 2) Details on the disease/condition /disability of the participants. 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 4) Details on the incidental findings policy.	1) Registration in the EU database (when applicable). 2) Copy of authorisation/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.

3. Human cells / tissues		**Yes/No**	**Information to be provided in the proposal**	**Documents to be kept on file and provided on request**
Does your activity involve the use of human cells or tissues *(other than those covered by section 1)***?**			Please provide information in one of the subcategories below.	
If **YES**:	Are they human embryonic or foetal cells or tissues?		1) Origin of human foetal tissues/cells. 2) Details on informed consent procedures. 3) Confirmation that the informed consent has been obtained. 4) If applicable, details on the induced human pluripotent cell lines.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets. 3) If applicable, registration certificates of the cell lines and project from the hPSCreg.
	Are they available commercially?		1) Details on cell types and provider (company or other).	1) Copies of import licences (if relevant).
	Are they obtained within this project?		1) Details on cell types including the source of the material, the amount to be collected and the procedure for collection.	1) Copies of ethics approvals (if relevant). 2) Informed consent forms and information sheets.

This project is co-funded by the European Union as part of the Horizon Europe programme,
Marie Sklodowska-Curie Actions call COFUND 2023 and under the Grant Agreement N°101179124.

			2) Details on the duration of storage and what will be done with the material at the end of the activity. 3) Confirmation that informed consent has been obtained.	
	Are they obtained from another project, laboratory or institution?		1) Details on cell types. 2) Country where the material is stored. 3) Details of the legislation under which material is stored. 4) Details on the duration of storage and what will you do with it at the end of the project? 5) Name of the laboratory/institution. 6) Country where the laboratory/institution is located. 7) Confirm that material is fully anonymised or that consent for secondary use has been obtained.	1) Authorisation by primary owner of cells/tissues (including references to ethics approvals). 2) Copies of import licences (if relevant). 3) Statement from the primary laboratory/institution that informed consent has been obtained.
	Are they obtained from a biobank?		1) Details on cell types. 2) Details on the biobank (name and country where it is located). 3) Details of the legislation under which material is stored. 4) Confirmation that material is fully anonymised or that consent for secondary use has been obtained.	1) Copies of import licences (if relevant). 2) Statement of biobank that informed consent has been obtained.

4. Personal Data		**Yes/No**	**Information to be provided in the proposal**	**Documents to be kept on file and provided on request**
Does your activity involve processing of personal data?			1) 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. 2) Details of the informed consent procedures with regard to the data processing (if relevant). 3) Explanation as to how all of the processed data is relevant and limited to the purposes of the project ('data minimisation' principle). 4) Justification of why personal data will not be anonymised/pseudonymised (if relevant). 5) Details of the data transfers (type of data transferred and country to which data are transferred).	1) Informed consent forms and information sheets (if relevant). 2) Data management plan (if relevant). 3) Data protection impact assessment (if relevant).
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,		1) Justification for the processing of special categories of personal data (if relevant). 2) Justification to why the project objectives cannot be reached by processing anonymised/ pseudonymised data (if applicable).	1) Declaration confirming compliance with the laws of the country where the data were collected.

This project is co-funded by the European Union as part of the Horizon Europe programme, Marie Sklodowska-Curie Actions call COFUND 2023 and under the Grant Agreement N°101179124.

	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.)*?		1) Details of the methods used for tracking, surveillance or observation of participants. 2) Details of the methods used for profiling. 3) Assessment of the ethics risks related to the data processing operations. 4) Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded and harm will be prevented. 5) 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.	1) Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR (if relevant).
Does your activity involve further processing of previously collected personal data *(including use of pre-existing data sets or sources, merging existing data sets)***?**			1) Details of the database used or of the source of the data. 2) Details of the data processing operations. 3) Explanation as to how the rights of the participants/data subjects will be safeguarded. 4) Explanation as to how all of the processed data is relevant and limited to the purposes of the project ('data minimisation' principle). 5) Justification of why the data will not be anonymised/ pseudonymised (if relevant).	1) 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. 2) Permission by the owner/manager of the data sets *(e.g., social media databases)* (if applicable). 3) Informed Consent Forms + Information Sheets + other consent documents (if applicable).
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.*			1) Details of the types of personal data and countries involved. 2) Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded.	1) Confirmation that data transfers will be made in accordance with Chapter V of the General Data Protection Regulation 2016/679.
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 data and countries involved.*			1) Details of the types of personal data and countries involved.	1) 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?			1) Details on the personal data to be processed and the legal basis for the processing. 2) Risk assessment for the data processing operations. 3) Explanation as to how harm will be prevented and the rights of the participants/data subjects will be safeguarded.	1) Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR (if relevant).

5. Third Countries	**Yes/No**	**Information to be provided in the proposal**	**Documents to be kept on file and provided on request**
Will some of the activities be carried out in non-EU countries? *Specify the countries.*		1) Countries involved. 2) Risk-benefit analysis. 3) Details on activities are carried out in non-EU countries.	

This project is co-funded by the European Union as part of the Horizon Europe programme, Marie Sklodowska-Curie Actions call COFUND 2023 and under the Grant Agreement N°101179124.

