The European Research Council

Ethics review process under ERC grants

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PI-HI centric event, Paris

European Research Council

Established by the European Commission

Overview

- Mission of the ethics team within Horizon Europe
- Serious or Complex ethics issues
- Ethics appraisal procedure
  - Ethics review
  - Ethics monitoring
- Practical information

Ethics Review and monitoring

Mission

- To ensure that each ERC grants respect EU ethics principles in research
- To respect legal obligations
- HE Framework Programme - Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19) : *identify actions which raise complex or serious ethics issues*
- To support researchers handling ethics aspects of their proposals

Ethics Review and monitoring

Team

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

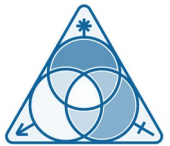
Ethics appraisal procedure in Horizon Europe – Key aspects

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

Serious 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



Ethics issues – Categories

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 - crosscutting issues: potential misuse of results

1. Human Embryonic Stem Cells and Human Embryos		Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?	○ Yes ◉ No	
Will they be directly derived from embryos within this project?	○ Yes ◉ No	
Are they previously established cells lines?	○ Yes ◉ No	
Are the cell lines registered in the European registry for human embryonic stem cell lines	○ Yes ◉ No	
Does this activity involve the use of human embryos?	○ Yes ◉ No	
Will the activity lead to their destruction?	○ Yes ◉ No	
2. Humans		**Page**
Does this activity involve human participants?	○ Yes ◉ No	
Are they volunteers for non medical studies (e.g. social or human sciences research)?	○ Yes ◉ No	
Are they healthy volunteers for medical studies?	○ Yes ◉ No	
Are they patients for medical studies?	○ Yes ◉ No	
Are they potentially vulnerable individuals or groups?	○ Yes ◉ No	
Are they children/minors?	○ Yes ◉ No	
Are they other persons unable to give informed consent?	○ Yes ◉ No	
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	○ Yes ◉ No	
Does it involve invasive techniques?	○ Yes ◉ No	
Does it involve collection of biological samples?	○ Yes ◉ No	
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	○ Yes ◉ No	
Is it a clinical trial?	○ Yes ◉ No	
Is it a low-intervention clinical trial?	○ Yes ◉ No	

Serious 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**

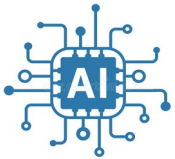
4. Personal data
   - **Special categories** of personal data – minimisation principle
   - Unclear roles and data processing techniques under **GDPR**
   - Consult with the HI's Data Protection Officer

Serious or complex ethics issues - Examples

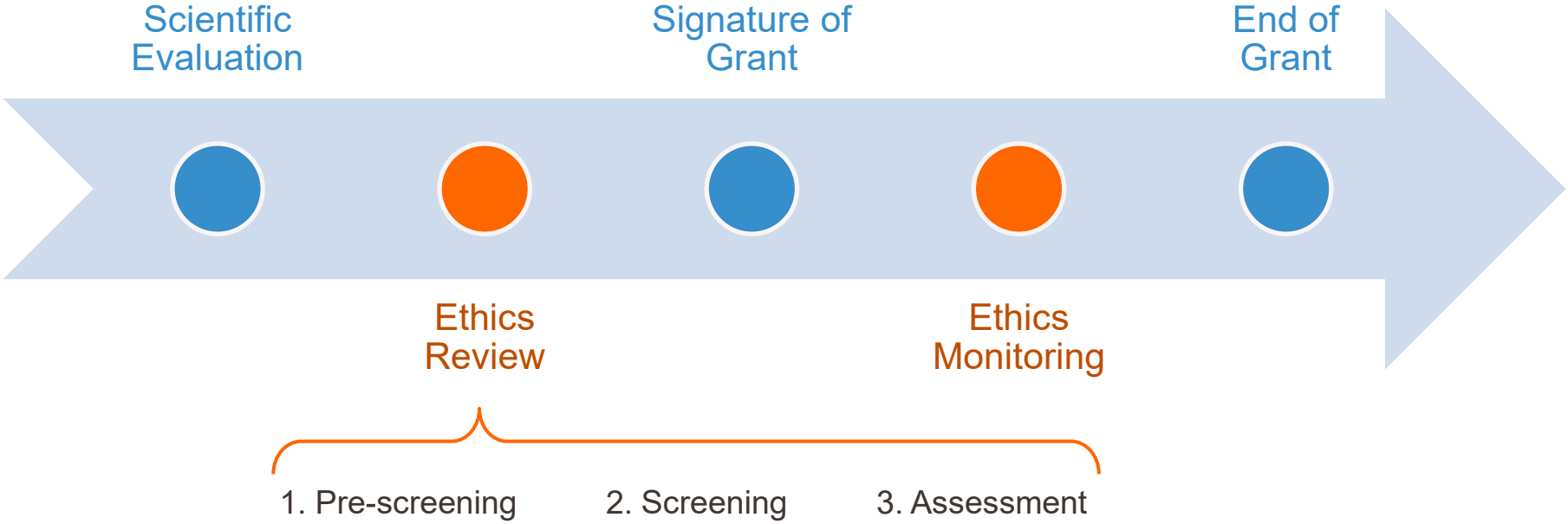
5. Animals
   - Severity of the experiments
   - Work with **Non-human primates**

