

The European Research Council



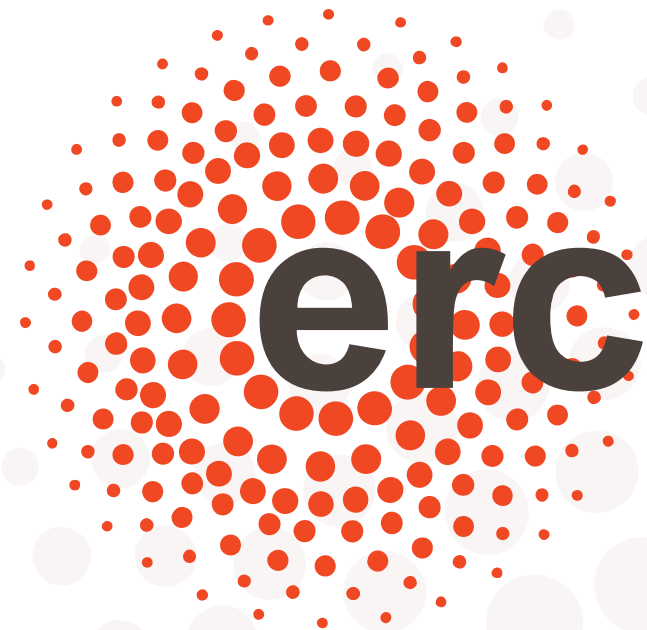
European Research Council

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Ethics review and monitoring

Veronica Martinez Ocaña
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Reunión Universidades Españolas
Oficina Europea Crue-CRUP
Brussels, 11 April 2019





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Ethics Review and Monitoring

- 1. Why an Ethics Review?**
- 2. Ethics review and monitoring processes**
- 3. Main ethics issues**
- 4. Questions**

Ethics Review – Why

Three aims:

- To respect legal obligations
- To respect ethical principles in research
- To help researchers think about and elaborate on the ethics aspects of their projects

Ethics Review – Why

Legal base

- Art.19 in H2020 – Regulation (EU) 1291/2013
- Art. 13 & 14 Rules for Participation - Regulation (EU) 1290/2013
- Grant Agreement (article 34): general obligation of beneficiaries to comply with ethical principles and applicable law

Article 14

Ethics review

1. The Commission shall systematically carry out ethics reviews for proposals raising ethical issues. That review shall verify the respect of ethical principles and legislation and, in the case of research carried out outside the Union, that the same research would have been allowed in a Member State.

