

Eurostars Ethics Appraisal Process

This document explains how the Ethics Appraisal process is performed under Eurostars-3 calls.

Eurostars is part of the European Partnership on Innovative SMEs. The [partnership is co-funded by the European Union through Horizon Europe.](#)

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Version 1

| HISTORY OF CHANGES | | |
|--------------------|------------------|---|
| Version | Publication date | Changes |
| Version 1 | April 2023 | Original version |
| Version 1.1 | July 2023 | Page 5: new information on procedures in case of "No Ethics Clearance" have been added. |

Introduction

Integrity and ethics are key components of and a prerequisite for achieving excellence in research and innovation.

In line with the EU Regulation 2021/695 establishing Horizon Europe¹, and following an ethics-by-design approach, Eurostars considers ethics as an integral part of research and research projects, from their conceptual phase until their end.

All project applications must comply with ethical principles and relevant national, European, and international legislation, including the Charter of Fundamental Rights of the European Union² and the European Convention on Human Rights and its protocols.³

To ensure that Eurostars projects adhere to the highest ethical standards, projects must undergo an Ethics Appraisal process. This runs from the evaluation of your application through the lifetime of your project.

Your consortium's responsibilities start during the submission phase when you are expected to include ethical considerations in your project design. You will need to identify ethical issues potentially arising from your project and explain how you will address them in your application form. **This stage is referred to as the Ethics Self-Assessment.**

Later, during the evaluation process, your application will undergo an Ethics Review performed by ethics experts. The experts examine your application and review your Ethics Self-Assessment. At this stage, **you may be contacted to provide feedback on ethical issues potentially arising from your project.** Depending on the results of the review, your application may receive ethics clearance, conditional clearance, or no clearance.

Finally, if your application is approved, we will expect you to carry out your project in compliance with ethical standards and relevant legislation. If specific ethics requirements are established during the Ethics Review, your consortium will also have to meet those requirements. **To ensure compliance, during your project lifetime, your consortium may undergo ethics checks and audits.**

The Ethics Appraisal process

Below is an explanation of each step of the Ethics Appraisal process and your responsibilities and obligations as applicants and participants.

Ethics Self-Assessment

This is the first step of the Ethics Appraisal process.

¹ [Regulation \(EU\) 2021/695 of the European Parliament and of the Council of 28 April 2021 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 \(Text with EEA relevance\), Art. 18 and 19.](#)

² https://www.europarl.europa.eu/charter/pdf/text_en.pdf.

³ https://www.echr.coe.int/documents/convention_eng.pdf.

While preparing your application, you must identify ethics issues potentially arising from your project and complete the ethics-related section of your application form. In this section, you must:

- reply to question 14 of the application form, and
- upload a completed ethics issues table.

Question 14 asks you to state if there are any ethical or legal issues linked to the objective, methodology or impact of your project. If there are any, you must describe them and explain how you plan to address them in compliance with the EU and/or national legal framework.

To help you identify ethical or legal issues related to your project, you need to complete an ethics issues table. Through several questions, this document guides you in the identification of eleven most common ethics categories. The table includes a field where you can describe any other ethics issues not related to those categories.

The ethics issues table must be submitted to Eureka as part of your application form. Together with question 14, it will be examined during the evaluation of your application.

Read the full guidelines on the ethics self-assessment at www.myeurekaproject.org, in the [Eurostars Library section](#).

Ethics Review

All Eurostars applications that successfully pass the remote experts' evaluation and the legal and financial viability check undergo an Ethics Review. This is performed by independent ethics experts commissioned by the Eureka Secretariat. The goal of the experts is to screen all applications and identify those that raise serious and/or complex ethics issues.

If necessary, the experts can set requirements for applicants to be met before their project can start and/or during their project lifetime. Requirements are defined in proportion to the severity of the ethics issues, following a risk-based approach.

To carry out the Ethics Review, the experts screen each application against the application form, including applicants' answer to question 14 and the ethics issues table. All applications are screened bilaterally by a pair of experts.

The ethics screening can have three possible outcomes:

1. Ethics Clearance

Your application receives ethics clearance if:

- your project does not raise any ethics issues, or
- your project raises ethics issues that are not serious and/or complex, you have identified them and adequately explained how you will address them in accordance with national, European, and international legislations.

In the case of ethics clearance, the experts will not set requirements for your consortium to meet. However, this does not mean that your consortium has no obligations to fulfill. Your Ethics Screening Report may contain recommendations, such as the appointment of an ethics mentor,⁴ to help you comply with the legislation.⁴ Moreover, your project may be subject to ethics checks⁵ or review.