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

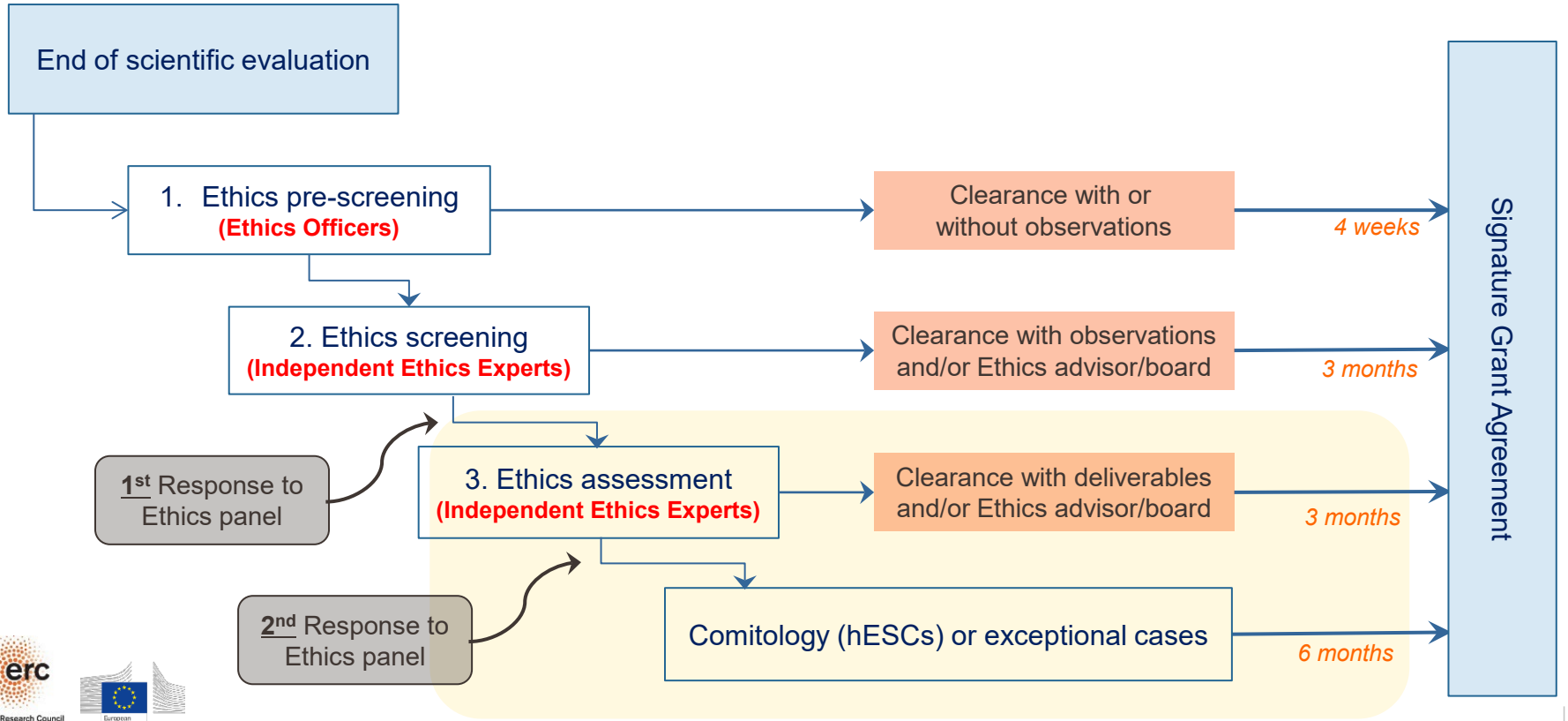
8. Artificial Intelligence
   - Influence on **human decision**
   - Profiling and bias



