Guide on Ethics Appraisal Procedure in Horizon Europe

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1. Introduction

Ethics compliance is considered crucial to achieve true research excellence in all Horizon Europe activities.[1] All Horizon Europe projects must therefore comply with **ethics principles** and relevant **Union**, **national** and **international law**, including the Charter of Fundamental Rights of the European Union[2] and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols,[3] as well as the European Code of Conduct for Research Integrity,[4] published by ALLEA.[5]

In Horizon Europe programme, »particular attention shall be paid to the principle of proportionality, to the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and to the need to ensure protection of the environment and high levels of human health protection«.[6] Activities should have exclusive focus on civil applications. Research activities that are prohibited in all Member States will not receive funding. Additionally, funding will not be granted to any Member State for research activities that are prohibited within that Member State. Certain activities relating to human embryos are not eligible for EU funding, and the use of human embryonic stem cells might be financed under certain conditions.[7]

This guide is meant as an aid for researchers at University of Ljubljana planning to submit their research project proposal for EU funding in understanding the process of ethics appraisal procedure. When preparing the proposal for submission, the researcher should assess **ethics aspects in the project**. Based on the proposed project methodology, objectives, and potential impact, it is necessary **to identify elements that may pose ethical issues or risks**. Further, **measures to address and mitigate these risks should be implemented**, in accordance with relevant legislation (Union, national, and international), conventions and declarations, national authorisations and ethics approvals.

Ethics approvals should be obtained from relevant ethics committees such as national ethics committees (e.g. Committee of the Republic of Slovenia for Medical Ethics – for studies in the area of health, biomedical research, testing of new drugs, use of complementary traditional and alternative forms of diagnostic, treatment and rehabilitation; Ethics Committee for Animal Experiments – for studies involving animals) or Faculty/University Ethics Committees (e.g. University of Ljubljana's Committee for Ethics in Research Involving Human Subjects), hospital Ethics Committees, and others.

Those engaged in research at University of Ljubljana must also comply with the codes of ethics and integrity, including the Code of Ethics of the University of Ljubljana[8] and Code of Ethics for Researchers at the University of Ljubljana.[9] Further guidance on the management of research ethics and integrity issues at UL can be found on the UL website »Ethics and Integrity in Research«.

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[1] EU (2025). *Horizon Europe (HORIZON) HE Programme Guide* (version 5.1). Brussels: European Commission. Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf.
[2] EU (2012). *Charter of Fundamental Rights of the European Union.* Official Journal of the European Union, C 326. Available at: https://eur-lex.europa.eu/eli/treaty/char_2012/oj/eng/pdf).
[3] Council of Europe (1950). *Convention for the Protection of Human Rights and Fundamental Freedoms*. Rome: Council of Europe. Available at: https://www.echr.coe.int/documents/d/echr/Convention_ENG.
[4] ALLEA (2023). *The European Code of Conduct for Research Integrity* (revised edition). Berlin: ALLEA – All European Academies. Available at: https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf.
[5] EU (2025, orig. 2021). *Regulation (EU) 2021/695 of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013*. Official Journal of the European Union, L 170. Available at: https://eur-lex.europa.eu/eli/reg/2021/695/oj/eng.
[6] Idem (pg. 29).
[7] Idem.
[8] University of Ljubljana (2009). *Code of Ethics*. Ljubljana: University of Ljubljana. Available at: https://www.uni-lj.si/assets/Sluzba-za-raziskovalno-dejavnost/Etika-in-integriteta/EN/Code-of-Ethics-UL.pdf.
[9] University of Ljubljana (2014). *Code of Ethics for Researchers.* Ljubljana: University of Ljubljana. Available at: https://www.uni-lj.si/assets/Sluzba-za-raziskovalno-dejavnost/Etika-in-integriteta/EN/Code-of-ethics-for-researchers.pdf.

2. Ethics appraisal procedure – A brief overview

The process addressing the ethics aspects of activities funded under the Horizon Europe Programme is known as the **ethics appraisal procedure**. It is described in the Horizon Europe (HORIZON) HE Programme Guide and includes the following main activities or elements that support researchers in ensuring ethical compliance throughout the project (Fig. 1):[10]

i) Ethics self-assessment of the proposal by the researcher, which is part of the submission phase of the project proposal.

ii) Initial ethics review procedure, which includes ethics screening and (if needed) further ethics assessment of the proposal, both of which are performed by the European Commission with support from independent ethics experts.

iii) Ethics mentor/ethics advisor/ethics advisory board, who may help the project to assure ethics compliance throughout the project.

iv) Ethics check/ethics review/ethics audit, which might be carried out during the project implementation to check compliance with the ethics requirements and are carried out by the European Commission with support from independent ethics experts.

