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Ethics in ERC Proposals and Projects

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Norway National Webinar on Ethics in the ERC
17 February 2022

European Commission

1. **Ethics process in HE – Key Aspects**
2. **Before the Ethics review**
3. **ERC ethics review in HE (pre-granting)**
4. **ERC ethics monitoring in HE (during the lifetime of the project)**
5. **References**

Ethics process in HE– Key Aspects: Why

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- To ensure that each ERC grant respects EU ethics principles in research
  - *Protecting the **subjects of research** and the **researchers***
- To respect legal obligations
  - *HE Framework Programme - Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19)*
  - *ERC Rules of submission and evaluation: any proposal which contravenes ethical principles and/or does not comply with security rules may be rejected from the evaluation, selection and award procedure at any time.*
- To help researchers considering and elaborating on the ethics aspects of their ethics complex projects

ERC ethics process in HE – Key aspects

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Responsibilities

- Responsibility for ethics lies with the ones carrying out the research
- Accountability lies with the signatory of the Grant Agreement, the HI
- Trust in researchers and scientific institutions to manage ethics issues with which they are familiar
- Principle of subsidiarity

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ERC ethics process in HE – Key aspects

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Serious and Complex ethics issues

- Guidelines

  Identifying serious and complex ethics issues in EU-funded research

- Undergo an ethics assessment
- Outstanding ethics requirements become contractual obligations as part of the grant agreement

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ERC ethics process in HE – Key aspects

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Serious and 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

ERC ethics process in HE – Key aspects

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Keep on file documents vs deliverables

- Used at any step of the ethics process
- HI/PI must handle the ethics issues in the proposed activities in line with National and European legislation
- EthSR should inform about conditions needed to ensure ethics compliance
- No contractual deliverables will be generated
- All relevant documentation must be kept on file and provided upon request

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ERC ethics process in HE – Key Aspects

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Ethics deliverables

- Contractual obligation (as in H2020)
- Reporting from ethics advisor or ethics board
- Only for grants with serious or complex ethics issues
- ERC will assign an Ethics Officer (EO), who will monitor the ethics aspects and support PI and HI

Ethics Review and Monitoring

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1. Ethics process in HE – Key aspects
2. Before the Ethics review
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Before the ethics review - Application

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- **Ethics Issues tables**
- **Ethics self-assessment (Part A)**
- **Annexes** can be included (approvals, authorizations,…)

Before the ethics review – EIT

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1. Human embryonic stem cells (hESCs) & human embryos
2. Research involving humans
3. Human cells or tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment, health and safety
8. **Artificial intelligence**
9. Other ethics issues

Crosscutting issue: potential misuse of results

Before the ethics review - EIT

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- Artificial Intelligence added as an activity potentially raising ethics issues

8. Artificial Intelligence			Page
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	○ Yes	◉ No	

- **Misuse** and **dual use** excluded from ethics issues table and added in new security table
  - Security Issues Table: misuse issues concerning security rules (for instance activities that could result in the development of chemical weapons that could be adapted for criminal activities).
  - Ethics table: Any potential misuse issues not covered in the Security Issues Table should be flagged and analysed under the relevant ethics sections (humans, personal data, animals, environment, health and safety, artificial intelligence, other ethics issues, etc).

Before the ethics review - Do's and don’ts

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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 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!)

Before the ethics review -You're not alone!

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- Ethics committees
- Data protection officers
- Persons specialized in your domain and /or in ethics
- Ethics Adviser or Board
- ERC internet site – www.erc.europa.eu
- Guidance – How to complete your ethics self-assessment?