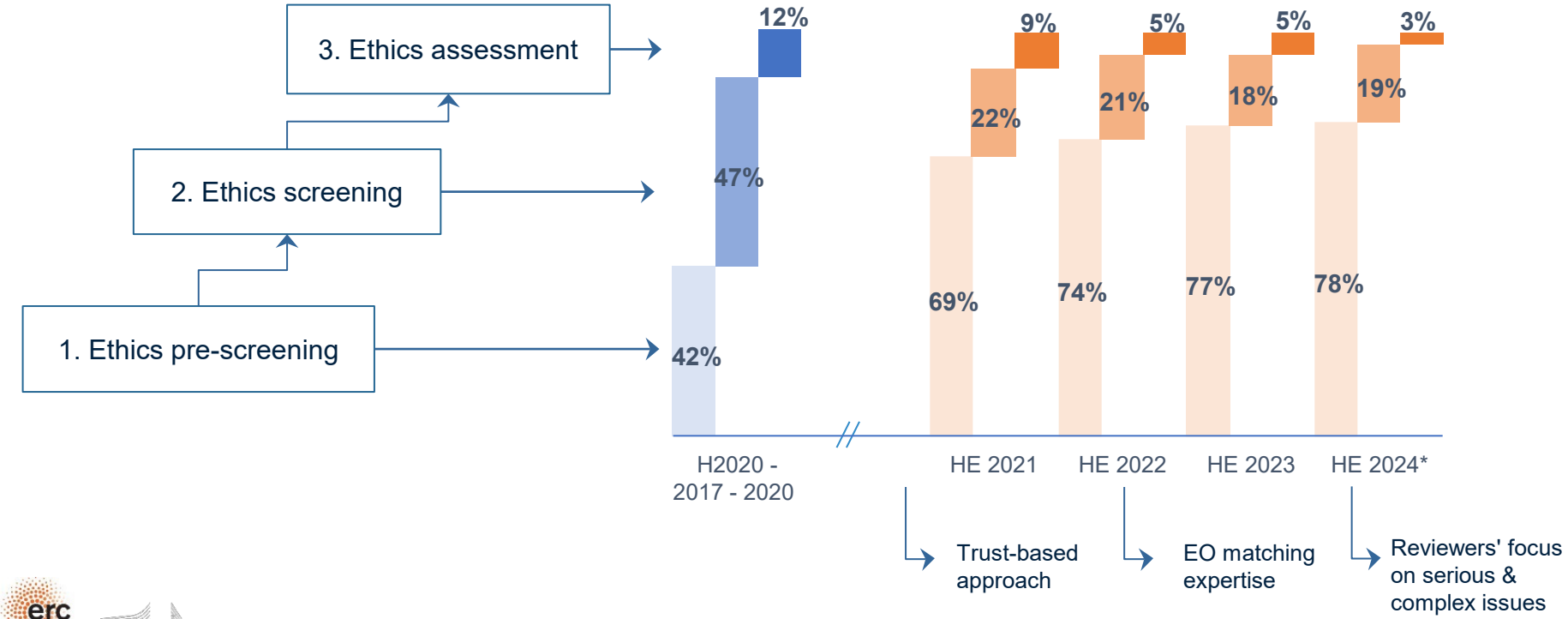
Ethics Review Process



Ethics Review Process



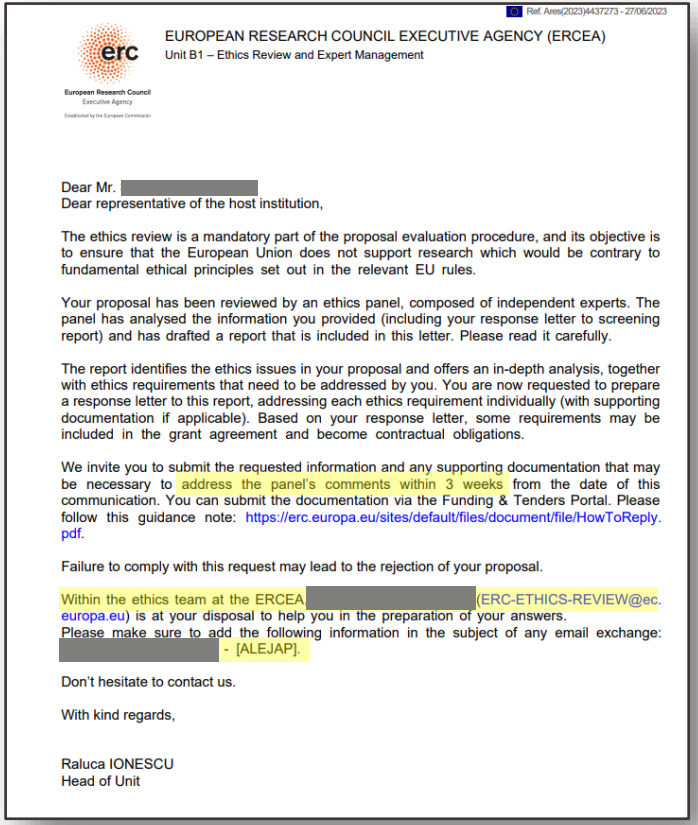
Ethics Review – Clearance ratios



* AdG24 call not included

Practical information during pre-granting

- When needed, an **Additional information request** is sent to the applicants after Screening and Assessment
  - List of ethics issues identified
  - Analysis of the ethical dimension of the proposal
  - Pending issues to be answered within 3 weeks
  - Contact point of your ethics officer
    - 123456-Acronym-**[CAMICH]**
- Ethics Summary Report



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

European Research Council Executive Agency
Established by the European Commission

