



MSCA-NET

POLICY-BRIEF: ETHICS

Deliverable 3.13

NETWORK OF THE MARIE SKŁODOWSKA-CURIE ACTIONS NATIONAL CONTACT POINTS

Task 3.6	Policy Briefs
Issued by:	DLR
Issued date:	18 February 2025
Work Package Leader:	INNOVATIONAUTH (IL)

TABLE OF CONTENTS

Introduction 2

Introduction to Ethics in Horizon Europe..... 2

Guiding Principles and Rules..... 4

Ethics in the MSCA 4

- Ethics in MSCA proposals..... 4
- Additional considerations in the different MSCA funding lines 5

Conclusion..... 6

References and resources 7

Introduction

This policy brief aims to provide researchers and organisations with a short and comprehensive overview of the requirements relating to ethics in the Marie Skłodowska-Curie Actions (MSCA). The brief is not intended to duplicate or otherwise replace existing EU guidance but will bring different information resources together and provide direct signposting to the most relevant resources.

Research is likely to raise ethics issue in a number of ways. Research activities might involve human participants or animals or it might involve the use of substances or processes that may cause harm to the environment, such as animals, plants and fauna, water, seas and oceans, and humans. Researchers and their teams must always prioritize the safety of the researchers and the environment, ensuring that proper precautions are in place when conducting high-risk experiments. Privacy and data protection issues might also play a crucial role in research activities. This policy brief examines the importance of considering ethical issues in any proposal under Horizon Europe, with a particular focus on the MSCA.

Introduction to Ethics in Horizon Europe

For all EU-funded activities, the ethical dimension is an essential aspect of the research process and ensuring ethical compliance is considered crucial for achieving true research excellence. Thus, ethics play a central role in all phases of a project, from planning and application as well as submission to implementation and completion. Ethical considerations should therefore be considered from the very beginning.

At the submission stage, a mandatory ethical self-assessment ("Ethics self-assessment") by filling out the **Ethics Issues Table (see page 5)** is required. For each ethical issue ticked in the Ethics Issues Table a more detailed **Ethics self-assessment** must be submitted. In this self-assessment applicants must outline the ethical aspects of their proposal and their compliance with ethical principles.

All proposals above threshold and considered for funding then undergo an **Ethics Appraisal Procedure**¹. This procedure ensures that all activities funded under Horizon Europe adhere to fundamental ethical principles. The Ethics Appraisal Procedure encompasses the **Ethics Review Procedure**, carried out prior to the project's initiation, as well as **Ethics Checks, Reviews**, and **Audits** conducted throughout the project's duration.

First the **Ethics Review Procedure** is carried out by independent ethics experts before the Grant Agreement signature.

The Review begins with an **Ethics Screening**, which may include a pre-screening to confirm the absence of ethics issues if none were identified in the proposal by the applicant.

This process may be followed by a more detailed **Ethics Assessment** if needed. This stage entails a detailed and comprehensive analysis of ethical issues for those proposals that present serious or complex ethical issues, or involve the use of human embryos or human embryonic stem cells. If the proposal undergoes an Ethics Assessment, an ethics summary report (EthSR) will be generated, outlining the ethics issues identified in the proposal, along with the corresponding ethics requirements and recommendations for the applicant. The EthSR will serve as a reminder to beneficiaries regarding the ethical concerns associated with their proposal. Beneficiaries must retain all pertinent documentation and provide specific documents upon request, following a risk-based and trust-based approach.

¹ Further information about the Ethics Appraisal Procedure can be found in the [HE Programme Guide](#), p. 23-28.

There are four potential outcomes of the **Ethics Assessment** that are presented in the table below:

Potential Outcome:	
1) Ethics clearance	<ul style="list-style-type: none"> • No ethics issues are identified or all identified ethics issues have been satisfactorily addressed by the applicant. • No specific ethics requirements are included in the Grant Agreement. • The general ethics requirement applicable to all grants still apply.
2) Conditional ethics clearance	<ul style="list-style-type: none"> • Specific ethics requirements, which must be addressed either during grant preparation or implementation, are outlined in the EthSR. • Such requirements may involve appointing an independent ethics advisor or an ethics committee, modifying the methodology to align with ethical principles, or providing additional information and documents. • If ethics requirements are due only after the project begins, they are automatically incorporated into the Grant Agreement as “ethics deliverables” and will be included in an automatically generated work package called “ethics requirements”.
3) Request for additional information	<ul style="list-style-type: none"> • If there are complex ethics issues or missing information, additional details may be requested.
4) No ethics clearance	<ul style="list-style-type: none"> • If a proposal does not receive Ethics clearance after the second Ethics Assessment, it will be ineligible for funding and will be rejected.

