#HorizonEU

**THE EU
RESEARCH & INNOVATION
PROGRAMME**

2021 – 2027

**Ethics Appraisal Procedure
HORIZON EUROPE (HE)**

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European Commission
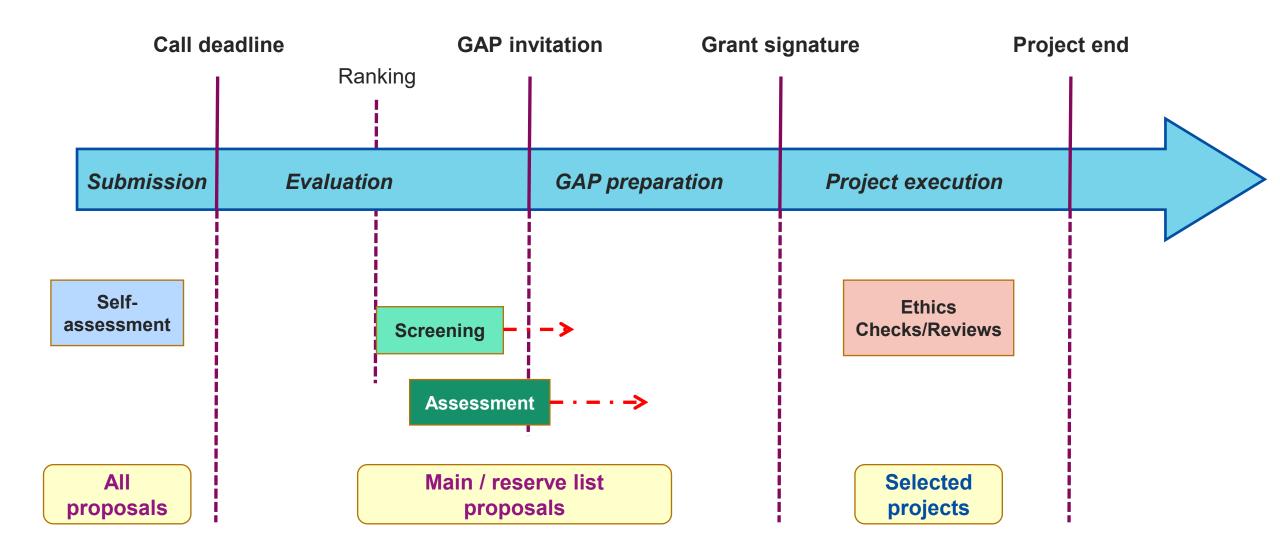
Research and Innovation

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2. 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

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Crosscutting issue: potential misuse of results

1. Human embryonic stem cells (hESCs) and human embryos

2. **Humans**

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Crosscutting issue: potential misuse of results

- **Misuse from the security perspective** is covered by the Security Screening.

  E.g. research activities that could generate knowledge, materials and technologies that could be adapted for criminal/terrorist activities; or result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery.

- **Misuse not related to the security dimension** will be analysed as part of the relevant ethics sections (humans, personal data, animals, environment, health and safety, artificial intelligence) or as 'other ethics issue'.

  E.g. the development of surveillance technologies that could curtail human rights and civil liberties.

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How should you prepare the ethics section of the proposal?

Step 1: The Ethics Issues Table

Application Forms

Proposal ID **XXXXXXXXX**   Acronym **XXXXXXX**

4 – Ethics and Security

Ethics issues table

This table should be completed as an essential part of your proposal. Please go through the table and indicate which elements concern your proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any of the questions,

- *indicate in the adjacent box at which page in your full proposal further information relating to that ethics issue can be found, and*
- *provide additional information on that ethics issue in the Ethics Self-Assessment section.*

For more information on each of the ethics issues and how to address them, including detailed legal references, see the guidelines 'How to Complete your Ethics Self-Assessment'.

2. HUMANS			Page
Does this activity involve human participants?		○ Yes ○ No	
If **YES**:	Are they volunteers for nonmedical 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	
If **YES**:	Does it involve invasive techniques?	○ Yes ○ No	
	Does it involve collection of biological samples?	○ Yes ○ No	

Step 2: Self-assessment

If any YES in the Ethics issues Table… → Ethics Self-assessment

HE Regulation (Article 19 (2)):

- 'Legal entities participating in an action shall provide:

(a) an ethics self-assessment <u>identifying and detailing all the foreseeable ethics issues</u> related to the <u>objective, implementation and likely impact</u> of the activities to be funded, including a confirmation of compliance (…) and a description of <u>how it will be ensured</u>.'

Step 2: Self-assessment

- Explain how ethics issues will be addressed

    → Describe the ethical and legal requirements applicable to your research and how they will be met

- List appropriate documents that will be provided/kept on file as evidence

- Applications should be 'Ethics Ready'

Step 2: 'How-to'

Section 2: HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
Does your activity involve human participants?		☐	☐	Please provide information in one of the subcategories below	
If YES:	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	☐	☐	1) Details on recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on unexpected findings policy.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they healthy volunteers for medical studies?	☐	☐	1) Details of the recruitment, inclusion and exclusion criteria and informed	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.