Dear Mr. [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 response letter to screening report) 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 offers an in-depth analysis, together with ethics requirements that need to be addressed by you. You are now requested to prepare a response letter to this report, addressing each ethics requirement individually (with supporting documentation if applicable). Based on your response letter, some requirements may be included in the grant agreement and become contractual obligations.

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.

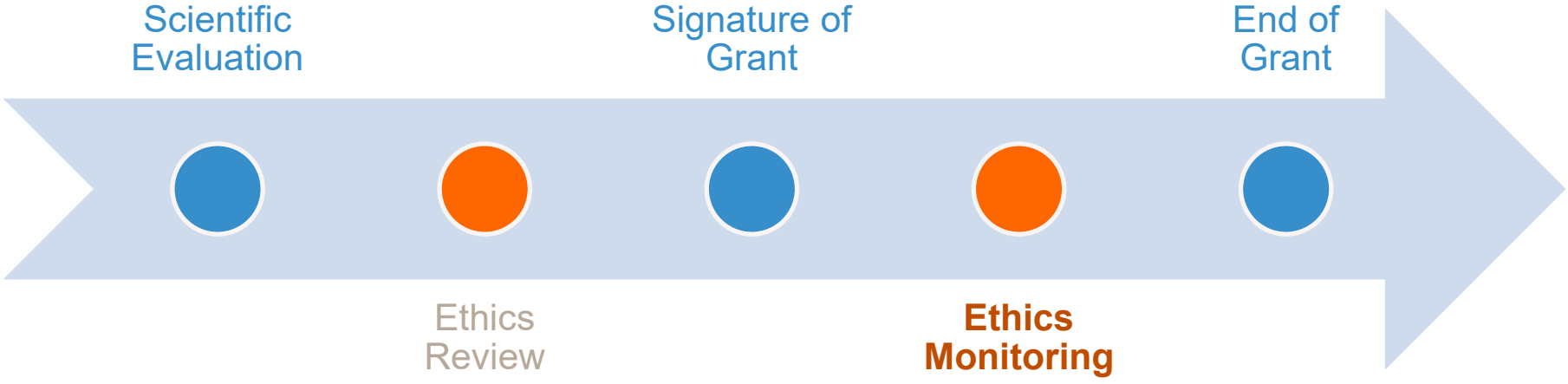
Within the ethics team at the ERCEA, [redacted] (ERC-ETHICS-REVIEW@ec.europa.eu) is at your disposal to help you in the preparation of your answers.
Please make sure to add the following information in the subject of any email exchange: [redacted] - [ALEJAP].