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Ethics review procedure

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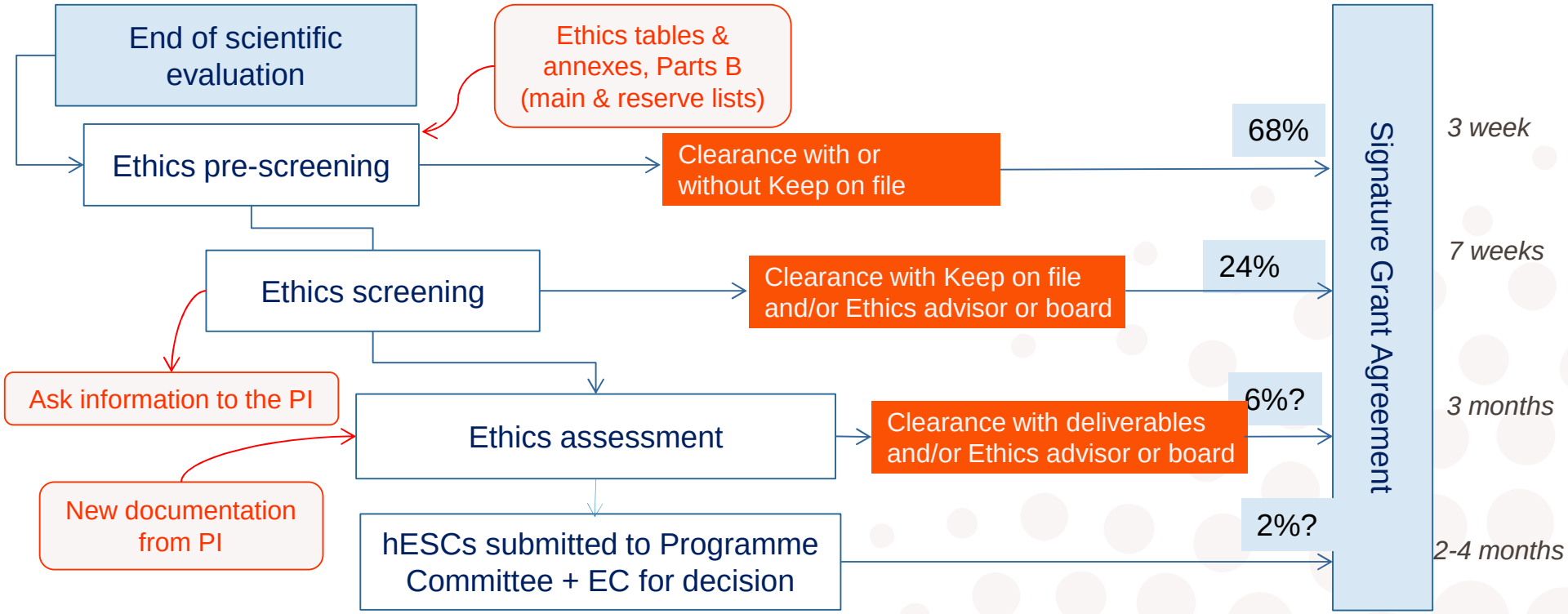

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Additional information requests

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

Dear [redacted]
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 panel has analysed the information you provided (including your self-assessment) and has drafted a report that is included in this letter. 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 by the panel so that they can be further analysed.

We invite you to submit the requested information and any supporting documentation that may be necessary to address the panel's comments 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, Anne-Sophie IOTTI (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:
[redacted]

Don't hesitate to contact us.

With kind regards,

Bernardus TUBBING
Head of Unit

HUMANS:

- More detailed information on the procedures and criteria to identify/recruit research participants
- More detailed information on the informed consent procedures for the research participants, including for the processing of personal data
- Clarification of whether vulnerable individuals/groups will be involved, and, if so, adequate measures to protect them, prevent coercion and undue inducement, exacerbation of their vulnerability, and minimise the risk of harm and/or stigmatisation
- Description of incidental/unexpected findings procedures and related disclosure policy
- Copies of opinions/approvals by ethics committees and/or competent authorities for the research with humans together with the full application(s)

Example of questions to be answered

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Do's and don'ts

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Do

- Provide as much information as you can in your answer
- Provide a point-by-point answer to the questions asked
- Contact the EO (in time) if you have doubts or need help understanding the report
- Provide approvals and official documents, if you have them
- Provide english translations of official documents written in languages other than the 24 EU languages

Don't

- Don’t worry if you don’t have all the official documents in place in time and don’t delay your submission to provide those without consulting with the EO. They can be provided afterwards
- Don't forget to sign your answer

Ethics Summary Report - Clearance

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

[redacted]

Dear representative of the host institution,

We have now finalised the ethics review process of your proposal. Please find attached the ethics summary report. It provides an analysis of the ethics issues involved in your proposal, and it may bring some particular concerns to your attention.

