

Please insert the following information		Check the box on the left for YES and the box on the right for NO		
Application number:				
Application acronym:				
1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS				
Does your research involve Human Embryonic Stem Cells (hESCs)?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Will they be directly derived from embryos within this project?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are they previously established cells lines?	☐	☐	(If yes, please indicate the related page and section in the Application form)

	Are the cell lines registered in the European registry for human embryonic stem cell lines?	☐	☐	(If yes, please indicate the related page and section in the Application form)
Does your activity involve the use of human embryos?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Will the activity lead to their destruction?	☐	☐	(If yes, please indicate the related page and section in the Application form)

Does your activity involve the use of other human embryonic or foetal tissues / cells?	☐	☐	(If yes, please indicate the related page and section in the Application form)	
2.HUMANS				
Does your activity involve human participants?	☐	☐	(If yes, please indicate the related page and section in the Application form)	
If YES:	Are they volunteers?	☐	☐	(If yes, please indicate the related page and section in the Application form)

	Are they healthy volunteers for medical studies?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are they patients for medical studies?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are the potentially vulnerable individuals or groups?	☐	☐	(If yes, please indicate the related page and section in the Application form)

	Are they children/minors?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are there other persons unable to give informed consent?	☐	☐	(If yes, please indicate the related page and section in the Application form)
Does your activity involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Does it involve invasive techniques (e.g., collection of humans cells or tissues, surgical or medical	☐	☐	(If yes, please indicate the related page and section in the Application form)

	<i>interventions, invasive studies on the brain, TMS etc.)?</i>			
	Does it involve collection of biological samples?	☐	☐	(If yes, please indicate the related page and section in the Application form)
Does your activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 356/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Is it a clinical trial?	☐	☐	(If yes, please indicate the related page and section in the Application form)

	Is it a low intervention clinical trial?	☐	☐	(If yes, please indicate the related page and section in the Application form)
3.HUMAN CELLS / TISSUES				
	Does your research involve human cells or tissues (other than those covered by <i>section 1</i>)?	☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Are they human embryonic or foetal cells or tissues?	☐	☐	(If yes, please indicate the related page and section in the Application form)

	Are they available commercially?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are they obtained within this project?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are they obtained from another project, laboratory, or institution?	☐	☐	(If yes, please indicate the related page and section in the Application form)

	Are they obtained from a biobank?	☐	☐	(If yes, please indicate the related page and section in the Application form)
4.PROTECTION OF PERSONAL DATA				
Does your activity involve processing of personal data?		☐	☐	(If yes, please indicate the related page and section in the Application form)
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, please indicate the related page and section in the Application form)

	Does it involve processing of genetic, biometric or health data?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (<i>such as, surveillance, geolocation tracking etc.</i>)?	☐	☐	(If yes, please indicate the related page and section in the Application form)
Does your research involve further processing of previously collected personal data (secondary use) (<i>including use of pre-existing data sets or sources merging existing data sets, sharing data with non-EU member states</i>)?	☐	☐	(If yes, please indicate the related page and section in the Application form)	

It is planned to export personal data from the EU to non-EU countries?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Specify the type of personal data and countries involved:			
Is it planned to import personal data (data transfer) from non-EU countries into the EU or from a non-EU country to another non-EU country?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Specify the type of personal data and countries involved:			
Does your research involve the processing of personal data related to criminal convictions or offences?		☐	☐	(If yes, please indicate the related page and section in the Application form)

5.ANIMALS				
Does your research involve animals?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Are they vertebrates?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are they non-human primates (NHP) (e.g., monkeys, chimpanzees, gorillas, etc.?)	☐	☐	(If yes, please indicate the related page and section in the Application form)

	Are they genetically modified?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are they cloned farm animals?	☐	☐	(If yes, please indicate the related page and section in the Application form)
	Are they an endangered species?	☐	☐	(If yes, please indicate the related page and section in the Application form)

6. NON-EU COUNTRIES

Will some of the activities be carried out in non-EU countries?

Specify countries involved:

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(If yes, please indicate the related page and section in the Application form)

In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?

Specify countries involved:

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(If yes, please indicate the related page and section in the Application form)

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.)?

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(If yes, please indicate the related page and section in the Application form)

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?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Specify the materials and countries involved:			
Is it planned to export any material – other than data - from the EU to non-EU countries?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Specify material and countries involved:			

Does your activity involve low and/or lower-middle income countries?		☐	☐	(If yes, please indicate the related page and section in the Application form)
If YES:	Detail the benefit-sharing actions planned:			
Could the situation in the country put the individuals taking part in theresearch at risk?		☐	☐	(If yes, please indicate the related page and section in the Application form)
7.ENVIRONMENT, HEALTH AND SAFETY				
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)?		☐	☐	(If yes, please indicate the related page and section in the Application form)

Does this activity deal with endangered fauna and/or flora and/or protected areas?	☐	☐	(If yes, please indicate the related page and section in the Application form)
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)?	☐	☐	(If yes, please indicate the related page and section in the Application form)

8. ARTIFICIAL INTELLIGENCE

Does your research involve the development, deployment and/or use of Artificial Intelligence-based systems?

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(If yes, please indicate the related page and section in the Application form)

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)?

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(If yes, please indicate the related page and section in the Application form)

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)?

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(If yes, please indicate the related page and section in the Application form)

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?	☐	☐	(If yes, please indicate the related page and section in the Application form)
Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above (e.g., subliminal, covert, or deceptive AI, AI that is used to stimulate addictive behaviours, life-like humanoid robots, etc.)?	☐	☐	(If yes, please indicate the related page and section in the Application form)
9. DUAL USE			
Does this research involve dual-use items in the sense of Regulation No 2021/821 or other items for which an authorisation is required?	☐	☐	(If yes, indicate the related page and section in the Application form)
10. EXCLUSIVE FOCUS ON CIVILIAN APPLICATIONS			

If YES	Could the activity result in the development of chemical, biological, radiological, or nuclear weapons and the means for their delivery?	☐	☐	(If yes, please indicate the related page and section in the Application form)
12. OTHER ETHICS ISSUES				
Are there any other ethics issues that should be taken into consideration? Please specify:		☐	☐	(If yes, please indicate the related page and section in the Application form)