Don't hesitate to contact us.

With kind regards,

Raluca IONESCU
Head of Unit

Ethics Monitoring process



Ethics Monitoring

- **Pending ethics issues** to be addressed during grant implementation
  - Ethics deliverables
  - Ethics advisor/board
  - Ethics review

- **Amendments** that significantly change the description of action and may raise new ethics issues
  - Change in HI – inherited ethics obligations

- **Adaptable** to the research calendar
  - Ethics issues must be always addressed before experimentation begins
  - Ethics deliverables are contractual obligations

- **ERCEA** can ask for **“Keep on File” documents at any time** during (and even after) the implementation of the grant

Ethics Monitoring

European Commission | Funding & tender opportunities
Single Electronic Data Interchange Area (SEDIA)

My Project(s) > Actions > Manage Project > Continuous Reporting > Deliverables

Work Pac	Delivera	Deliver	Deliverable Name	Description	Lead I	Type	Dissemin	Due Date	New Due Da	Delivery Da	Approval Date	Status
WP1	D1.1	D1	Data Management Plan	Drafting Data Management Plan		DMP	SEN	31 Mar 2023				Pending
WP2	D2.1	D2	H - Requirement No. 1	Project-specific templates of the information s...		Ethics	SEN	31 Mar 2023				Pending
WP2	D2.2	D3	H - Requirement No. 2	Copies of opinions/approvals by ethics committe...		Ethics	SEN	31 Mar 2023				Pending
WP2	D2.3	D4	POPD - Requirement No. 3	For personal data that are to be transferred fr...		Ethics	SEN	31 Mar 2023				Pending
WP2	D2.4	D5	POPD - Requirement No. 4	A project specific data organisation strategy m...		Ethics	SEN	31 Mar 2023				Pending
WP2	D2.5	D6	H - Requirement No. 5	As the project may collect data on activities w...		Ethics	SEN	31 Mar 2023				Pending
WP2	D2.6	D7	NEC - Requirement No. 6	Detailed information on the fair benefit-sharin...		Ethics	SEN	30 Sep 2024				Pending
WP2	D2.7	D8	NEC - Requirement No. 7	An assessment of the risks to research particip...		Ethics	SEN	31 Mar 2023				Pending

- Ethics deliverables are deliverables of the type **Ethics**
- Each **deliverable** due date is **adjusted** according to the **needs** of research activity during the lifetime of the grant
- Access to the F&T portal shared between PI and HI

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Ethics Monitoring

Pending	- Deliverable is still required to be provided or has been re-opened to upload future documentation
Submitted	- Deliverable has been submitted
Pending	- Deliverable due date has passed
Draft	- Deliverable still to be properly submitted, cannot be closed or approved by ERCEA
Approved	- Deliverable has been approved

Practical information during project implementation

- An **Ethics Monitoring Note** is sent every time a monitoring is carried out
  - List of deliverables to be fulfilled
  - Detailed comments on the submitted documents/explanations
  - If an ethics deliverable needs to be further addressed later during the project, the **deliverable** is **reopened**, and an **automatic email** is sent informing that the deliverable has been **rejected**. **Do NOT panic**! – Read the deliverable comments on the portal

Dear Participant,

We regret to inform you that the deliverable 'D1.1 - HCT - Requirement No. 2' for your above project has been rejected. For more details, please log on to the Funding & Tenders Portal > My Project(s) (https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/myarea/projects) and click on Actions > Manage Project.

Regards,
Grant Management Services

Please do not reply to this message
This message has been automatically generated by the Grant Management Services of the European Commission.

Ethics Monitoring

- **Special monitoring activities:**
  - **Ethics review of grant Amendments**

    Amendment requested by the researcher and host institution that raise serious and/or complex ethics issues
  - **Ethics Review after granting**

    Recommended by the ethics experts during the pre-granting ethics review

    Requested by the ethics officer in charge of the grant

    Randomly selected

➢ Research activity to be designed after the start of the grant
➢ Outstanding/pending complexity yet to be resolved
➢ Scenarios where ethics misconduct was alerted to the ERCEA

HI' Support throughout the Project life is crucial

PI-HI Collaboration

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

Practical information – useful links

- **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

- ERC Website – Managing your projects – Ethics

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

Practical information – 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!

Share your opinion ☺

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