

The European Research Council

Ethics requirements in your ERC application

Carolina C. Ávila

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European Research Council

Established by the European Commission

Overview



- **Why? what? Who?**
- **Serious and Complex ethics issues**
- **Ethics' section of the ERC application**
- **Do's and don'ts**
- **Sources of information**

Why is there an ethics section in the application?

- To ensure that each ERC grant respect EU ethics principles in research
- To allow supporting researchers handling ethics aspects of their proposals
- To respect legal obligations

✓ *HE Framework Programme - Regulation 2021/695: Eligible actions and ethical principles (**Article 18**) and Ethics (**Article 19**)*



Ethics process in HE – Who is involved?

Responsibility and Trust

- Responsibility for ethics lies with the ones carrying out the research, the **researchers**
- Accountability lies with the signatory of the Grant Agreement, the **HI**

ERCEA: Trust in **researchers and HI** to comply with ethics principles; Union, national and international law



Ethics in your application

- **Ethics Issues table (Part A)**
- **Ethics self-assessment (Part A)**

*i) Ethical dimension of the objectives, methodology
and likely impact*

ii) Compliance with ethical principles and relevant legislation

- **Annexes** can be included (approvals, authorizations,...)



Ethics in your application – Ethics Issues Table

1. Human Embryonic Stem Cells and Human Embryos
2. Human participants
3. Human cells / tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment & Health and Safety
8. Artificial Intelligence
9. Other ethics issues
10. Crosscutting issue: potential misuse of results

The screenshot shows a section of an ethics application form titled "4 - Ethics & security". It contains a table of questions with checkboxes for "Yes" and "No" and a "Page" indicator. The questions cover various ethical and security concerns, such as the use of human embryos, human participants, personal data, and animals. The form is partially obscured by a redacted area at the top.

Question	Yes	No	Page
1 Human Embryos (from Section 2)			
Does this activity involve human embryos from Clin Bellco?	<input type="checkbox"/>	<input type="checkbox"/>	
Does this activity involve the use of human embryos?	<input type="checkbox"/>	<input type="checkbox"/>	
2 Human			
Does this activity involve human participants?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	7.8
Are they volunteers for non-medical studies (e.g. social or human sciences research)?	<input type="checkbox"/>	<input type="checkbox"/>	
Are they healthy volunteers for medical studies?	<input type="checkbox"/>	<input type="checkbox"/>	
Are they patients for medical studies?	<input type="checkbox"/>	<input type="checkbox"/>	
Are they potentially vulnerable individuals or groups?	<input type="checkbox"/>	<input type="checkbox"/>	
Are they disadvantaged?	<input type="checkbox"/>	<input type="checkbox"/>	
Are they other persons unable to give informed consent?	<input type="checkbox"/>	<input type="checkbox"/>	
Does this activity involve interventions (e.g. surgical and emerging therapies) involving: biomedical treatments, etc. (on the study participants)?	<input type="checkbox"/>	<input type="checkbox"/>	
Does this activity involve conducting clinical trials on animals for the purpose of: developing, testing, or validating pharmaceuticals, biological, radiopharmaceutical, or advanced therapy medicinal products ?	<input type="checkbox"/>	<input type="checkbox"/>	
3 Personal Data (from Section 2)			
Does this activity involve the use of human cells or tissues?	<input type="checkbox"/>	<input type="checkbox"/>	
4 Personal Data			
Does this activity involve processing of personal data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	7.8
Does this involve the processing of special categories of personal data (e.g. genetic, biometric, and health data, racial/ethnic, religious, political opinions, sexual or philosophical beliefs)?	<input type="checkbox"/>	<input type="checkbox"/>	
Does this involve profiling (automated) monitoring of individuals, or processing of large scale or special categories of data or sensitive methods of data processing (such as, surveillance, predictive modelling, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	
Does this activity involve further processing of previously collected personal data for a purpose other than that for which the data were originally collected?	<input type="checkbox"/>	<input type="checkbox"/>	
Is it planned to import personal data from the EU to non-EU countries? Specify the type of personal data and countries involved.	<input type="checkbox"/>	<input type="checkbox"/>	
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? Specify the type of personal data and countries involved.	<input type="checkbox"/>	<input type="checkbox"/>	
Does this activity involve the processing of personal data related to criminal convictions or offences?	<input type="checkbox"/>	<input type="checkbox"/>	
5 Animals			
Does this activity involve animals?	<input type="checkbox"/>	<input type="checkbox"/>	
6 Non-EU Countries			