Ethics Review – Why

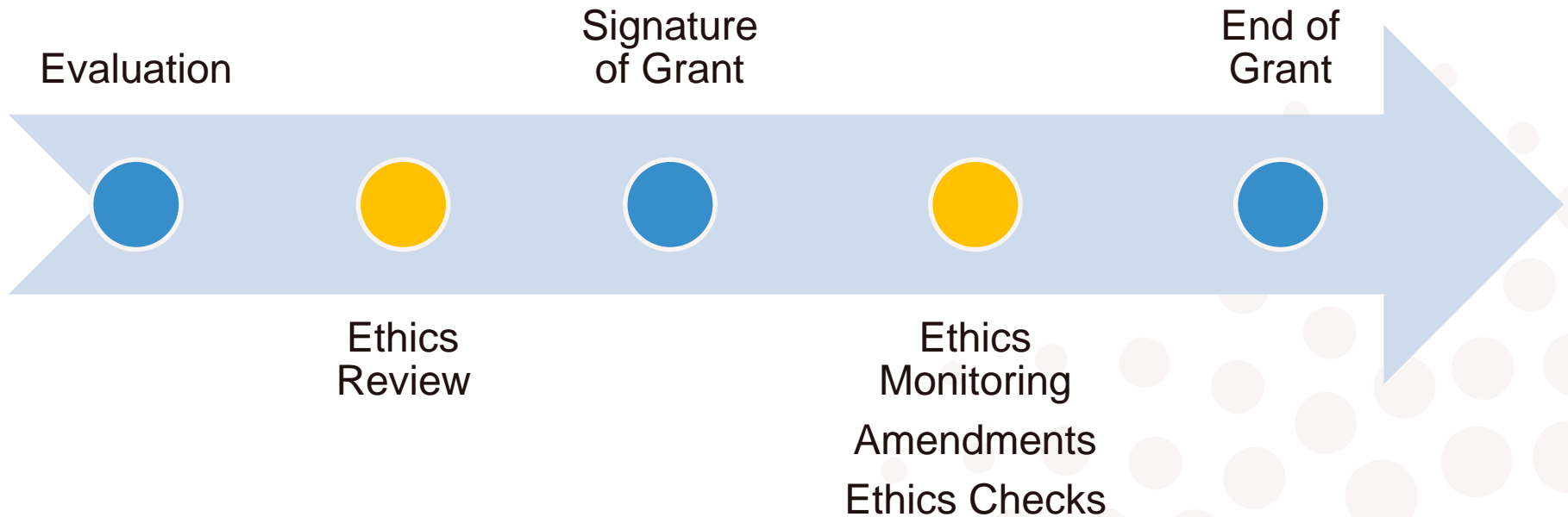
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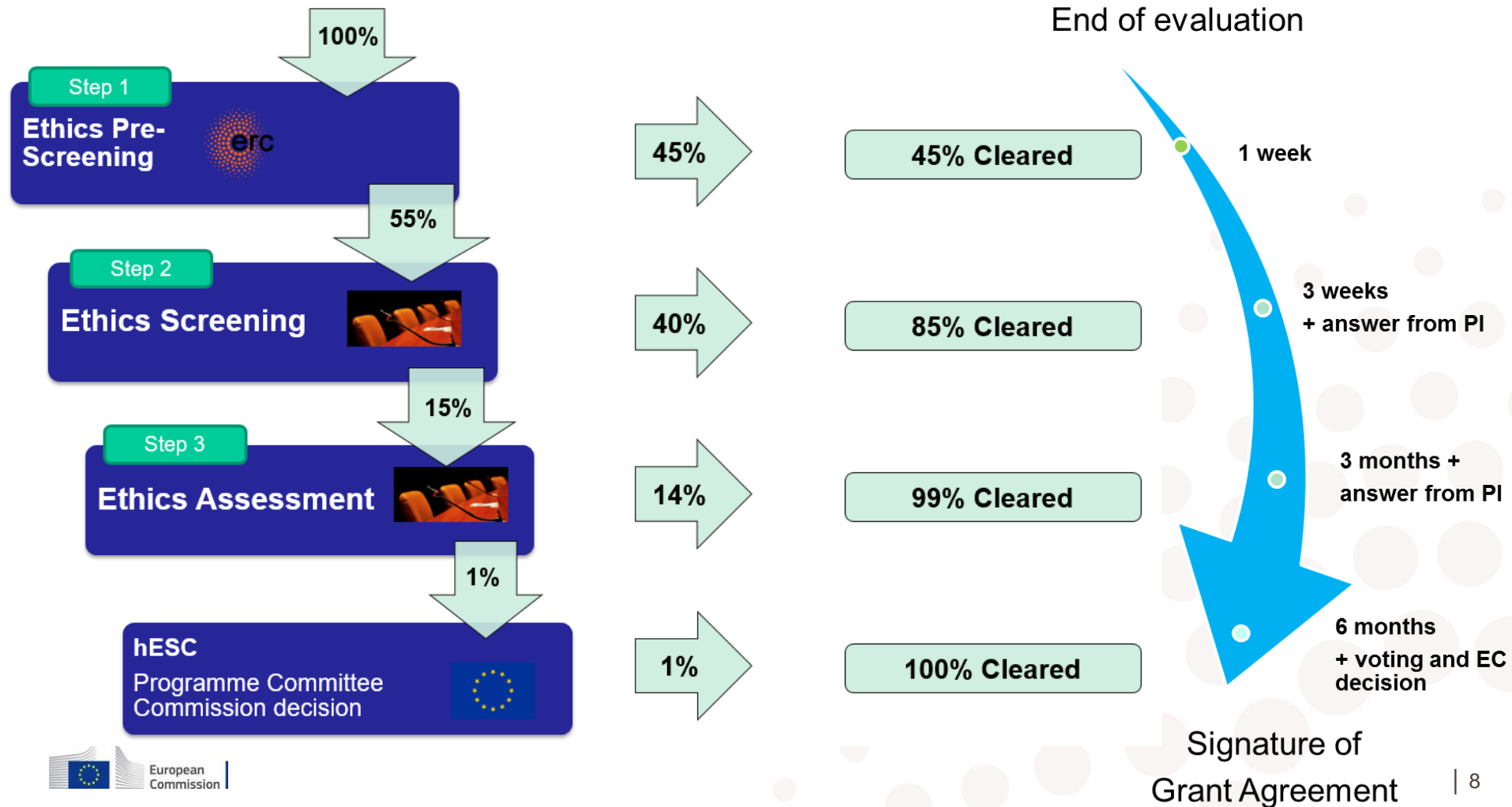
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Procedure - How



