



# Ethics Advisors and Ethics Advisory Boards

## Roles and Function in EU-funded Projects

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Disclaimer: The guidance offered in this note cannot anticipate the outcome of the (ethics) evaluation of any application for EU funding, nor of any related monitoring or audit procedures executed during or after the lifetime of the project. It is quite plausible that proposed activities on very similar topics or involving similar techniques are assessed differently, in terms of the ethics issues raised, their seriousness and/or complexity, and how this ought to be addressed. The guidance offered in this note therefore cannot create any new obligations on the European Commission or its Executive Agencies, nor can the European Commission or any person acting on their behalf be made responsible for the use made of it.

This Guidance note has been drafted by a panel of experts at the request of the European Commission (DG Research & Innovation) to assist applicants/beneficiaries of Horizon Europe and other EU-funded programmes in appointing/working with an independent Ethics Advisors or Ethics Advisory Board, and guide Ethics Advisors and Board Members in the execution of their tasks.

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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 applications for funding, the **Ethics Appraisal Procedure** ensures that all activities carried out under Horizon Europe are conducted in compliance with fundamental ethical principles. As a result, in order to receive funding, all shortlisted proposals undergo an **Ethics Review** before the Grant Agreement signature. The **Ethics Review** may result in specific **ethics recommendations and ethics requirements**, that are included in the Grant Agreement as specification of the general obligation that all activities are in compliance 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 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.

When the appointment of an Ethics Advisor or Board is required as a result of the **Ethics Review**, the **Ethics Summary Report** resulting from the Ethics Review 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. When the appointment of an Ethics Advisor or Ethics Board is proposed by the applicant, on the other hand, the role and mandate of the Ethics Advisor or Board will also be included in the Description of Work (DOW) included in the Grant Agreement. Although this is not obligatory, it is highly recommended that an Ethics Advisor or Board appointed in such a capacity produces written reports and/or advice that are included in the project's deliverables.

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)
- The '[How-to complete your ethics self-assessment](#)' guideline

<b>HISTORY OF CHANGES</b>		
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<a href="#">1.0</a>	05.07.2021	<ul style="list-style-type: none"><li>▪ Initial version</li></ul>
2.0	15.02.2023	<ul style="list-style-type: none"><li>▪ Adaptation of the guidance to the Horizon Europe ethics appraisal process and terminology</li><li>▪ Inclusion of Annexes II, III &amp; IV</li></ul>

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## Introduction

This document aims to provide guidance on the roles and operation of **Ethics Advisors (EAs)** and **Ethics Advisory Boards (EABs)** appointed to monitor, guide and counsel EU-funded projects. The target audience for this document includes Ethics Advisors and Ethics Advisory Board Members, applicants, beneficiaries or other participating partners, as well as ethics experts and the staff members of the European Commission and its Executive Agencies. The aim is to offer a focused and practical guidance for EAs and EABs in projects funded under **Horizon Europe** or any other EU Funding Programmes.

Activities funded under Horizon Europe are principally research and innovation-related activities, and therefore the focus of this guidance. However, this does not preclude that the ethical guidance formulated here may not be applicable and useful for other categories of funded activities or in other contexts.

Promoting a culture grounded in the highest ethics and integrity standards enables the expected trust and fruitful relationship between science and society that is essential for the renewed European Research Area.<sup>1</sup> The consideration of ethical issues, starting at the conceptual stage of a proposal, enhances the quality of research, increases its likely social impact, promotes research integrity, promotes a better alignment of research with social needs and expectations and, finally, supports the societal uptake of the results of research because high ethical standards generally merit public trust. In this spirit, the Commission aims to build a relationship between research and innovation and ethics that is collaborative and constructive. However, it must be stressed that ethics advice is not to be treated as a trivial matter and ethical 'errors' can have serious repercussions for projects and their impact.

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<sup>1</sup> Council Recommendation (EU) 2021/2122 of 26 November 2021 on a Pact for Research and Innovation in Europe, <http://data.europa.eu/eli/reco/2021/2122/oj>

## 1. Definitions and Clarifications

- 1.1. An “**Ethics Advisor**” (EA) is an individual ethics expert giving advice on issues of ethical gravity that relate to the planned and/or ongoing research in the context of an EU-funded project, and, if required, report to the Commission/Executive Agency/Funding Body. An “**Ethics Advisory Board**” (EAB) consists of three or more ethics experts, working together as panel in performing these tasks.

