EUROPEAN UNION

EUROPEAN DEFENCE FUND

Ethics in EDF

Tutorial

DG DEFIS unit A3
EDF Implementation:
Defence Technologies

European Commission | DEFIS

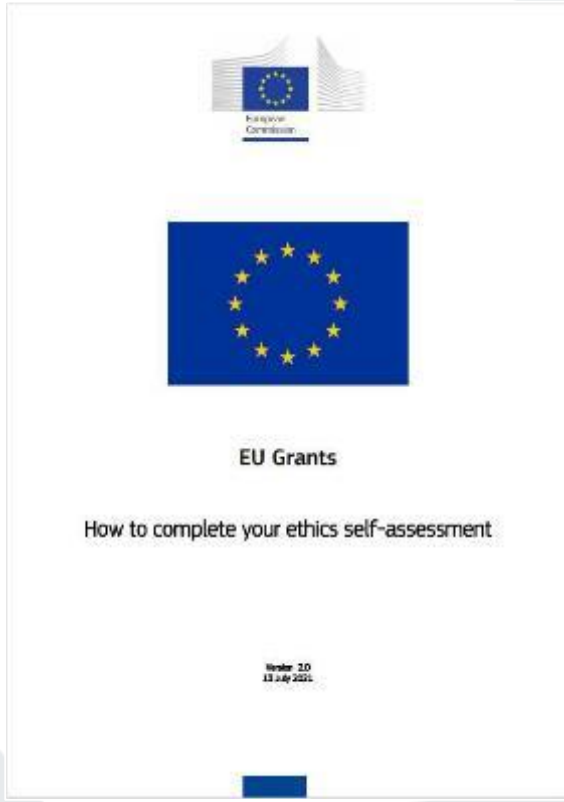
Ethics issues table and ethics self-assessment

Part A

4 - Other questions

Ethics Issues Table ?

1. Human embryonic stem cells and human embryos		Page
Does this activity involve human embryonic stem cells (hESCs)?	◉ Yes ○ No	12
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 line	○ Yes ◉ No	
Does this activity involve the use of human embryos?	○ Yes ◉ No	
2. Humans		**Page**
Does this activity involve human participants?	◉ Yes ○ No	14
Are they volunteers for non medical studies (e.g. social or human sciences)?	○ Yes ◉ No	
Are they healthy volunteers for medical studies?	○ Yes ◉ No	
Are they patients for medical studies?	◉ Yes ○ No	15
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, tracking and tracing etc.) on the study participants?	○ Yes ◉ No	
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014) (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)?	○ Yes ◉ No	
3. Human cells / tissues		**Page**
Does this activity involve the use of human cells or tissues (not covered by section 1)?	○ Yes ◉ No	
4. Personal data		**Page**
Does this activity involve processing of personal data?	○ Yes ◉ No	



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how-to-complete-your-ethics-self-assessment_en.pdf (europa.eu)

Example

Application forms

Proposal ID **SEP-211155725**

Acronym **ThisCanBeDeleted**

4 - Ethics & security

Ethics Issues Table

?

This Table should be completed as an essential part of your 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 technical annex 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	
Does this activity involve the use of human embryos?	○ Yes ◉ No	
2. Humans		**Page**
Does this activity involve human participants?	○ Yes ◉ No	

Example

Does this activity involve the use of human embryos?	○ Yes ◉ No	
2. Humans		**Page**
Does this activity involve human participants?	◉ Yes ○ No	
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 (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	◉ Yes ○ No	
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**

2.3 Ethics issues checklist

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	☐	☐	1) Details on the	1) Copies of ethics

Ethics self-assessment

Part A

Ethics Self-Assessment ?

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.)

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Compliance with ethical principles and relevant legislation

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 EU/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 country, they should also be allowed in at least one EU Member State.

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Thank you for your attention!

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