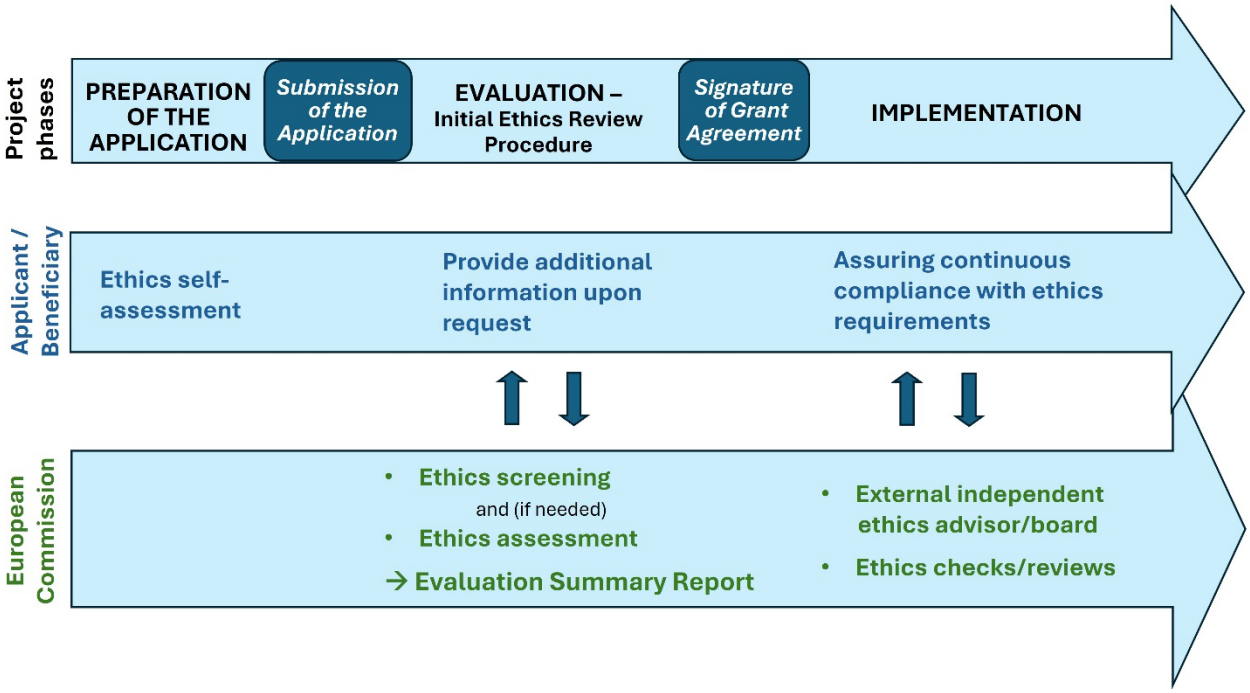

Fig. 1: Process of ethics appraisal procedure for Horizon Europe projects

[10] See above note 1.

3. Ethics self-assessment during the preparation of the project proposal

In the process of submitting the application, the ethics self-assessment is performed in two steps, namely: the applicant firstly identifies potential ethics issues and completes the **Ethics Issues Table** (Step 1), and, further, elaborates on the identified potential ethics issues by completing the **Ethics Self-Assessment** (Step 2), whereas both sections are part of Part A – an online application form that can be found at EU Funding & Tenders Portal.

For support and guidance in completing the ethics self-assessment, researcher should refer to the document How to complete your ethics self-assessment,[11] a comprehensive guidance issued by the European Commission which offers support in **identifying potential ethics issues** related to the project and **suggests ways to suitably address them** (e.g. by specifying which actions should be taken and which documents obtained).

Step 1: According to the **Ethics Issues Table** (Fig. 2), the ethics categories are as follows:

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

   Examples: Research activities involving the use of human embryonic stem cells and/or human embryos.