EC process first step: Ethics Screening

Ethics Experts screen all proposals to identify main ethics issues, and flag them for the next steps

➔ No ethics issues? ➜ **CLEARED**

➔ Ethics issues? ➜ **FLAGGED**

  ➔ Beneficiaries further deal with issues, in accordance with national and European legislation – **no further requirements** in the Ethics Screening Report

  ➔ **!** Experts can require **ethics check or review** or external <u>independent ethics advisor or board</u>

➔ Serious and/or complex ethics issues? ➜ **ETHICS ASSESSMENT**

Ethics Appraisal Process: Assessment

- Performed by **at least four external experts** (with one of them acting as raporteur).

- Uses the **full Ethics Issues Table** (same as in the proposal) and verifies the applicable ethics issues.

- Defines **ethics requirements** for ethics issues not satisfactorily addressed in the proposal.

- Decides if the grant should be subject to an **ethics check or ethics review** during the project implementation.

- Decides if the beneficiaries need to appoint an **independent ethics advisor or ethics board** (if yes, this request is implemented as an ethics requirement).

- **Outcome:**

  - **Ethics clearance** — proposals without serious or complex ethics issues, no requirements.

  - **Conditional ethics clearance —** at least 1 requirement is entered.

  - **Additional information requested —** only if the elements can easily be gathered.

  - **Go to second ethics assessment** — only in exceptional cases when it is not possible to formulate a list of suitable requirements. **Required to declare a proposal NOT ethically acceptable.**

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Serious and/or complex ethics issues?

- **Examples**:

  - Research involving **profiling and/or systematic monitoring of individuals or group of individuals, and/or intrusive methods of data processing** (e.g. data-mining, web-crawling, social network analysis, geolocation tracking).

  - Research resulting in the **transfer of special category data to countries with inadequate data protection regimes**, without the knowledge or explicit consent of the data subjects.

  - Research that employs **covert methods or deception** that may cause harm to participants (or researchers), or entails participation in **unlawful activities**

  - Research that appears to **take advantage of differences in standards or the absence of legislative protection** for research participants.

  - Guidelines on serious and complex cases

ANNEXES
Key principles and points of attention of common ethics issues

Human participants

- Humans must be considered as 'research participants' whenever they are:

  - **recruited, observed, actively engaged, or in any other way may be influenced, manipulated, or directed by the research**.

  - Regardless of the nature, methods, or topic of the proposed research activities (e.g. collecting biological samples, using personal data, medical interventions, interviews, observations, tracking etc.), **ethical issues may arise in any research involving humans**.

Ethics issues in social sciences & humanities?

Potential harm to human participants (and researchers!)

- E.g. psychological distress, social exclusion, security risks, …

Incidental findings

- E.g. violence, child abuse, security threats, …

Internet and social media research

- Consult the relevant **terms and conditions of the platforms** they will be using to obtain your data

- Ascertain **whether the data are really public** (open platforms vs password-protected fora)

Artificial Intelligence

Key principles and points of attention

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Artificial intelligence

Self-assessment: Could the AI system/technique <u>stigmatise or discriminate</u> against people (based on sex, race, ethnic/social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?

→ Explain how potential bias, discrimination and stigmatization will be avoided.

→ **‘Ethics by design’ methodology**: concrete steps for each phase in the development process. E.g.:

- **Check for algorithmic bias during the detailed development phase**. Data could be processed in a biased way, and therefore algorithms should be checked for this. (E.g. by using counterfactual evaluation methods)

- Ensure that interface design honours principles of universal accessibility, and avoid the introduction of functional biases in the detailed development phase that make the system unequally functional for different end-users.

Artificial intelligence

EU Artificial Intelligence Act

Coming up

Date	Application: The following rules start to apply:	Related AI Act Content
2 August 2025	• Notified bodies (Chapter III, Section 4), • GPAI models (Chapter V), • Governance (Chapter VII), • Confidentiality (Article 78) • Penalties (Articles 99 and 100)	Article 113(b)
Date 2 August 2026	**Application:** The remainder of the AI Act starts to apply, except Article 6(1).	Related AI Act Content Article 113

Research involving non-EU countries

Key principles and points of attention

Research involving non-EU countries

Activities carried out in a non-EU country must:

1. **Comply with the laws of that country**

2. **AND be legal in at least one EU Member State**

Personal Data transfers?

- Covered under the **PERSONAL DATA** section, but **the same principles** apply!

➜ Privacy and data protection laws of non-EU country (! Data sovereignty provisions)

➜ General Data Protection Regulation (Chapter V)

➜ EU Member States derogations under the national legislation, e.g. pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data.

Personal Data transfers?

There is no cloud
it's just someone else's computer

- **4** possible 'legal basis' for data transfers:

    1. Explicit consent

    2. Adequacy decision

    3. Data transfer agreement with standard contractual clauses

    4. Binding corporate rules (approved by data protection authority)

    + some exceptions (E.g. 'specific justification' situations (Article 49 GDPR))

- ‼ <u>Use anonymized data whenever possible</u>. Pseudonymise to minimize risks

- ‼ Remote access to a server in non-EU country is also a data transfer

Key Sources:

HE Framework Programme Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19)

Horizon Europe Model Grant Agreement (MGA) (Article 14 and Annex 5)

HE Specific Programme Decision 2021/764

HE Programme Guide

How to complete your ethics self-assessment

ALLEA European Code of Conduct for Research Integrity