Ethics Self-Assessment

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.)

Remaining characters 4594

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

Remaining characters 5000

Serious and/or complex ethics issues

- ❖ Potential to violate **fundamental rights** or freedoms
- ❖ Potential to result in significant **harm**
- ❖ Particularly complicated methods or **technologies** that have not been sufficiently tested and give rise to uncertainty
- ❖ Raise significant ethics issues '**at scale**'
- ❖ Raise multiple or '**intersectional**' ethics issues
- ❖ **Insufficient** ethics awareness



Serious and/or complex ethics issues - Examples

1. Human Embryonic Stem Cells and Human Embryos
 - Scientific Evaluators to confirm necessity to use hESC
 - Programme Committee vote and EC decisions
2. Human participants
 - Medical/invasive studies
 - Experiments with vulnerable individuals such as certain patients, prisoners and/or children
4. Personal data
 - Special categories of personal data
 - Unclear roles and data processing techniques under GDPR



Serious and/or complex ethics issues - Examples

5. Animals

- Severity of the experiments
- Work with Non-human primates



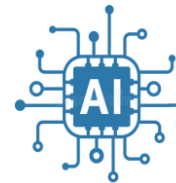
6. Non-EU countries

- Ethics dumping
- Dangerous settings



8. Artificial Intelligence

- Influence on human decision
- Profiling and bias



Annexes (examples)

- A more detailed ethics self-assessment (in English)
- Previously obtained ethics approvals or ethics applications
- Specific documents such as a Data Management Plan / Data Impact Assessment,
- Informed consent and information sheets for research participants
- Recruitment strategy
- Biosafety lab certification



Ethics in your application- Do's and don'ts



- Include reflection on ethics right from the start
- When in doubt, always tick the issue and elaborate on your doubts
- Give us information that will allow us to differentiate between serious/complex and non serious/non complex ethics issues
- Include relevant annexes
- Check the guidelines



- Don't think that issues depend on the general domain your research belongs to
- Don't do it in the last 5 minutes before submission of your proposal
- Do not abstain from ticking thinking that it will go unnoticed (and/or that it will be less work to do!)



Ethics in your application: You're not alone

- Ethics committee/Institutional Review Board
- Data Protection Officer
- Legal department
- HI's previous experience



Ethics in your application: guidance documents



EU Grants

How to complete your ethics self-assessment

Version 2.0
13 July 2021



Identifying serious and complex ethics issues in EU-funded research

05 July 2021



Practical information – some more useful documents

- [Guidance note on potential misuse of research results](#)
- [Guidance note on research focusing exclusively on civil applications](#)
- [Guidance note on research on refugees, asylum seekers and migrants](#)
- [Ethics and data protection](#)
- [Ethics in Social Science and Humanities](#)
- [Position of the European Network of Research Ethics Committees \(EUREC\) on the Responsibility of Research Ethics Committees during the COVID-19 Pandemic](#)
- [Functional Magnetic Resonance Imaging](#)
- [Research Ethics in Ethnography/Anthropology](#)
- [Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects](#)
- [SIENNA Ethical guidance for research with a potential for human enhancement](#)
- [Guidelines on ethics by design/operational use for Artificial Intelligence](#)
- [Guidance on Information Requirements and Chemical Safety Assessment](#)
- [Global Code of Conduct for Research in Resource-Poor Settings](#)



Thank You!

More information: erc.europa.eu



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