Ethics Obligations in Horizon Europe

Horizon Europe (HE), as well as other European Programs requires applicants and grant beneficiaries to comply with the ethics and research integrity obligations defined in Art. 19 of "Horizon Europe Framework Programme and Rules for Participation Regulation (EU) 2021/695 (OJ L 170, 12.5.2021)", to the "highest ethical standards" and "EU values" referred to in Article 14 of the Model Contract (Grant Agreement); to the principles of Research Integrity, collected in The European code of conduct for research integrity (ALLEA).[1]

A summary of mandatory and recommended ethics practices is available in section 12 of the Horizon Europe Programme Guide.

Ethics obligations in HE are divided into:

- Ethical appraisal (application phase)
- Ethics review (evaluation phase)
- Ethics checks, reviews, audits (implementation phase)

SUBMISSION PHASE:

Ethics Appraisal:

In the Online Part on the F&T Portal (PART A or Administrative Forms) under Section 4 - *Ethics & Security* you must answer questions asked in an **ethics issues table**. If you answer YES to one or more of the questions, indicate the page number where the topic is covered in Part B (B2 for ERC, B1 for MSCA) and complete the Ethics Self-Assessment section found at the end of the first table. In some sections an affirmative answer opens up additional questions.[2] The issues in question are relevant to most European programmes.

The ethics issues covered are:

1. Human embryonic stem cells (hESCs) and human embryos (hEs)
2. Humans
3. Human Cells/Tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment, Health, Safety
8. Artificial Intelligence (AI)
9. Other Ethics Issues

[1] Research fields that are not eligible for HE funding are: human cloning for reproductive purposes; research intended to modify the genetic heritage of human beings which could make such changes heritable; research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer; destruction of human embryos (for example, for obtaining stem cells. In addition, no funding shall be provided within or outside the Union for research activities that are prohibited in all Member States, and no funding shall be provided in a Member State for a research activity which is forbidden in that Member State.

[2] In particular, the following is required:
(a) an ethical self-assessment in which all foreseeable ethical issues related to the objective, implementation and likely impact of the activities to be funded are identified and described, including a confirmation of compliance with ethical principles and regulations and a description of how this will be ensured;
b) confirmation that the activities will comply with the European Code of Conduct for Research Integrity published by ALLEA and that no activities excluded from funding will be carried out (Art 18 EU Regulation 2021/695 (OJ L 170, 12.5.2021);
(c) for activities carried out outside the Union, confirmation that the activities in question would have been authorized in a Member State;
(d) for activities involving the use of human embryonic stem cells, where appropriate, a detailed description of the licensing and control measures to be taken by the competent authorities of the Member States concerned, as well as the ethical approvals to be obtained prior to the start of the activities in question.

The **ethics self-assessment** is mandatory for all proposals with one 'yes' in the **ethics issues table.**
It is composed by two parts:

- Explain the identified ethics issues in relation to the ethical dimension of the objectives, methodology and likely impact: in this part you are required to identify ethical issues, guided by the answers given in the ethics issues table. It is advised to provide appropriate documents as evidence, or, in lack of these, timeframes for approvals/authorizations
- Explain how you will address the ethics issues identified in the table above, in compliance with ethical principles and relevant legislations (cite and demonstrate compliance with national and European regulations. For activities carried out in non-EU countries, they should be allowed in at least one Member State).

Following the ethics self-assessment, you need to fill in the **security issues table**, where you state whether you deal with classified information, whether you can expect misuse of knowledge and results in the project or other security issues. Again, answering YES to some questions opens up additional questions.

EVALUATION/GRANT PREPARATION PHASE:

Ethics Review:

In addition to their scientific merit, all applications are evaluated on the basis of their ethical and social impact.

All proposals above threshold with a view to funding undergo an **ethics review**[3], carried out by independent experts.

The Ethics review consists of:

- (Optional) Ethics **pre-screening** by at least two ethics evaluators (external experts or qualified members of staff) with or without issues flagged, to confirm or not the absence of ethics issues.

  Possible outcomes:
  - If presence of ethics issues is detected → flagged for screening
  - If no ethics issues detected → ethics clearance

- **Ethics screening** by at least two ethics evaluators (external experts). The key goal is to identify proposals that raise serious or complex ethics issues and must go a full ethics assessment where ethics requirements can be defined.

  Possible outcomes:

  - If no/ non-critical ethics issues → ethics clearance OR
  - If not serious/complex ethics issues are detected → beneficiaries have to further deal with ethics issues in accordance with national and European legislation – no further analysis or requirements in the Ethics Summary Report → ethics clearance

[3] Issues covered by the ethics review: human rights and protection of human beings; animal protection and welfare; data protection and privacy; health and safety; environmental protection; artificial intelligence

- If not serious/complex ethics issues → beneficiaries further deal with ethics issues in accordance with national and European legislation and need to appoint external independent ethics advisor or board → conditional ethics clearance
- Serious or complex issues or involvement of hESC or He→ screening report to be answered and ethics deliverables in GA→ **Ethics Assessment**

GRANT PREPARATION PHASE

In case of presence of serious or complex ethics issues:

- **Ethics assessment**, an in-depth analysis of the ethics issues by a panel of at least 5 external experts. The key goal is to identify additional measures that must be implemented during grant preparation or later during grant implementation, for ethics issues not satisfactorily addressed in the proposal. The **ethics assessment** can lead to ethics requirements that are inserted as obligations in the grant agreement and that are proportionate to the severity of the ethics issues, according to a risk-based approach.