Ethics Review procedure in ERCEA



What is expected from the applicant? (Ethics Self-Assessment)

Ethics Issues Table

Ethics self-assessment

- **Description** of the potential ethics issues of the proposed action regarding its objectives; the methodology and the possible implications of the results;
- **Explanation** of how the ethical requirements set out in the work programme will be fulfilled;
- **Statement** about how the proposal meets the national legal and ethical requirements of EU and/or third country where the action is to be performed;
- **Indication** of which particular authorisations may be needed during the lifetime of the project.

Annexes (approvals, authorizations,...)

Do's and don'ts

Do

- Include reflexion on ethics right from the start
- Take it as a way to broaden the perspective on your subject
- When in doubt, always tick the issue and elaborate on your doubts

Don't

- Don't think that issues depend on the general domain your research belong 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!)

What is expected from the applicant? Additional Information Requests



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After Screening and/or Assessment:

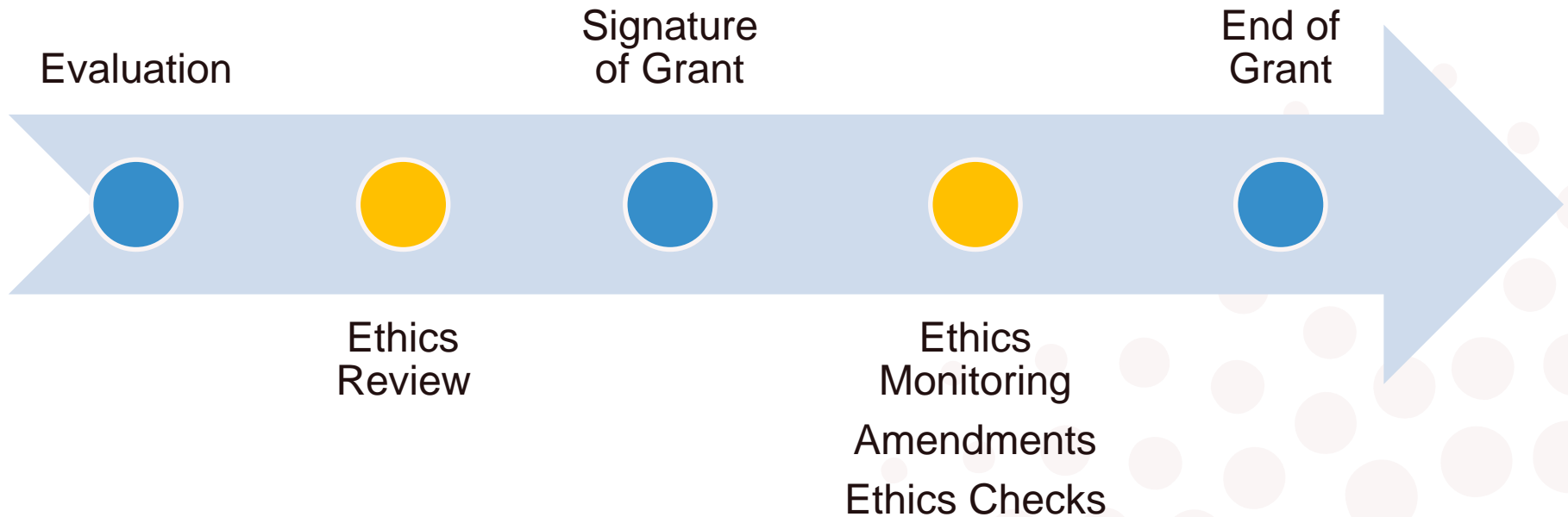
Explanatory Note (signed and dated by PI):

- It should address all requirements present at Screening and Assessment Information Request, one by one

Any **extra documents** needed to meet the Requirements : approvals, authorisations, training certificates,...

- When authorisation/approval is pending, an indicative timeframe should be provided

Procedure - How



Ethics issues to be monitored

- The **open ethics issues (ethics deliverables)** at the signature of Grant Agreement
- In case of amendments (changes of HI, changes of DoA,...)
 - **New ethics issues** that may arise
 - In case of substantial changes with **complex ethics issues** an **Ethics Review** may be needed.