No further action is required from you before the signature of the Grant Agreement.

The responsibility for an ethically sound implementation of the project lies with the scientists and organisations that carry out the work. However, contractually, the responsibility lies with the Host Institution as signatory of the Grant Agreement. Collectively, the beneficiaries carry the responsibility to follow the ethical provisions laid out in, and deriving from, the Horizon Europe Framework Programme.

ERC grants have a long duration and offer considerable freedom to the Investigator(s) to (re) direct the research. Should the research develop in directions that raise additional ethics questions - not covered in this report – this should be brought to the attention of the ERCEA, either by means of an amendment, or informally by contacting the ERCEA Ethics Sector (ERC-ETHICS-MONITORING@ec.europa.eu, [redacted]n subject line).

With kind regards,

Victor LOSADA GONZALEZ
Acting Head of Unit

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Ethics Summary Report - Clearance

European Research Council

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Ethics Issues

On the basis of the proposal's methodology and the ethics self-assessment provided, the ethics review identified the following ethics issues:

No ethics issues were identified.

Ethics analysis

This section summarises and concludes the analysis performed during the ethics review.

No ethics issues were identified in this proposal. It is therefore cleared for granting.

Ethics clearance – no issues

Ethics Issues

On the basis of the proposal's methodology and the ethics self-assessment provided, the ethics review identified the following ethics issues:

Environment, Health and Safety

- This activity involves the use of substances or processes that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, as a possible impact)

Ethics analysis

This section summarises and concludes the analysis performed during the ethics review.

The research described in this proposal appears to involve the ethics issues as noted in the table above. We draw your attention in particular to the necessity to ensure that the appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed by the staff involved in this project, and particularly in the work with high-power lasers. The proposal is ethically cleared for granting, in the understanding that the ethics issues will be managed by the PI and the institution(s) involved, in compliance with the provisions of the Grant Agreement. All relevant documentation should be kept on file and provided upon request.

Ethics clearance – with issues & documents to KoF

Ethics Summary Report - Clearance

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External Independent Ethics Advisor / Board

This section identifies if the project is requested to appoint an external independent ethics advisor or an ethics board.

Appointment of an ethics board is foreseen.
A first periodic report is anticipated at month 12 after the project starts.
Due to a number of ethically sensitive aspects of the proposal which are not clarified sufficiently, an independent Ethics Board must be established and include members with the relevant expertise (transgender clinical psychology, clinical endocrinology, personal data protection) to monitor the ethical concerns of this project. Periodic reports from the Ethics Board must be provided in yearly intervals. The ethics report should discuss how ethical issues were handled by the research team during the reporting period (including unexpected findings policy), if any new issues emerged, and how they can be addressed (if applicable). The ethics report must include copies of relevant authorisations, as well as related documentation. The applicant is invited to send the CVs of the suggested members of the Board and discuss their appointment with the Ethics Officer as soon as possible. Guidance for Ethics Advisors/Boards can be found under: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/roles-and-functions-of-ethics-advisory-ethics-advisory-boards-in-ec-funded-projects_he_en.pdf.

Annexes:

Ethics clearance – with issues & Ethics board requested (after a secreening or assessment panel)

Ethics Summary Report – Conditional Clearance (after assessment)

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We have now finalised the ethics review process of your proposal. Please find attached the ethics summary report. This report provides an analysis of the ethics issues of your proposal and includes a list of requirements that need to be fulfilled in order to guarantee that the ethical standards of H2020 are ensured. For each requirement, the report indicates whether the requirement has already been fulfilled or whether it still needs to be addressed during the execution of the grant agreement.

Please note that this list of requirements is not exhaustive. The beneficiary remains responsible for following the ethical principles laid out in Treaties of the European Union and the Horizon 2020 framework programme, even when no ethics requirements are defined by the Agency.

No further action is needed from you before the signature of the grant agreement.

