



International Network for Knowledge and Comparative Socioeconomic Analysis of Informality
and the policies to be implemented for its formalisation in the European Union and Latin America

Horizon Europe Project 101182756 — INSEAI 2023
REAA — Marie Skłodowska-Curie Actions & Support to Experts A.3 – MSCA Staff Exchanges

Ethic Advisers Board (EAB)

The EAB should consist of at least two people, and ideally three, who have between them expertise in sociology and economics, along with ethics expertise.

The EAB will:

- 1) Provide to the project consortium an initial evaluation of the ethical and legal issues involved in the research before any research is undertaken;
- 2) Ensure that all ethical and legal approvals are obtained in all participating countries before any research is undertaken;
- 3) Ensure that the same ethical and legal research standards are maintained in non-EU countries as those in EU countries;
- 4) Provide oversight over the transfer of data between countries;
- 5) Monitor and provide guidance over the use of artificial intelligence (AI) in the analysis of data and the development of models.

Deliverables should be provided at: M1: providing details of EAB members and its establishment; M24: providing details of the initial ethical evaluation and advice provided to the consortium and reassurance that this has been followed; M48: providing a final evaluation of the ethical issues raised by the primary research and the use of AI.

The project will involve research with human participants in many EU and non-EU countries, and an Ethics Advisory Board (EAB) must be appointed to support the Consortium's capacity to address these issues at month 1 of the project.

Reports by the Ethics Advisory Board

Many activities funded under **Horizon Europe** raise ethics issues, for example, relating to the involvement of vulnerable research participants, the conduct of animal experiments, or privacy and data protection issues. Therefore, in addition to the scientific evaluation focusing on the scientific merit of funding applications, the **Ethics Appraisal Procedure** ensures that all activities carried out under Horizon Europe are conducted in compliance with fundamental ethical principles. As a result, to receive funding, all shortlisted proposals undergo an **Ethics Review** before the Grant Agreement (GA) signature. The **Ethics Review** may result in specific **ethics recommendations and ethics requirements** that are included in the GA as specification of the general obligation that all activities comply with ethical principles (including the European Code of Conduct for Research Integrity) and relevant legislation (including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights).

To advise and assist the Beneficiary/Consortium/Principal Investigator in understanding and appropriately addressing the ethics issues raised by their activities, the **appointment of an external independent Ethics Advisor or Board** may be appropriate, in particular when the ethics issues can be considered as serious and/or complex. The appointment of an Ethics Advisor or Ethics Board can be voluntarily **proposed by the applicant** in their application or can be obligatory as a result of the **Ethics Review**. In the latter case, the Ethics Advisor or Board may have to **report independently to the Commission/Executive Agency/Funding Body**, in addition to their role of advising the Beneficiary/Consortium.

During the GA preparation, successful applicants receive **the Ethics Summary Report**, which provides an overview of the ethics issues raised by the proposed activities, the ethics opinion of the evaluation panel, and, *if applicable*, specific **ethics recommendations and ethics requirements**. Some ethics requirements may have to be fulfilled before the GA may be signed; others are added to the GA as contractual obligations and corresponding deliverables. When the appointment of an Ethics Advisor or Board is required, the **Ethics Summary Report** will specify the reasons for the appointment, the main elements of the **Advisor's or Board's mandate**, and the scope and periodicity of their reporting duties.

Please note that the advisor or board is expected to start working at the beginning of the project, unless explicitly instructed otherwise, and that **the Ethics Advisor or Board members are not responsible for the Beneficiary's/Consortium's compliance with the ethics requirements**.

This **template** can be used by the independent Ethics Advisor or Board for reporting to the Commission/Executive Agency/Funding Body about the ethics issues raised by a project's activities, the advice offered to the Beneficiary/Consortium/Principal Investigator, and their progress in addressing them.

For further guidance on the appointment, role and reporting duties of the Ethics Advisors and Ethics Advisory Boards in EU-funded projects, please consult the **Guidance Note on The Roles and Function of the Ethics Advisor and the Ethics Advisory Board in EU-funded Projects**.

For more **information** on the Ethics appraisal process for Horizon Europe and further guidance on specific ethics issues and how to address them, please consult the Horizon Europe Programme Guide (section 12) and the 'How-to complete your ethics self-assessment' guideline.

How the EAB works

- Beneficiary/Coordinator/Principal Investigator must:
 - provide EAB with the contact details for **all** consortium partners, if applicable;
 - give EAB access to **all** information/documentation necessary and relevant for EAB reporting;
 - include EAB in relevant correspondence, meetings, and discussions.
- An Ethics Advisory Board Member must be independent from the Beneficiaries of the project and execute EAB responsibilities in complete **independence** of other professional and academic commitments.
- EAB must notify the Beneficiary/Coordinator/Principal Investigator of any professional, financial, family or other personal links, or any other relationships or shared interests, that could result in a conflict of interest. The Beneficiary/Coordinator/Principal Investigator must notify the Commission/Executive Agency/Funding Body without delay.
- An Ethics Advisor or Advisory Board Member must maintain **strict confidentiality** in relation to all information and evidence coming to EAB's knowledge in the context of EAB assignment.
- Ethics Advisor(s)/Advisory Board(s) should recall that:
 - The reports and advice offered should be pragmatic/workable, clearly explained and justified (with reference to the principles, criteria, approaches being applied, and the sources of this guidance), and be **understandable** by the partners so that appropriate actions can be taken.
 - **The scope and length of the reports should be proportional to the seriousness/complexity of the ethics issues raised by the project's activities**, and, if applicable, be in accordance with the mandate included in the **Ethics Summary Report**.
 - An Ethics Advisory Board should aim to give **consensus-based** recommendations. In cases where no consensus can be reached, it is recommended that the report provide a transparent overview of its discussion to project management, detailing why definitive advice was not possible.
 - The main role of the Ethics Advisor/Board is to provide guidance to the beneficiary/consortium on how to best address the ethics issues to facilitate the beneficiary's/consortium's ethics compliance. The report

should demonstrate how these challenges have been addressed and what role the Ethics Advisor/Board played in this process.

- EAB contact point is the Beneficiary/Coordinator/Principal Investigator, who is responsible for ethics compliance and for reporting to the Commission/Executive Agency/Funding Body. However, should you need to contact the Commission/Executive Agency/Funding Body directly, please write to Aleksandra SCHOETZ SOBCZAK SCHOETZ SOBCZAK