Possible outcomes:

- **Ethics clearance**: ethics section can be transferred to Part B in DoA
- **Conditional Ethics Clearance**: subject to compliance to ethics requirements (during grant preparation and/or during the grant implementation). Requirements due after project start become ethics deliverables, to be included in the GA-ethics requirements WP.
- **Second ethics assessment or more information needed:** GA is postponed
- **No ethics clearance (after second assessment):** proposal is rejected

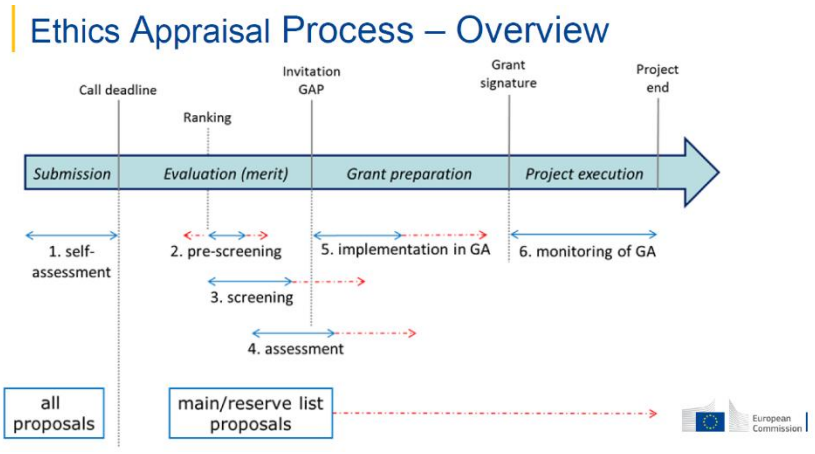
IMPLEMENTATION PHASE

Checks, reviews, audits

For sensitive projects identified by ethics experts:

- **Checks:** internal check by the project officer or ethics officer, may be supported by ethics experts
- **Review**: elaborate review and in-depth procedure carried out by up to 5 external ethics experts
- **Audit**: in case of substantial breaches of ethical principles, carried out by Commission

⚠ The checks, post-grant reviews and audits can result in an amendment of the grant agreement. In severe cases, it can lead, upon the decision of the Commission services to a reduction of the grant, its termination or any other appropriate measures, in accordance with the provisions of the grant agreement



For further information

What is new compared to Horizon 2020:

https://www.youtube.com/watch?v=QJtGzWmBQBw&ab_channel=EUScience%26Innovation

Specific Information for social science research:

Specific guidelines for ethnographic and anthropological research https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-in-social-science-and-humanities_he_en.pdf and https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/research-ethics-in-ethnography-anthropology_he_en.pdf .

Research involving migrants and refugees : Guidance note —Research on refugees, asylum seekers & migrants.

For projects involving personal data: https://www.unitn.it/ricerca/95517/privacy-e-ricerca-scientifica; possible transfer to third parties, import from extra EU or export to non-EU countries: see Unitn privacy and research web-page, for protection and compliance with the GDPR)

In case of research involving animals: Unitn body for animal welfare; https://www.unitn.it/alfresco/download/workspace/SpacesStore/dc14549a-9c69-4487-8b3a-b62907e717c7/procedure%20operative_OPBA.pdf

In the case of research conducted in resource-poor settings:

HE Global of Conduct for research in resource-poor settings: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/global-code-of-conduct-for-research-in-resource-poor-settings_he_en.pdf

For animal and natural resources use indicate compliance with the UN Convention on Biodiversity; genetic resources: Access and Benefit Sharing Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511

In the case of research with environmental impact: Do No Significant Harm Principle (DNSH): Article 17 of Regulation (EU) No 2020/852

In case of research concerning artificial intelligence:

Ethics By Design and Ethics of Use Approaches for Artificial Intelligence

https://futurium.ec.europa.eu/en/european-ai-alliance/pages/altai-assessment-list-trustworthy-artificial-intelligence; self-assessment in order to evaluate the reliability of their AI systems under development, based on 7 basic requirements: https://altai.insight-centre.org/Identity/Account/Register

Guide prepared by APRE ("Design and Consortium Agreement" Guidelines for the Processing of Personal Data in Horizon 2020 Projects): https://apre.it/wp-content/uploads/2021/05/APREquaderni_GDPR_n1.pdf.

Discussion/communication on AI at the EU level https://futurium.ec.europa.eu/en/european-ai-alliance

For more information on the concept of misuse:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/guidance-note-potential-misuse-of-research-results_he_en.pdf

For research involving human beings:

Consistency with the principles of the Declaration of Helsinki and the Oviedo Convention on Human Rights and Biomedicine (for clinical research);

it is necessary to apply to the University's Research Ethics Committee for projects that involve risks to the psychological and physical well-being of the subjects involved, and which may possibly also restrict their own right to confidentiality, information and autonomy in decision-making, or of that of the health care company.

See https://www.apss.tn.it/Azienda/Operatori-e-partner/Comitati/Comitato-etico-per-le-sperimentazioni-cliniche in case of clinical research or research conducted on hospital premises;

Safety procedures under Legislative Decree 81/08 and the certifications and courses that those who access the laboratories must have taken;

The internal regulations on occupational health and safety, issued by R.D. No. 574 of Oct. 5, 2017. More information on safety procedures can be obtained directly from the laboratory manager.