2. **Humans**

   Examples: Research involving human participants in any form, including but not limited to surveys, interviews, focus groups, observational studies, collection of biological samples (e.g. blood for biomarker analysis), or clinical studies.

3. **Human cells or tissues (not covered by category 1)**

   Examples: Research involving human cells or tissues other than human embryonic stem cells, including established cell lines, primary cells, induced pluripotent stem cells (commercially obtained or obtained from human tissues within the project or from another project), or human tissue samples (e.g. excess material from routine medical procedures).

4. **Personal data**

   Examples: Research involving processing of personal data (e.g. collection, recording, structuring, storage, adaptation, alteration, retrieval, etc.). This category often applies also when research involving human participants in involved, as activities such as conducting interviews or collecting human biological samples often include the processing of personal data.

5. **Animals**

   Examples: Research activities involving animals (e.g. mice, rats, non-human primates, farm animals).

6. **Non-EU countries**

   Examples: Research activities involving partners from non-EU countries (which includes Associated Countries[12]) or research activities involving ethics issues that are being conducted in non-EU countries, including import/export of materials, samples, or data (other than Personal data, which should be checked under the category 4).

[11] European Commission (2021). *How to Complete your Ethics Self-assessment* (version 2.0). Brussels: European Commission. Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf.

[12] European Commission (2026). *EU Grants: List of participating countries (HE)* (version 3.8). Brussels: European Commission. Available at: list-3rd-country-participation_horizon-euratom_en.pdf.

7. **Environment, health and safety**

   Examples: Research activities involving hazardous chemicals, biological agents, or other harmful materials that may pose risks to the health and safety of researchers or others participating in research, and/or have potential negative impacts on the environment.

8. **Artificial intelligence**

   Examples: Research involving the development and/or use of artificial intelligence systems or methods within the project that may raise ethics issues (e.g. transparency, human oversight, impact on fundamental rights…)

9. **Other ethics issues**

   Examples: Any other aspects of the research not covered by the categories above that may raise ethical concerns or dilemmas.

10. **Crosscutting issue: potential misuse of results**

    Examples: Research that involves or generates materials, methods, technologies, or knowledge that could potentially be misused for unethical or harmful purposes.

Given the proposed methodology and nature of the project, i.e. involvement or non-involvement of the ethics issues listed in the categories above, the applicability of each category should be declared by ticking »Yes« or »No« next to the questions for each ethics category listed in the Ethics Issue Table, as well as indicating the page number(s) in Part B of the proposal where information relevant to each item/ethics issue can be found.

Step 2: In case any of the ethics categories have been selected (i.e., at least one question in the Ethics Issue Table has been answered with »Yes«), an **Ethics Self-Assessment** (the narrative part that follows the Ethics Issue Table) must be completed by providing more specific and detailed information on applicable ethics issues and how they will be addressed. The Ethics Self-Assessment includes two sections (Fig. 2):

- In the section **Ethical dimension of the objectives, methodology and likely impact**, researcher should describe, in line with the research objectives, which activities will be involved (e.g. interviews with participants, inclusion of vulnerable groups, clinical studies, collection of biological samples, animal experiments, etc.), and provide a more detailed description of the methodology for each activity. This includes the procedures for obtaining informed consent, the possibility for participants to withdraw from the study, inclusion and exclusion criteria for participant selection, measures for the protection of personal data (e.g. anonymisation or pseudonymisation), approval by the relevant ethics committee, availability of appropriate authorisations, evidence of adequate training or certification, etc.
  In addition, potential negative impacts of the research on humans, animals, or the environment should be recognised, together with a clear description of the measures that will be implemented to prevent or mitigate these impacts (e.g. potential negative impact of hazardous chemicals can be mitigated by proper disposal of hazardous waste by authorised institutions, use of appropriate personal and laboratory protective equipment, and adequate staff training).

- In the section **Compliance with ethical principles and relevant legislation** researcher should describe how compliance with ethical principles and relevant legislation will be ensured (e.g. provide reference to the ethics approvals obtained, along with statements confirming compliance with applicable, general and research areas specific guidelines and regulations).

In view of space constraints (sections are currently limited to 5000 characters), an annex to Part B can also be used as additional space for describing ethical aspects of your proposal.

