The European Research Council

Ethics requirements in your ERC application

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European Research Council

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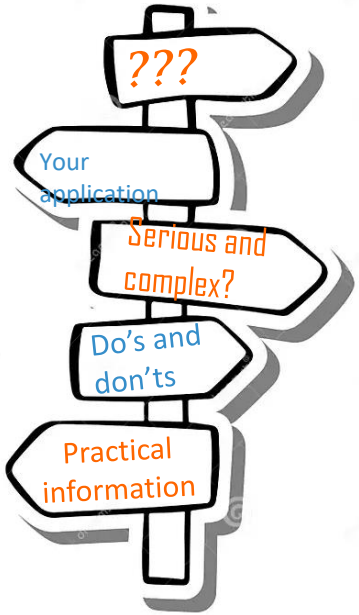
Overview



- **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)**

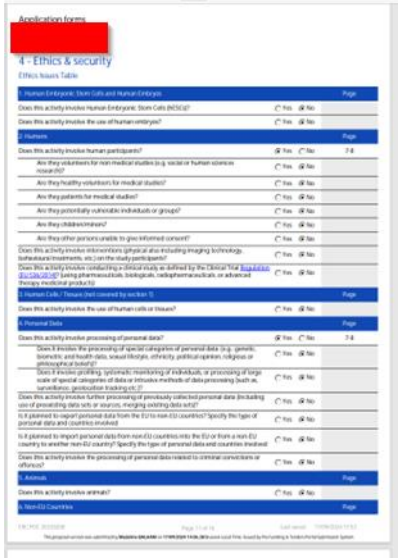
i) Ethical dimension of the objectives, methodology and likely impact

ii) Compliance with ethical principles and relevant legislation

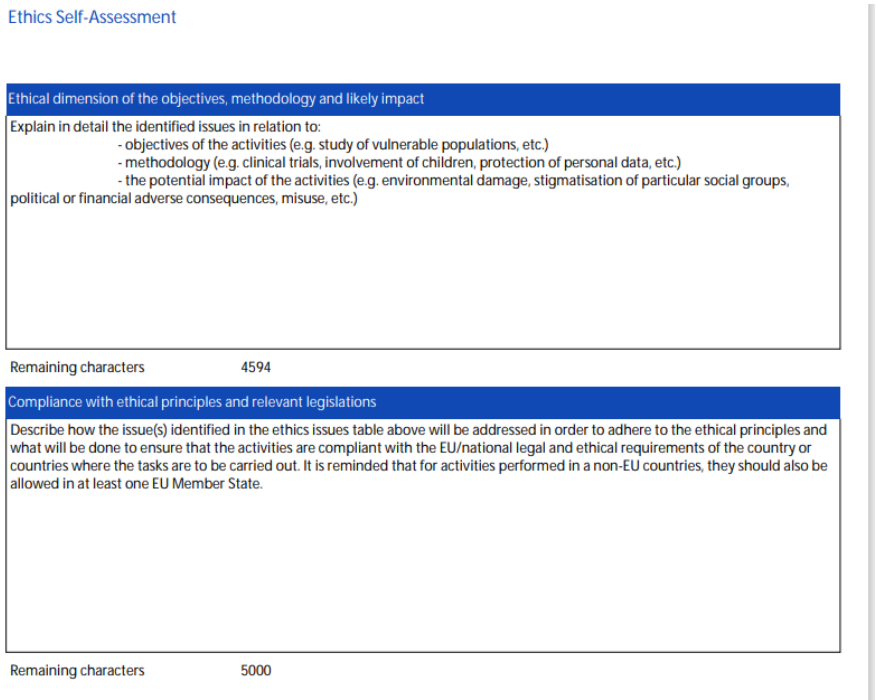
- **Annexes** can be included (approvals, authorizations,…)

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



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.)

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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.

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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

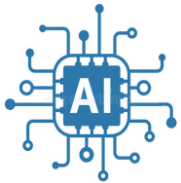
4. Personal data
   - Special categories of personal data
   - Unclear roles and data processing techniques under GDPR

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

Do

- 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

- 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

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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