Ethics Checks and **Reviews** can also take place during project implementation. The Ethics Check is an internal check conducted by the project officer, potentially with the support of ethics experts. In contrast, the Ethics Review is a comprehensive and detailed process performed by up to five external ethics experts. Checks and reviews are based on documents submitted by the participants. They may also involve invitations to meetings in Brussels or on-site visits.

In cases of significant breaches of ethical standards, the European Commission can initiate an **Ethics Audit**. Checks, post-grant reviews and audits may lead to amendments of the grant agreement. For serious violations, the European Commission reserves the right to reduce funding, terminate the grant, or implement other measures specified in the grant agreement.

Overview of the Ethics Appraisal Steps²

Activity	Who?	When?	How?
Ethics Self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics Screening	Ethics experts (and/or qualified staff in case a pre-screening is conducted)	Evaluation phase	Review of application material
Ethics Assessment (for proposals involving hESC/hE or flagged as serious or complex)	Ethics experts	Evaluation/Grant preparation phase	Review of application material
Ethics check/review/audit	Project Officer and/or Ethics officer and/or Ethics experts	Implementation phase	Review of project deliverables/interview with applicants/onsite visit

² HE Programme Guide, p. 26f.

Guiding Principles and Rules

Regulation (EU) 2021/695 establishing Horizon Europe: Article 19 Ethics

“Actions carried out under the Programme shall comply with **ethical principles** and **relevant Union, national and international legislation**, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

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**.”

Model Grant Agreement (MGA): Article 14 and Annex 5

Article 14:

“The action must be carried out in line with the **highest ethical standards** and the applicable EU, international and national law on ethical principles.”

The specific ethics rules are outlined in **Annex 5**:

Annex 5 specifies that beneficiaries must conduct their actions in adherence to ethical principles, including **research integrity**, and comply with applicable **EU, international, and national laws**, including human rights frameworks. Funding is prohibited for activities banned in all EU Member States or in specific Member States where they are illegal. Beneficiaries must respect rights such as **privacy, non-discrimination, and environmental protection**, and also ensure that activities are exclusively for **civil purposes**. Activities like **human cloning for reproductive purposes** or **creating human embryos** solely for research are not permitted. Research must uphold **integrity, reliability, honesty, and accountability**, following ethical guidelines and obtain **necessary approvals** before starting ethically sensitive tasks.

Beneficiaries and participating organisations must adhere to the obligations outlined in Annex 5 of the Horizon Europe MGA and ensure that researchers involved in projects are informed of these obligations – this of course also applied to MSCA-funded projects.

Ethics in the MSCA

Ethics play a central role in the MSCA, ensuring that research conducted under its framework adheres to the highest ethical standards. The MSCA emphasize integrity, inclusivity, and societal responsibility in all research activities. Projects must comply with national, European, and international ethical guidelines, addressing issues such as informed consent, data protection, and the welfare of research subjects – both human and animal. All potential ethical implications have to be identified and properly managed.

Ethics in MSCA proposals

Doctoral Networks (DN), Postdoctoral Fellowships (PF), COFUND, Staff Exchanges (SE) and MSCA and Citizens

In **Part A** of the proposal applicants must fill in under **4 - Ethics & security** the **Ethics Issues Table** which is a structured tool designed to help applicants identify and address potential ethical issues in

their MSCA research proposals. It is a mandatory component of the application process, ensuring that all projects comply with ethical standards and legal requirements.

The following topics are covered in the Ethics Issues Table:

1. *Human Embryonic Stem Cells and Human Embryos*
2. *Humans*
3. *Human Cells / Tissues (not covered by section 1)*
4. *Personal Data*
5. *Animals*
6. *Non-EU Countries*
7. *Environment, Health and Safety*³
8. *Artificial Intelligence*
9. *Other Ethics Issues*⁴

Applicants must review the table and indicate whether their project raises any ethical concerns in the listed areas. For each ethical issue ticked in the Ethics Issues Table a more detailed **Ethics Self-Assessment** must be submitted. Here applicants must address the ethical aspects of the objectives, methodology, and potential impact of their MSCA project, while also explaining how they will adhere to ethical principles and applicable laws. By completing the Ethics Issues Table, applicants to MSCA calls demonstrate their commitment to conducting responsible and ethically sound research.

Any **additional information** that cannot be included in the ethics self-assessment in Part A should be included in **Part B2.6 (PF)**⁵ and **Part B2.4 (COFUND)**⁶ of the proposal. For DN and SE there is no additional information foreseen in Part B2. For MSCA and Citizens, there is no dedicated section for further information on ethics in Part B. The applicant declarations and the ethics self-assessment are incorporated into the description of the action (Annex 1 of the grant agreement) and establish obligations for the beneficiaries.