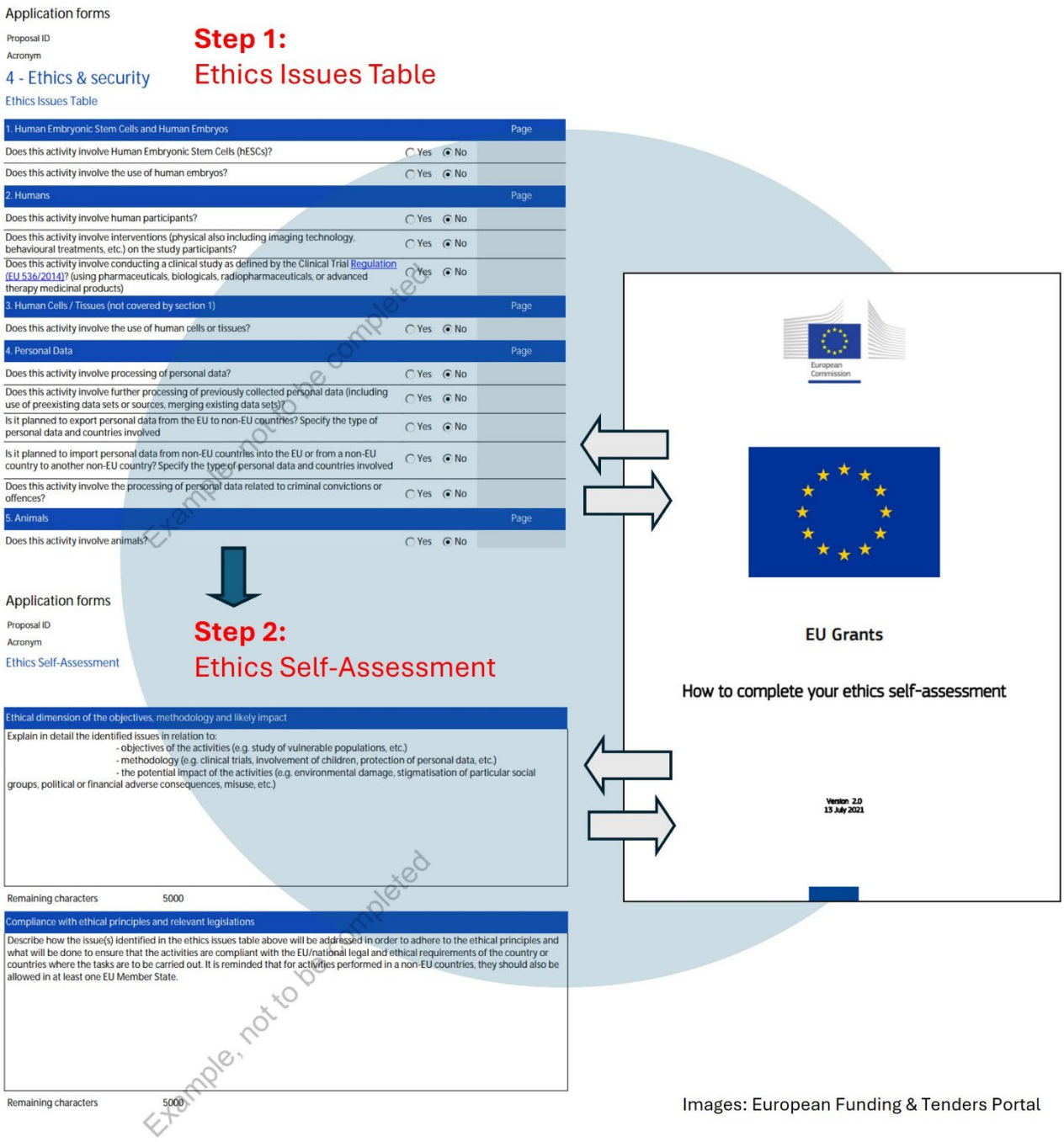

Fig. 2: Process of the ethics self-assessment of the project proposal

4. Initial ethics review procedure of the project proposal

Upon submission of the project proposal via EU Funding & Tenders Portal, two distinct processes take place. While the **scientific evaluation** evaluates quality and impact of the proposal, the **initial ethics review,** namely, ethics screening and/or ethics assessment**,** is conducted afterwards and evaluates ethics compliance of your proposal.

