

## 5<sup>th</sup> edition - Seed Projects for Interdisciplinary Research within the Strategic Areas of the University of Coimbra

### Guide to Ethics and Security Issues in research proposals

The tables below aim to guide candidates in the identification of ethical and security issues regarding their proposal to “*Projetos Semente de Investigação Interdisciplinar - 2024*” and support the preparation of subpart 3.5. *Ethics Self-Assessment* of the proposal template. These tables are based on the Ethics and Security issues required to be taken into account by applicants and beneficiaries of EU projects funded by the European Commission (EC). For more information on each of the ethical and security issues and how to address them see the guidelines [‘How to Complete your Ethics Self-Assessment’](#) from the European Commission.

### Ethics issues table

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, provide additional information on that issue in the Ethics Self-Assessment of your proposal.

1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		
Does this activity involve Human Embryonic Stem Cells (hESCs)?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Will they be directly derived from embryos within this project?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they previously established cells lines?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does this activity involve the use of human embryos?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Will the activity lead to their destruction?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. HUMANS		
Does this activity involve human participants?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they healthy volunteers for medical studies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they patients for medical studies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they potentially vulnerable individuals or groups?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they children/minors?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are there other persons unable to give informed consent?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Does it involve invasive techniques?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Does it involve collection of biological samples?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does this activity involve conducting a clinical study as defined by the Clinical Trial <a href="#">Regulation (EU 536/2014)</a> ? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Is it a clinical trial?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Is it a low-intervention clinical trial?	<input type="checkbox"/> Yes <input type="checkbox"/> No

3. HUMAN CELLS / TISSUES (not covered by section 1)		
Does this activity involve the use of human cells or tissues?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Are they human embryonic or foetal cells or tissues?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they available commercially?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they obtained within this project?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they obtained from another project, laboratory or institution?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they obtained from biobank?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. PERSONAL DATA		
Does this activity involve processing of personal data?		<input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If YES:	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.)?	
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?		<input type="checkbox"/> Yes <input type="checkbox"/> No
5. ANIMALS		
Does this activity involve animals?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Are they vertebrates?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they non-human primates (NHP)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they genetically modified?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they cloned farm animals?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Are they endangered species?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. OTHER COUNTRIES		
Will some of the activities be carried out outside Portugal?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Specify the countries:	
Do the activities undertaken in other countries raise potential ethics issues?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If YES:	Specify the countries:	
Does this activity involve <a href="#">low and/or lower-middle income countries</a> ? (if yes, detail the benefit-sharing actions planned in the self-assessment)		<input type="checkbox"/> Yes <input type="checkbox"/> No
Could the situation in other counties put the individuals taking part in the activity at risk?		<input type="checkbox"/> Yes <input type="checkbox"/> No
7. ENVIRONMENT, HEALTH and SAFETY		
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)?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Does this activity deal with endangered fauna and/or flora / protected areas?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Does this activity involve the use of substances or processes 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, as a possible impact)?		<input type="checkbox"/> Yes <input type="checkbox"/> No

8. ARTIFICIAL INTELLIGENCE	
Does this activity involve the development, deployment and/or use of Artificial Intelligence based systems? (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).	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. OTHER ETHICS ISSUES	
Are there any other ethics issues that should be taken into consideration?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Please specify:	

### **Security issues table**

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, please provide additional information on this security issue in the Security self-assessment section below.

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

<sup>1</sup> 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".