(example from H2020)

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 Summary Report – Conditional Clearance (after assessment)

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Ethics Issue	Requirement	Category
Humans	Project-specific templates of the information sheets and informed consent forms in a language and terms understandable by the research participants must be provided. The templates must include all the relevant information regarding the protection of personal data. This must be submitted as a deliverable before research with humans begins. Number of months to fulfill the requirement after the project starts: **18**	Deliverable
Humans	The applicant must clarify whether minors ("young followers", "Muslim youth") will be involved and, if so, a justification for their participation must be provided. If applicable, the applicant must confirm that relevant national and EU law safeguards will be complied with and clarify how consent/assent will be ensured in case minors are involved in the project (e.g. from social media platforms or apps). Reasons: *No minors will be involved. Active observation of children will not take place*	Not Applicable
Humans	Detailed information on the unexpected findings policy must be provided. In case of unexpected findings, the disclosure policy must be described.	Fulfilled
Animals	The applicant must provide proof that the staff involved in the procedures with animals has received adequate education and training before performing any of the functions described in art.23 of the Directive 2010/63/EU, for example by providing copies of training certificate(s) /personal licence(s).	Keep on file

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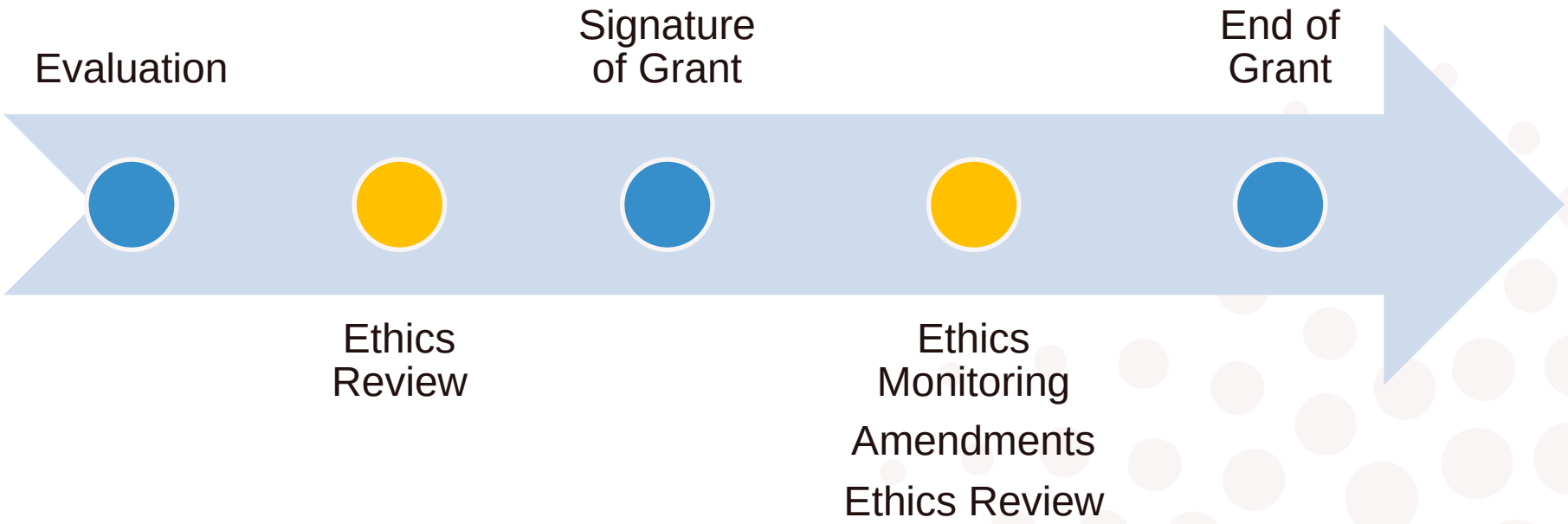

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Ethics issues to be monitored

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- 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.

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Personalized assistance by an ethics officer

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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]

New in HE

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Ethics review during project implementation

- Conducted with independent ethics experts
- By recommendation of the ethics experts or the EO for serious ethics issues or
- Randomly, for projects cleared with “Keep on file” documents

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Useful documents

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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 (under REACH, including guidance for nanomaterials)
Global Code of Conduct for Research in Resource-Poor Settings

The end

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Thank you for your attention

Carolina.avila@ec.europa.eu

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