4. 1 Ethics screening

The ethics screening takes place during or shortly after the scientific evaluation. In the ethics screening, based on your (the applicant's) inputs in Ethics Issues Table and Ethics-Self Assessment and on the contents of the whole proposal (such as Part B and CV), the ethics aspects of your proposal are assessed. The result of ethics screening, the **Ethics Summary Report (ESR)**, is sent to the applicant, highlighting all ethics issues identified. It may also suggest appointing an ethics mentor or require the appointment of an independent ethics advisor/ethics board, and/or require a subsequent ethics check or an ethics review to be conducted to help ensure ethics compliance during the course of the implementation of the project – which of these measures will be taken or proposed is based on how well the ethics aspect has been addressed by the applicant and how serious or complex ethics issues in the proposed research are *per se*.[13]

The possible outcomes of the ethics screening are:[14]

i) Ethics clearance
ii) Conditional ethics clearance (e.g. obligation to nominate an external independent ethics advisor or ethics board)
iii) Ethics assessment

4. 2 Ethics assessment

Proposals with »serious or complex ethics issues« are further evaluated in the ethics assessment prior to the signature of the Grant Agreement. Examples of serious and complex ethics issues include e.g. processing of special categories of personal data (formerly known as »sensitive personal data«), AI applications involving human-machine cooperation, participation of children from developing countries, involvement of non-human primates, potential misuse or vulnerable populations). Proposals involving human Embryonic Stem Cells (hESCs) or human Embryos (hE) automatically proceed to the ethics assessment. For more information and examples on serious and/or complex ethics issues, see Guidelines on serious and complex ethics issues in EU-funded research.[15]

Based on the results of the ethics screening, the applicant is requested to provide additional information and/or documentation. The ethics assessment is then conducted based on this additional information. The ethics assessment can lead to ethics requirements that are included as obligations (Deliverables) in the Grant Agreement. As a result of an ethics assessment, applicant receives an Ethics Summary Report with an ethics opinion on the proposal.[16]

The possible outcomes of the ethics assessment are:[17]

i) Ethics clearance
ii) Conditional ethics clearance (inclusion of specific ethics requirements in the Grant Agreement)
iii) Request for additional information or a second assessment
iv) No ethics clearance (after the second assessment), i.e. proposal cannot be financed

[13] See above note 1.
[14] Idem.
[15] European Commission (2021). *Identifying Serious and Complex Ethics Issues in EU-funded research*. Brussels: European Commission. Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/guidelines-on-serious-and-complex-cases_he_en.pdf.
[16] See above note 1.
[17] Idem.

5. Mechanisms to ensure ethics compliance throughout the project's duration

5. 1 Project-wide ethics compliance

The beneficiary must ensure that **the proposal is ethically compliant before any relevant project activities begin** and remains so **throughout the whole duration of the project.** All documentation related to the project (e.g., ethics approvals, authorisations, certifications, etc.) must be always retained and made available to the European Commission upon request. In case a third party is involved, the beneficiary is responsible that all activities of a third party are ethically compliant.

It is worth noting that the beneficiary is also *legally bound* to be ethically compliant throughout the implementation of the project, as a general requirement applicable to all grants – which is included in all Ethics Summary Reports – states that »the beneficiaries must ensure that all ethics issues related to activities in the grant are addressed in compliance with ethical principles, the applicable international and national law, and the provisions set out in the Grant Agreement. This includes the ethics issues identified in this report and any additional ethics issues that may emerge in the course of the grant. In case any substantial new ethics issues arise, beneficiaries should inform the granting authority. For each ethics issue applicable, beneficiaries must follow the guidance provided in the How to complete your ethics self-assessment.«

5. 2 Managing new ethics issues

In case any new ethics issues arise during the implementation of the project, they must be appropriately addressed. This means that, when necessary, updated ethics approvals must be obtained from the relevant ethics committees or authorisation bodies, and the notification that they have been obtained must be communicated to the European Commission, which may also request these approvals to be submitted as deliverables.