2. Conditional Ethics Clearance

Your application receives conditional ethics clearance if your project raises ethical issues that are not serious and/or complex but you need to appoint an ethics mentor, or an independent advisor or board.

The experts can request before you can obtain the public funding and/or after the start of your project, the appointment of an ethics mentor, an external independent ethics advisor or an ethics board (with a minimum of three experts)⁶ to oversee the ethical concerns in your project and ensure full ethical compliance with relevant legislation.

This request may become a contractual obligation; failure to meet it could lead to postponement of the obtainment of public funding or the temporary suspension of your project.

To verify compliance, the experts can set ethics checks to be performed at key moments of your project. The checks are performed by Eureka, in collaboration with independent ethics experts.

3. Ethics assessment

The ethics assessment is an evaluation performed by a panel of a minimum of five ethics experts. Your application will undergo an ethics assessment if:

- a. It involves the use of Human Embryos (hE) or Human Embryonic Stem Cells (hESCs). In this case, the assessment is carried out by the European Commission's Directorate-General for Research and Innovation (RTD).
- b. It raises other serious and/or complex ethics issues.

An application raises serious and/or complex ethics issues when, among others:

- it has the potential to violate fundamental rights and freedoms or undermine fundamental EU values,
- it has the potential to result in significant harm to researchers, research participants, the public, animals, or the environment,
- may not have exclusive focus on civil applications,
- it raises multiple or 'intersectional' ethics issues (e.g., research into marginalised or vulnerable individual groups that exposes them to the risk of stigmatization, exclusion, reprisals, or increased marginalisation),
- the area of research is the subject of widespread ethical debate among scientists and ethicists,

⁴ See page 9: The role and functions of the Ethics Mentor.

⁵ See page 6: Definition of Ethics Checks.

⁶ Please see the European Commission guidelines on the role and function of the Ethics advisor/board at this link: 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.

- there are grave doubts regarding the capacity of the researchers or the participating institutions to effectively mitigate the risks.

For a comprehensive description of what constitutes a serious and/or complex ethics issue, please read the European Commission's [Guidelines on serious and/or complex ethics issues](#).

The ethics assessment can have three possible outcomes:

1. **Ethics Clearance:** if the panel considers the ethics issues as no longer serious and/or complex.
2. **Conditional Ethics Clearance,** including the definition of ethics requirements.
3. **No Ethics Clearance:** in this case, the application cannot be funded.

If your application receives a “No ethics clearance”, you are granted the possibility to provide additional information – within 2 weeks from the notification of the results – after, a second ethics assessment from independent ethics experts, is required.

A second assessment panel is performed by 5 independent ethics experts which role is to assess your application together with the newly provided information. The project will receive a new ethics status.

- a) The second assessment panel confirms the ethics status based on the new information provided. **The project cannot be funded.**
- b) The second assessment panel changes the ethics status based on the new information provided. **The project can be funded.**

The results of the ethics screening and the ethics assessment are provided to applicants in the **Ethics Screening Report**.

If you want to appeal the ethics result, after the second assessment - in case of “No ethics clearance” – and you think this was due to a procedural mistake, you can submit a redress request.

Ethics Check and Audits

Should your application be approved, your ethics self-assessment and your Ethics Screening Report become part of your Grant Agreement, giving rise to binding contractual obligations which may later be checked for compliance through ethics checks and audits.

The checks are performed by the Eureka Secretariat, in collaboration with two independent ethics experts. Checks can be planned:

- prior to the commencement of relevant activities/studies/research,
- in a specific month, or
- after an ethics approval is obtained,

according to what is indicated in the Ethics Screening Report.

Prior to the check, the consortium must send relevant documents needed to perform the check, as listed in the Ethics Screening Report. Documents should be submitted one month before the check.

Once the check is finalised, the consortium will receive an Ethics Check Report detailing the check results. The results include:

- a) The consortium met all ethics requirements; as such, no more requirements or checks are needed, and the project is cleared.
- b) The consortium partially met the ethics requirements. Another Ethics Check is scheduled.
- c) The consortium failed to meet the requirements or new ethics issues have been identified. New ethics requirements, not previously listed in the ethics screening report, could be formulated. A new check is scheduled.

Please note: Failing to comply with ethics requirements might lead to the suspension of public funding until the requirements are met. Should non-compliance persist, the project may be withdrawn from the programme.

What are my responsibilities as a Eurostars applicant?