Ethics Checks

- Ethics Checks are organised by the Commission
- Performed by Ethics Experts
- May involve on-site visits
- The experts produce an Ethics Check Report which is sent to the PI

ERC Executive Agency is in charge of:

- Communication with the PI
- Issue the ethics clearance

Personalized assistance by an ethics officer

Within the ethics team,

James Bond (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:

123456 – AcrOnYm- [JBond]

Should you have any questions about this note, please contact your ethics officer,

Mary Poppins (ERC-ETHICS-MONITORING@ec.europa.eu).

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

123456 – AcrOnYm- [MPopp]

Ethics Review and Monitoring

1. **Why an Ethics Review?**
2. **Ethics review and monitoring processes**
3. **Main ethics issues**
4. **Questions**

Main ethics issues

- Human embryos/foetus and human Embryonic Stem Cells (hESC)
- Research on human beings
- Human cells/tissues
- Research on animals
- Privacy and use of personal data
- Research in low income countries & countries at risk
- Environmental protection
- Dual Use & misuse

Main ethics issues

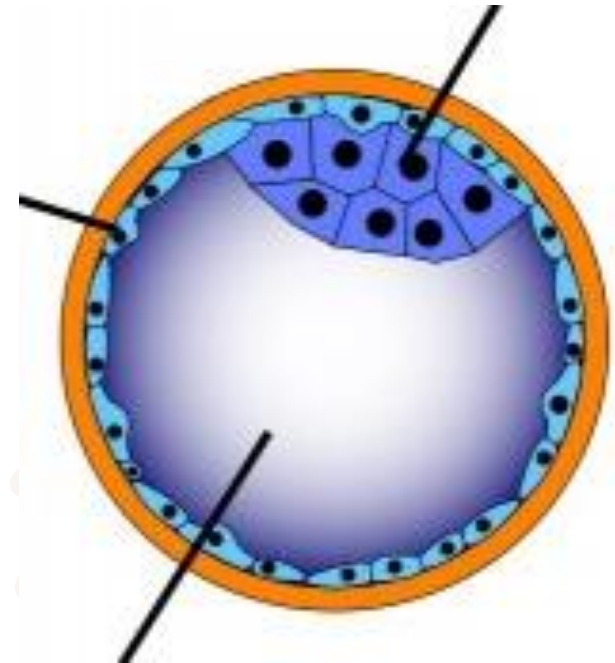
Human embryos/foetuses

No destruction of the embryos!

Human Embryonic Stem Cells

Scientific Evaluators to confirm NECESSITY to use hESC

Programme Committee and EC decision



Main ethics issues

Human cells/tissues

Commercially available (origin, source)

Obtained within the project (ethics approval)

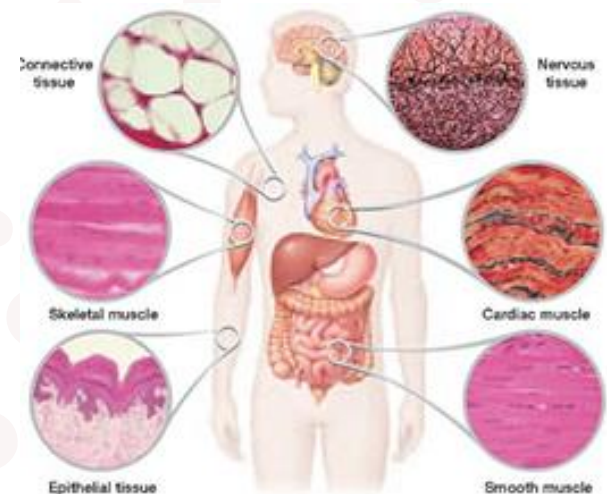
Originate from another laboratory or from clinical practice (secondary use)

Biobanks (access)