5. 3 Ethics-by-Design

Continuous ethics compliance of the project can be effectively supported through the **Ethics-by-Design** approach. Ethics by Design is an approach for systematically and comprehensively including ethical considerations in the design and development process of a new technological system. Researchers are required to consider ethics aspects from the design phase of the proposal, embedding ethics requirements directly into the scientific methodology rather than treating them as post-hoc additions.[18] Systematic integration of ethics considerations throughout the process ensures that the methodology is appropriately developed, and all necessary authorisations and ethics approvals are obtained in a timely manner. Ethics-by-Design approach is especially useful for mitigating ethical risks in more complex scenarios, such as projects involving extensive use of personal data, or when dealing with emerging and highly innovative technologies (e.g., artificial intelligence, organoids). In these cases, ethics challenges can be more difficult to identify due to the rapidly evolving nature of these fields and the uncertainties associated with fast-paced developments.

5. 4 Ethics tasks and work packages

To ensure ethics aspects are properly addressed throughout the project, activities related to ethics may be included already in the proposal (Part B) as a dedicated **ethics-related work package** or individual **ethics-related tasks**, with corresponding **deliverables** (e.g. compiling all relevant ethics approvals and authorisations before relevant research activities begin).[19]

[18] Borrett, D. S., Sampson, H. and Cavoukian, A. (2016). Research Ethics by Design: A Collaborative Research Design Proposal, *Research Ethics*, 13(2), 84–91. Available at: https://doi.org/10.1177/1747016116673135); Brey, P. and Dainow, B. (2024). Ethics by Design for Artificial Intelligence, *AI Ethics*, 4, 1265–1277. Available at: https://doi.org/10.1007/s43681-023-00330-4).
[19] See above note 1.

5. 5 Ethics mentors, ethics advisors, and ethics advisory boards

An ethics mentor, advisor, or advisory board may be engaged to support ethics compliance when the researcher lacks the expertise to adequately address relevant ethics issues, or when the project involves complex or significant ethics issues. These roles provide ongoing guidance throughout the project and can also be proactively proposed by the applicant during the proposal preparation and the initial ethics self-assessment.

Ethics mentor can be someone from researcher's institution (internal and hence not considered 'independent'), who has relevant expertise in the relevant scientific field, along with respective legal and ethical frameworks, and can therefore support the researcher in maintaining ethics compliance and helping address potential evolving ethics issues. They can also help the researcher with preparing ethics applications or obtaining other relevant documentation (e.g. authorisations). **Ethics advisor** must be independent and external (i.e. not linked to your institution and be free from any Conflict of Interest) and advises on appropriate management of ethics issues in the project. Ethics advisor must have expertise in the relevant research area including the ethics perspective. Assignment of an independent **ethics advisory board** is meaningful when the proposal involves several different research areas, which cannot be covered by one expert. While an ethics mentor is not required to report to the European Commission on their work, this is obligatory for the ethics advisor and ethics advisory board. Likewise, while support from an ethics mentor is usually provided without remuneration, services of the ethics advisor or ethics advisory board tend to be remunerated. The costs of the work of an independent ethics advisor or ethics advisory board can be included in the project budget and may, for example, be secured from the project's management funds. For more information refer to the document Ethics Advisors and Ethics Advisory Boards - Roles and Function in EU-funded Projects.[20]

5. 6 Ethics checks, ethics reviews, and ethics audits

To ensure compliance with ethics requirements, the European Commission may conduct ethics checks, reviews, or audits throughout the project's duration. Projects requiring such further ethics scrutiny can already be identified during the ethics screening or ethics assessment, although such procedures can also be initiated directly by the European Commission later. The purpose of these procedures is to assist beneficiaries in managing ethical issues arising from their research and, where necessary, to implement preventive or corrective actions.

An **ethics check** consists of an internal evaluation by the project officer or an ethics officer, potentially supported by independent ethics experts. An **ethics review** is a comprehensive and in-depth assessment carried out by a panel of independent ethics experts. Both procedures rely on information provided by the beneficiaries, who may be invited to participate in discussions regarding the issues under review. **Onsite visits to the beneficiary's institutions** may also be arranged during ethics reviews, if needed. In case of substantial breach of ethics principles, research integrity or relevant legislation, the European Commission can carry out an **ethics audit** in accordance with the provisions and procedures set out in the Grant Agreement. Ethics checks, reviews and audits may, in cases of identified non-compliance, result in an amendment to the grant agreement or, in severe cases, lead to a reduction of the grant, its termination or other appropriate measures.[21]

[20] European Commission (2023). *Ethics Advisors and Ethics Advisory Boards: Roles and Function in EU funded Projects* (version 2.0). Brussels: European Commission. Available at: 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.
[21] See above note 1.