In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? *Specify the countries.*		1) Details on the materials and the countries involved.	1) Copies of ethics approvals and other authorisations or notifications (if required). 2) 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).
Is it 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.)***?**		1) Details on the type of local resources to be used and modalities for their use.	1) For human resources: copies of ethics approvals. 2) 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)*.
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? *For data imports, see section 4. For imports of human cells or tissues, see section 3. Specify the material and countries involved.*		1) Countries involved. 2) Details on the type of materials to be imported.	1) Copies of import licences/ Material Transfer Agreement (MTA).
Is it planned to export any material (other than data) from the EU to non-EU countries? *For data exports, see section 4. Specify the material and countries involved.*		1) Countries involved. 2) Details of the type of materials to be exported.	1) Copies of export licences/ Material Transfer Agreement (MTA).
Does this activity involve low and/or lower middle-income countries? *If yes, detail the benefit-sharing actions planned.*		1) Details on the benefit sharing measures. 2) Details on the responsiveness to local needs. 3) Details on the procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the activity at risk?		1) Details of the safety measures you intend to take, including training for staff and insurance cover.	1) Insurance coverage (if relevant).

6. Artificial Intelligence	Yes/No	Information to be provided in the proposal	Documents to be kept on file and provided on request
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?		1) 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). 2) Details on the measures taken to avoid bias in input data and algorithm design;	1) Detailed risk assessment accompanied by a risk mitigation plan (if relevant). These must cover the development, deployment and post-deployment phases. 2) Copies of ethics approvals (if relevant).

		3) Explanation as to how the respect to fundamental human rights and freedoms (e.g., human autonomy, privacy and data protection) will be ensured; 4) 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, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority)***?**		1) 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 or human rights, or economic, social or political decisions)***?**		1) Detailed explanation on how humans will maintain meaningful control over the most important aspects of the decision-making process. 2) Explanation on how the presence/role of the AI will be made clear and explicit to the affected individuals.	1) 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, mass surveillance)* **and/or environmental impacts either through intended applications or plausible alternative uses?**		1) Justification of the need for developing/using this particular technology. 2) 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, AI that is used to stimulate addictive behaviours, lifelike humanoid robots, etc.)***?**		1) Detailed explanation on how the potential ethics issues will be addressed and the measures set in place to mitigate ethics risks.	1) Detailed risk assessment accompanied by a risk mitigation plan. These must cover the development, deployment and post- deployment phases.

7. Animals		**Yes/No**	**Information to be provided in the proposal**	**Documents to be kept on file and provided on request**
Does your activity involve animals?			1) Details on the numbers of animals to be used, nature of the experiments, procedures and techniques to be used. 2) Details on species and rationale for their use. 3) Details on procedures to ensure animal welfare. 4) Details on implementation of the 3Rs Principle.	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.
If **YES**:	Are they vertebrates?		Same information as above.	Same information as above.
	Are they non-human primates (NHP) *(e.g., monkeys, chimpanzees, gorillas, etc.)*?		Same information as above plus: 1) Justification on why NHPs are the only subjects suitable for achieving your scientific objectives.	Same documents as above plus: 1) Personal history file of NHP *(See art 31 of Directive 2010/63)*.

This project is co-funded by the European Union as part of the Horizon Europe programme,
Marie Sklodowska-Curie Actions call COFUND 2023 and under the Grant Agreement N°101179124.

			2) Details on the purpose of the animal testing. 3) Details on the origin of the animals.	
	Are they genetically modified?		1) Number of animals to be used, nature of the experiments, procedures, anticipated impact and how this will be minimised. 2) Details on species and rationale for their use. 3) Details on procedures to ensure animal welfare. 4) Details on implementation of the 3Rs Principle.	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.
	Are they cloned farm animals?		Same information as above.	1) Copies of all appropriate authorisations for the supply of animals and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments. 3) Copies of authorisations for cloning (if required).
	Are they an endangered species?		1) Justification on why there is no alternative to using this species. 2) Details on the purpose of the activity.	1) Copies of authorisations for supply of endangered animal species (including CITES) and the project experiments. 2) Copies of training certificates/ personal licences of the staff involved in animal experiments.

8. Environment, Health and safety	Yes/No	Information to be provided in the proposal	Documents to be kept on file and provided on request
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)? *For activities involving animal experiments, see section 7.*		1) Risk-benefit analysis. 2) Show how you apply the precautionary principle (if relevant). 3) Details on safety measures to be implemented.	1) Safety classification of laboratory. 2) Copy of GMO and other authorisations (if required).
Does this activity deal with endangered fauna and/or flora / protected areas?		1) Details on endangered fauna and/or flora / protected areas.	1) Specific authorisations (if required).
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)? *For activities involving human participants, see section 2.*		1) Details of the health and safety procedures.	1) Safety classification of laboratory. 2) Host Institution safety procedures.

Co-funded by the European Union

This project is co-funded by the European Union as part of the Horizon Europe programme, Marie Sklodowska-Curie Actions call COFUND 2023 and under the Grant Agreement N°101179124.

9. Other ethics issues	Yes/No	Information to be provided in the proposal	Documents to be kept on file and provided on request
		1) Any relevant information.	1) Any relevant information.

Supervisors' signatures *(dated)*