The European Research Council

How to deal with **ethics** requirements

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Overview

- Why do we care about ethics?

- How to prepare an ethically sound application

- Practical information

Why do we care about ethics in research?

Worrying about ethics **=** respecting essential principles of our society

Ethics by design ⟹ stronger, more respectful and fairer research

Ethically sound research ⟹ society's trust in science

Innovative research ⟹ new ethical dilemmas without reference framework

Transparency and accountability

Principal Investigator + Host Institution

How to prepare an ethically-sound application?

Step 1: Identification of ethical challenges

- Research may require the collection of **sensitive personal data**, fieldwork in **conflict areas** or **animal testing** among many other issues

- It is crucial to identify ethical challenges **from the outset**.

- Need to detail ethical considerations and protocols clearly in the proposal

Ethics by design

How to prepare an ethically-sound application?

Step 2: Justify the need

- Reflect on the need for research in light of the ethical challenges

- Explain why it is essential and its potential benefits for society

- A well-argued justification demonstrates commitment and responsibility

Risk-benefit analysis

How to prepare an ethically-sound application?

Step 3: Familiarise yourself with ethical and legal frameworks

- Ethical codes and laws applicable to your research provide a safe space for your project

- Indicate relevant rules in the application to demonstrate ethical awareness and legal compliance

Reference frameworks

How to prepare an ethically-sound application?

Step 4: Reflect on appropriate measures for each risk

- Ethical issues can be mitigated if properly addressed during the experimental design

- Adapted informed consents for participants with disabilities, and advanced data anonymisation techniques are just some examples

Risk-mitigation strategies

How to prepare an ethically-sound application?

Step 5: Plan ethical oversight

- Consider appropriate ethical oversight at institutional and project level.

- Establish an ethical review framework, possibly through ethics committees or other structures

- Demonstrate long-term commitment to ethical standards.

Ethics approval

How to prepare an ethically-sound application?

Part A of the application:

Ethics issue table

- Human Embryonic Stem Cells and Human Embryos
- Human participants
- Human cells / tissues
- Personal data
- Animals
- Non-EU countries
- Environment & Health and Safety
- Artificial Intelligence
- Other ethics issues
- Crosscutting issue: potential misuse of results

Ethics self-assesment

- Ethical dimension of the objectives, methodology and likely impact
- Compliance with ethical principles and relevant legislation

+

Ethics annexes

- Additional documents

Practical information

- 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 and 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!)

- Do not try to do the ethics assessment entirely by yourself

Practical information

You are not alone!

Host Institution

- Data Protection Officer

- Legal department

- HI's previous experience

- Complex cases/amendments

ERC website

https://erc.europa.eu/managing-your-project/ethics

- How to complete your ethics self-assessment
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

- Guidelines on identifying serious and complex ethics issues in EU-funded research
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/guidelines-on-serious-and-complex-cases_he_en.pdf

- Horizon Europe Programme Guide
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

Practical information

- [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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The ethics appraisal procedure at ERCEA

Scientific Evaluation — Signature of Grant — End of Grant

Ethics Review — Ethics Monitoring
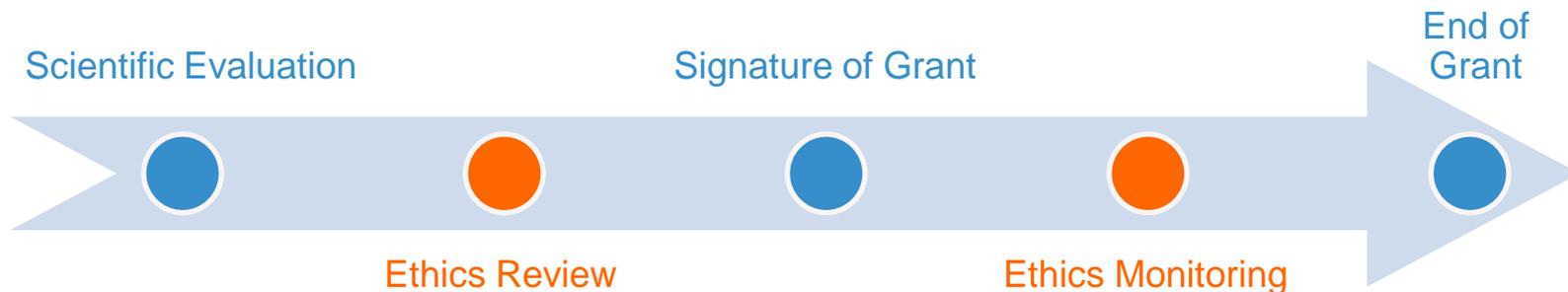
	1) Pre-screening	2) Screening	3) Assessment
Responsibility	Ethics officers	Panel of independent ethics experts	
Clearance rate	73%	21%	**6%**
Time	3 weeks	7 weeks	**3 months**