Keep track on the origin of the cells

Authorizations/licenses/ethics approvals

Fully informed consent of the donors



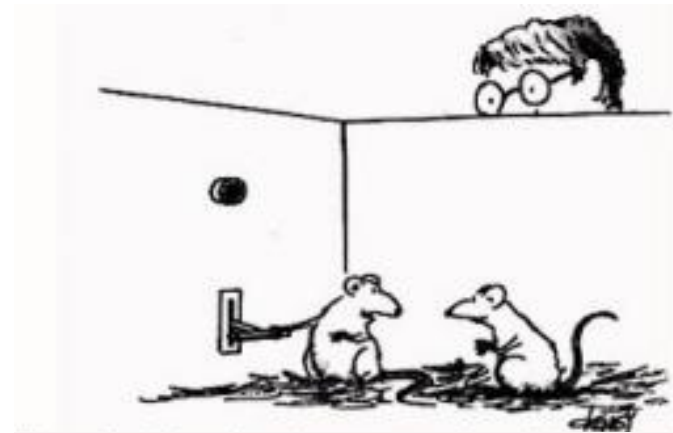
Main ethics issues

Research on animals

3Rs, animal welfare

Non-human primates: strict limits to their use

Directive 2010/63/EU



It's a rather interesting phenomenon. Every time I press this lever, that post-graduate student breathes a sigh of relief

Main ethics issues

Involvement of Human participants

Respect for autonomy

Non-maleficence

Beneficence

Justice

Informed consent is key!



The research ethics committee wasn't altogether sure about the university's new policy to encourage whistleblowing...

Main ethics issues

Informed consent is key!

Principles:

1. Respect for autonomy
2. Respect for dignity
3. Respect for persons

Valid if:

1. Adequate information
2. Voluntariness
3. Competence

Adapted to context

Special attention to vulnerable populations

Main ethics issues

Privacy and personal data

Data protection **by design** and **by default**

Key consideration at early stages and throughout its lifecycle

Data Protection Officers – Specific background and expertise

Data Protection Impact Assessment (DPIA)

Lawful Basis



Main ethics issues

Research in low and middle-income countries

Involving the communities where research takes place

- *Assessment of vulnerability*
- *Benefit sharing*
- *Absence of local ethics structures*



Use of local resources

- *Use of local materials or human resources*
- *Compensation policy*

War, epidemics and political pressure

- *Safety of participants*
- *Safety of researchers*

Main ethics issues

Environment & Health Safety

Toxic chemicals and/or explosives

Radioactive material

Pathogens

GMOs



Main ethics issues

Dual Use

Potential military application

Council Regulation (EC) No 428/2009

Misuse

Discrimination and stigmatisation: During research and/or dissemination of results

Misinterpretation of results: Preventing wrong political use of results



Useful links

ERC Ethics Annex available on-line

<https://erc.europa.eu/content/ethics-self-assessment-step-step>

For more information:

“How to complete your ethics Self-Assessment”

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

Useful links

European textbook on ethics in research

<https://publications.europa.eu/en/publication-detail/-/publication/12567a07-6beb-4998-95cd-8bca103fcf43>

Handbook on European data protection law

<https://publications.europa.eu/en/publication-detail/-/publication/5b0cfa83-63f3-11e8-ab9c-01aa75ed71a1/language-en>

H2020 Online Manual - Ethics

Reference documents

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

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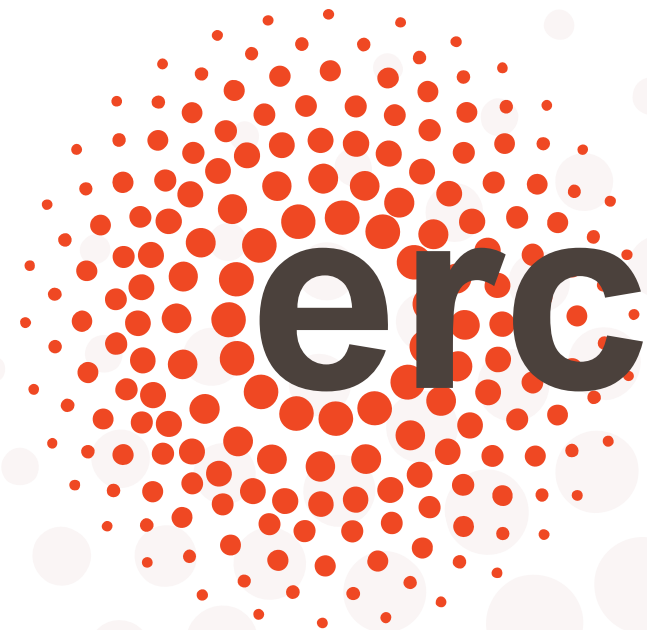
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Preguntas generales



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¿Cambios para el ERC en Horizon Europe?

Preguntas de carácter financiero

Consulta al Project Officer asignado al proyecto

Centralised mailbox: **ERC-C2@ec.europa.eu**

PI helpdesk mailbox: **ERC-C2-PI-HELPDESK@ec.europa.eu**