The enclosure of “ethics supporting documents” such as approvals, authorisations, templates etc. as annex is not a condition for the submission of a proposal. However, depending on the scope and complexity of the ethical issues raised in the proposal, providing additional documentation, such as “ethics supporting documents,” in a separate annex to Part B can enhance the effectiveness of the ethics appraisal. This risk-based approach requires submission of evidence of ethics compliance only if and as needed. Otherwise, supporting documents can be submitted as a deliverable after the project has received funding.

Additional considerations in the different MSCA funding lines

COFUND:

For MSCA COFUND programmes, it is often unclear in advance whether the fellowships to be funded will involve ethical issues, meaning that future ethics issues may not yet be identified at proposal stage. Therefore, it is crucial to outline how the proposal complies with both European and national legal and ethical requirements in the countries where the tasks raising ethical concerns will be carried out. Applicants should specifically describe the **ethics procedures** they will implement throughout the programme, including the **application, selection and evaluation phase**, the **monitoring and follow-up of projects**, and **ethics training**. Successful COFUND programmes, must specify the procedure for addressing proposals that raise ethical issues in their calls for proposals. For this reason, it’s advisable

³ The [MSCA Green Charter](#) is a code of good practice for all recipients of MSCA funding – individuals and institutions – promoting the sustainable implementation of research activities. All participants are expected to follow the Green Charter to the best of their ability and commit to as many of its guidelines as feasible throughout their projects.

⁴ Applicants can use this section to address emerging ethical issues or concerns that are not yet fully covered by the standard questions in the Ethics Issue Table, such as advancements in neurobiology, human-machine interaction, or nanotechnology.

⁵ [MSCA Postdoctoral Fellowships Proposal Template](#) (Version 5.0, 23 April 2024)

⁶ [MSCA COFUND Proposal Template](#) (Version 7.0, 17 October 2024)

that ethical aspects of research projects should already be considered during the recruitment process, e.g. by adding an ethics self-assessment section in the application form. When describing the committees involved in each stage of the selection, it should be pointed out that applicants might have to go through some form of ethics review at the host organisation's Ethics Committee depending on their planned research project.

The [proposal template for COFUND](#)⁷ also foresees a **dedicated work package** for **ethics** (work package 5). This underlines the importance that is ascribed to ethical aspects and ensures the appropriate handling of any ethics issues that may arise during the implementation of the programme.

For COFUND programmes it may be recommendable to have an **ethics advisor** as part of the **decision-making body**.⁸

DN and PF:

If applicants can already anticipate that ethics will be very relevant for their project, they can add an **ethics work package**.

Otherwise, such projects usually receive an additional ethics work package in the case of a batch review **when funded**.

Should any ethics concerns arise during project implementation that the fellow is not able to satisfactorily address with his or her supervisor and/or project coordinator, the general complaint's procedure should be followed.⁹

Applies to all MSCA programme lines except for MSCA and Citizens:

To stress the importance of ethics in research it is advisable to consider adding a **training in ethics** to the list of transferable skills doctoral candidates and postdocs acquire during their fellowship

Conclusion

Applicants and beneficiaries of Horizon Europe funded projects – and thus also MSCA-funded projects – must recognize the importance of conducting a thorough ethics self-assessment. Applicants and beneficiaries are fully responsible for ensuring a proper management of ethics compliance. Additionally, they must ensure they can provide proof of compliance at all times. Ethics should be understood as a means to empower researchers to act in the best interests of society, fostering trust based on common values and fundamental rights, such as human dignity, protection of privacy, and security.

⁷ [MSCA COFUND Proposal Template](#) (Version 7.0, 17 October 2024)

⁸ More details on the inclusion of Ethics Advisors and Ethics Boards can be found in the document: European Commission, [Ethics Advisory and Ethics Boards. Roles and Functions in EU funded Projects](#) (Version 2.0, 15 February 2023).

⁹ [Information package for Marie Skłodowska-Curie fellows](#)

References and resources

- [Horizon Europe Regulation 2021/695: Eligible actions and ethical principles \(Article 18\) and Ethics \(Article 19\)](#)
- [Horizon Europe Programme Guide](#)
- [MSCA Work Programme 2023-2025](#)
- [Horizon Europe Model Grant Agreement](#)
- [How to complete your ethics self-assessment](#)
- [Identifying serious and complex ethics issues in EU-funded research](#)
- [Ethics Advisory and Ethics Boards. Roles and Functions in EU funded Projects](#)
- [Online Manual on the Funding & Tenders Portal](#)
- [Ethics and data protection](#)
- [MSCA Postdoctoral Fellowships Proposal Template](#)
- [MSCA COFUND Proposal Template](#)
- [Information package for Marie Skłodowska-Curie fellows](#)
- [MSCA Green Charter](#)