Only proposals with **serious** and/or **complex ethics issues**

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The ethics appraisal procedure at ERCEA

- A dedicated team of interdisciplinary ethics officers.
- Collaboration with independent ethics experts.
- Guidance during the ethics review and monitoring.
- Matching our background and expertise to each research topic and its ethics issues.

To help beneficiaries to better manage projects in ethical terms

EU ethics principles

Legal obligations

The ethics appraisal procedure at ERCEA

Focus on 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
   - HI's past experience

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 – minimisation principle
   - Unclear roles and data processing techniques under GDPR
   - Consult with the HI's Data Protection Officer
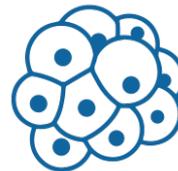
Serious and/or complex ethics issues - **Examples**

5. Animals
   - Severity of the experiments
   - Work with Non-human primates
   - Ethics committee/Institutional review Board

6. Non-EU countries
   - Ethics dumping
   - Dangerous settings

8. Artificial Intelligence
   - Influence on human decision
   - Profiling and bias
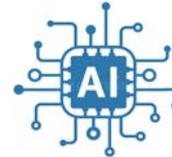
Practical information

You are not alone!

- The ethics officer responsible for your project is indicated in the ethics reports

- Please make sure to add the following information in the subject of any email exchange:

Project number – acronym – **[ALEJAP].**

HI
- Data Protection Officer
- Legal department
- HI's previous experience
- Complex cases/amendments

EUROPEAN RESEARCH COUNCIL EXECUTIVE AGENCY (ERCEA)
Unit B1 – Ethics Review and Expert Management

European Research Council
Executive Agency
Established by the European Commission

Dear principal investigator,

Dear representative of the host institution,

The ethics review is a mandatory part of the proposal evaluation procedure, and its objective is to ensure that the European Union does not support research which would be contrary to fundamental ethical principles set out in the relevant EU rules.

Your proposal has been reviewed by an ethics panel, composed of independent experts. The report included in this letter is based on the analysis done by the panel of the information you provided (including your self-assessment). Please read it carefully.

The report identifies the ethics issues in your proposal and provides detailed ethics observations as well as ethics questions for which clarifications are still needed. You are now requested to prepare a response letter to this report, addressing the questions raised in the report so that they can be further analysed.

We invite you to submit the requested information and any supporting documentation that may be necessary within 3 weeks from the date of this communication. You can submit the documentation via the Funding & Tenders Portal. Please follow this guidance note: https://erc.europa.eu/sites/default/files/document/file/HowToReply.pdf.

Failure to comply with this request may lead to the rejection of your proposal. At this stage, this communication should in no way be considered as a commitment of financial support by the European Union.

Within the ethics team at the ERCEA, Alejandro APARISI REY (ERC-ETHICS-REVIEW@ec.europa.eu) is at your disposal to help you in the preparation of your answers. Please make sure to add the following information in the subject of any email exchange: ▮▮▮▮▮ - ▮▮▮▮▮ - [ALEJAP].

Don't hesitate to contact us.

With kind regards,

Raluca IONESCU
Head of Unit

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