Here are some recommendations you should follow to ensure that your application successfully passes the Ethics Review:

- Include ethical considerations while designing your project. Do not wait until the last minute to seek advice or check requirements under National and European legislation. Use **ethics by design** methodology. The aim of such methodology is to ensure that ethical issues are addressed in the first place by using ethically focused activities throughout the design, development, and deployment phases of a project. Receiving advice from an **Ethics Mentor** since the design phase is highly recommended.
- Read the **guidelines** on the ethics self-assessment and ethics issues table.⁷
- Always **remain available** during the evaluation process. During the Ethics Review, you might be asked to clarify some of the ethics issues identified by the experts or to send some relevant documents (ex. ethics approvals, authorizations, etc.) that may help the experts evaluate your application.

If you have any questions on the process, contact the Eureka Secretariat by emailing ethics@eurostars-eureka.eu.

What are my responsibilities as a Eurostars participant?

Remember that failing to comply with ethics requirements might lead to the suspension of public funding until the requirements are met. Should non-compliance persist, the project may be withdrawn from the programme.

Here are some recommendations for participants in approved projects:

- Check the Ethics Screening Report.
- Carefully read the list of (missing) requirements.
- Take note of the date in which your Ethics Check is scheduled.⁸
- Prepare the missing documentation in advance; do not wait until the last minute. Documents should be sent to Eureka Secretariat ideally one month before the check.
- Inform the Eureka Secretariat in case you need more time to prepare your documentation.
- Keep on file and send upon request to the Eureka Secretariat relevant ethics documentation (ethics approvals, Ethics Mentor's report, etc.).
- Inform the Eureka Secretariat of any changes in your project activities (note that a new/different activity might lead to the formulation of new/different ethics requirements). On how to communicate and request changes, please see the [Guidelines for requesting changes](#).

⁷ <https://www.eurekanetwork.org/programmes/eurostars/guidelines>.

⁸ Ethics Check can be scheduled: In a specific month of the year, in a specific month according to the project duration (e.g. M6 = start date + six months), before the start of relevant activities.

If you have any questions on the process, contact the Eureka Secretariat by emailing ethics@eurostars-eureka.eu.

Annex

The role/mandate of the Ethics Advisor/Board

To advise and assist the beneficiaries in understanding and appropriately addressing the ethics issues raised by their project, the appointment of an external independent Ethics Advisor or Board may be appropriate, particularly when the ethics issues can be considered as serious and/or complex.

An Ethics Advisor or an Ethics Board⁹ is an individual independent ethics expert or a group of ethics experts who give advice to a researcher, research group or project consortium in the context of an EC-funded project. The work of these experts should facilitate, build upon and complement existing oversight regimes by competent ethical and legal authorities.

In accordance with the mandate, it is the **responsibility** of the Ethics Advisor or Board to:

- **Advise** the participant on identifying and addressing ethics issues,
E.g., 'The advisor must assist the participant in addressing ethical risks related to the involvement of children in the research, to ensure their interests are adequately protected and the consent procedures appropriate and submit yearly report.'
- **Report** independently to Eureka.
- Remain **independent** from the participants. Independence and impartiality will be essential in providing fair ethical judgements and expertise. Recruitment practice must take this into consideration.

The Ethics Advisor or Ethics Board should do whatever is necessary to diligently monitor the aims, objectives, methodology and implications of the research to ensure that it conforms to the highest ethical standards. This includes ensuring that researchers, research participants, and the general public are not exposed by the work of the project to activities that would be considered to be ethically unacceptable or even prohibited.

The choice between a single external independent Ethics Advisor and an Ethics Board (with a minimum of three experts) reflects the size of the grant and the severity of the ethics issues; the mandate needs to be proportional and tailored to the specifics of the project and the needs of the beneficiaries.

This means that for smaller projects, or projects that only raise a limited number of ethics issues (that nonetheless can be significant), the expertise of a single advisor can suffice to help the beneficiary to adequately address the ethics issues. For bigger projects, e.g., involving a high

⁹ See note n.6.

number of researchers, institutions and/or research activities, it may be impossible for one single advisor to properly oversee the project.

The role of the Ethics Mentor

An Ethics Mentor¹⁰ can be appointed to provide ethics guidance and advice. An Ethics Mentor can be a (senior) colleague, a member of the same department or institution. Hence, the key difference between an Ethics Advisor and an Ethics Mentor is that the Mentor does not have to be independent from the beneficiary and generally does not have any reporting duties, while the Ethics Advisor does. However, it is highly recommended that a report on the activities of the Mentor is kept on file and provided upon request from the Eureka Secretariat. An Ethics Mentor is usually appointed when the risk is lower or an independent advisor/board is not needed.

The appointment of an Ethics Mentor could be:

- Included as a **recommendation** for applications that are cleared at screening stage.
- Included as an **ethics requirement** for applications that receive ethics conditional clearance.

¹⁰ See note n.6.