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ETHICS AND SECURITY

<KIC NAME>

Version 1.0
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Ethics and Security

Ethics issues table

This table should be completed as an essential part of the BP 2021-2022 proposal. Please go through the table and indicate which elements concern your proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any of the questions,

- *indicate in the adjacent box at which page in your BP per se proposal further information relating to that ethics issue can be found, and*
- *provide additional information on that ethics issue in the Ethics Self-Assessment section.*

For more information on each of the ethics issues and how to address them, including detailed legal references, see the guidelines 'How to Complete your Ethics Self-Assessment'.

1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS			Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?		○ Yes ○ No	
If **YES**:	Will they be directly derived from embryos within this project?	○ Yes ○ No	
	Are they previously established cells lines?	○ Yes ○ No	
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	○ Yes ○ No	
Does this activity involve the use of human embryos?		○ Yes ○ No	
If **YES**:	Will the activity lead to their destruction?	○ Yes ○ No	
2. HUMANS			Page
Does this activity involve human participants?		○ Yes ○ No	
If **YES**:	Are they volunteers for non medical studies (e.g. social or human sciences research)?	○ Yes ○ No	
	Are they healthy volunteers for medical studies?	○ Yes ○ No	
	Are they patients for medical studies?	○ Yes ○ No	
	Are they potentially vulnerable individuals or groups?	○ Yes ○ No	
	Are they children/minors?	○ Yes ○ No	
	Are they other persons unable to give informed consent?	○ Yes ○ No	
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?		○ Yes ○ No	
Does it involve invasive techniques?		○ Yes ○ No	
Does it involve collection of biological samples?		○ Yes ○ No	

Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)		○ Yes ○ No	
If **YES**:	Is it a clinical trial?	○ Yes ○ No	
	Is it a low-intervention clinical trial?	○ Yes ○ No	
3. HUMAN CELLS / TISSUES (not covered by section 1)			Page
Does this activity involve the use of human cells or tissues?		○ Yes ○ No	
If **YES**:	Are they human embryonic or foetal cells or tissues?	○ Yes ○ No	
	Are they available commercially?	○ Yes ○ No	
	Are they obtained within this project?	○ Yes ○ No	
	Are they obtained from another project, laboratory or institution?	○ Yes ○ No	
	Are they obtained from biobank?	○ Yes ○ No	
4. PERSONAL DATA			Page
Does this activity involve processing of personal data?		○ Yes ○ No	
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)?	○ Yes ○ No	
	If **YES**: Does it involve processing of genetic, biometric or health data?	○ Yes ○ No	
	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.)?	○ Yes ○ No	
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?		○ Yes ○ No	
Is it planned to export personal data from the EU to non-EU countries?		○ Yes ○ No	
If **YES**:	Specify the type of personal data and countries involved:		
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country?		○ Yes ○ No	
If **YES**:	Specify the type of personal data and countries involved		

Does this activity involve the processing of personal data related to criminal convictions or offences?		○ Yes ○ No	
5. ANIMALS			Page
Does this activity involve animals?		○ Yes ○ No	
If **YES**:	Are they vertebrates?	○ Yes ○ No	
	Are they non-human primates (NHP)?	○ Yes ○ No	
	Are they genetically modified?	○ Yes ○ No	
	Are they cloned farm animals?	○ Yes ○ No	
	Are they endangered species?	○ Yes ○ No	
6. NON-EU COUNTRIES			Page
Will some of the activities be carried out in non-EU countries?		○ Yes ○ No	
If **YES**:	Specify the countries:		
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?		○ Yes ○ No	
If **YES**:	Specify the countries:		
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.)?		○ Yes ○ No	
Is it planned to import any material from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.		○ Yes ○ No	
If **YES**:	Specify material and countries involved:		
Is it planned to export any material from the EU to non-EU countries?		○ Yes ○ No	
If **YES**:	Specify material and countries involved:		
Does this activity involves low and/or lower-middle income countries, (if yes, detail the benefit-sharing actions planned in the self-assessment)		○ Yes ○ No	
Could the situation in the country put the individuals taking part in the activity at risk?		○ Yes ○ No	
7. ENVIRONMENT & HEALTH and SAFETY			Page

Does this activity involve the use of substances or processes 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)?	○ Yes ○ No	
Does this activity deal with endangered fauna and/or flora /protected areas?	○ Yes ○ No	
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing them (during the implementation of the activity or further to the use of the results, as a possible impact)?	○ Yes ○ No	
8. ARTIFICIAL INTELLIGENCE		Page
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	○ Yes ○ No	
9. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration?	○ Yes ○ No	
Please specify: (Maximum number of characters allowed: 1000)		

I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment as described in the guidelines 'How to Complete your Ethics Self-Assessment'. ☐

ETHICS SELF-ASSESSMENT

If you have entered any issues in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines "How to Complete your Ethics Self-Assessment" and complete the table below.

Ethical dimension of the objectives, methodology and likely impact
Explain in detail the identified issues in relation to: – objectives of the activities (e.g. study of vulnerable populations, etc.) – methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.) – the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)
Compliance with ethical principles and relevant legislations
Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the E U / national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for **activities performed in a non-EU countries**, they should also be allowed in at least one EU Member State.

Security issues table

Please indicate, by answering Yes or No to all of the questions in the below table, if the proposed activity will use and/or generate information which might raise security concerns. If an answer is Yes, then indicate in the adjacent box at which page in your full proposal further information relating to that issue can be found.

1. EU classified information (EUCI)[1]			Page
Does this activity involve information and/or materials requiring protection against unauthorised disclosure (EUCI)?		○ Yes ○ No	
If **YES**:	Is the activity going to use classified information as background[2] information?	○ Yes ○ No	
	Is the activity going to generate EU classified foreground[3] information as results?	○ Yes ○ No	
Does this activity involve HE associated and/or third countries?		○ Yes ○ No	
If **YES**:	Do participants from non-EU countries need to have access to EUCI?	○ Yes ○ No	
	Do the non-EU countries concerned have a security of information agreement with the EU	○ Yes ○ No	
2. MISUSE			Page
Does this activity have the potential for misuse of results?		○ Yes ○ No	
If **YES**:	Does the activity provide knowledge, materials and technologies that could be channelled into crime and/or terrorism?	○ Yes ○ No	
	Could the activity result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery?	○ Yes ○ No	
3. OTHER SECURITY ISSUES			Page
Does this activity involve information and/or materials subject to national security restrictions?		○ Yes ○ No	
If yes, please specify: *(Maximum number of characters allowed: 1000)*			
Are there any other security issues that should be taken into consideration?		○ Yes ○ No	
If yes, please specify: (Maximum number of characters allowed: 1000)			

[1] According to the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information, "European Union classified information (EUCI) means any information or material designated by an EU security classification, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union or of one or more of the Member States".

[2] Classified background information is information that is already classified by a country and/or international organisation and/or the EU and is going to be used by the project. In this case, the project must have in advance the authorisation from the originator of the classified information, which is the entity (EU institution, EU Member State, third state or international organisation) under whose authority the classified information has been generated.

[3] EU classified foreground information is information (documents/deliverables/materials) planned to be generated by the project and that needs to be protected from unauthorised disclosure. The originator of the EUCI generated by the project is the European Commission.