The provision to appoint an EA/EAB might arise as a requirement following the ethics review (and be a contractual obligation for the Beneficiary) or might be set forth by the Applicant/Beneficiary at its own initiative, as part of the original research proposal.

- 1.2. When their appointment is required as a result of the ethics review, the EA and EAB Members **must be independent and external** to the project and to the department(s) or group(s) conducting the research.

EAs/EABs must be independent from the Beneficiaries of the project and execute their responsibilities in full independence of other professional and academic commitments.

To be independent, EAs/EABs may not have any conflict of interests in relation to the project or its Beneficiary/ies. **Conflict of interest may arise from any economic interests, from any professional or financial constraints, from family or other personal links, or from any other relationships or common interests which may compromise the independent nature of the advisory work performed as well as of the report(s) to be submitted to the Commission/Executive Agency/Funding Body.**

EA/EAB Members must notify the project Coordinator of any professional, financial, family or other personal links, or any other relationships or common interests, that could result in a conflict of interest. The Coordinator must notify to the Commission/Executive Agency/Funding Body without delay.

EA/EAB Members may not reveal any information about the project's activities and its outcomes, without the express written approval of the Beneficiary/ies or the Commission/Executive Agency/Funding Body.

- 1.3. Alternatively, the appointment of an EA/EAB might have been proposed as part of the **original research proposal** and thereby become included in the Description of Work (DOW) and/or included in the **management structure** of the project. Whereas such EA/EAB Members may not be external to the projects, it is **highly advisable that the proposed EA/EAB is independent** from the Beneficiary/ies, as independence will be essential in providing valuable advice. It may avoid the mandatory appointment of an additional independent EA/EAB as a result of the ethics review. Even if work packages include ethical analysis and guidance as part of the project structure, the means for sustaining this independence of operation is essential.
- 1.4. Similar to the EA/EAB, an “**Ethics Mentor**” can be appointed to provide ethics guidance and advice. An Ethics Mentor can be a (senior) colleague, member of the same department or institution. Hence, the key difference with an EA/EAB is that the Mentor **may not be independent** from the beneficiary and generally does not have any reporting duties, although it is highly recommended that a report on the activities of the Mentor is kept on file. The appointment of an Ethics Mentor can be recommended or

required as a result of the ethics review and/or might have been proposed as a work package as part of the original research proposal and thereby become included in the Description of Work (DOW).

- 1.5. The EU Ethics appraisal process considers 'ethics' as including questions of legal and regulatory compliance as well as questions on moral principles, fundamental rights and values, and how these apply to research activities. It is part of a process of 'governance', that aims to ensure the protection of the rights and interests of all those affected by research and related activities, respect for fundamental EU values and human rights, and that EU funded research is not misused.

The aim of this document is to indicate how the mandate and operation of EAs and EABs is to contribute to a positive and operational research quality assurance strategy. However, EAs and EABs must retain the courage to be strict in cases where significant ethics problems arise, and their intervention is necessary to maintain high research ethics standards and meet the set ethical requirements. Therefore, the operation of EAs and EABs must be backed by a clear mandate and adequate resources.

- 1.6. The breadth and scope of the mandate of EAs/EABs may vary significantly, depending upon the following factors, among others:
- Anticipated seriousness and/or complexity of the ethics issues and the potential risks
  - The size of the project and, the number of ethics issues it raises
  - The existing legal and ethical oversight structures
  - The overall maturity of the proposal
  - The level of ethics experience/expertise of the researcher(s) involved

Hence, **the mandate and role of the EA/EAB will need to be proportional and tailored to the specifics of the project and the needs of the Beneficiary/ies**. For further guidance on this issue, please consult [Annex III](#).



## 2. Appointment/Recruitment, Expertise and Membership Criteria

- 2.1. As a general rule, **the choice between an EA and EAB should reflect the size of the grant and the number, severity and complexity of the ethics issues raised by the activities.** In practice, 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 number of researchers, institutions and or research activities, however, it may be impossible for one single advisor to properly oversee the project. What is more, when there is a broader variety of ethics issues raised by the activities of the beneficiary, multiple areas of expertise might be needed to ensure proper advice and monitoring of the ethics issues.
- 2.2. The **appropriateness of the EA's or EAB members' competencies and proven expertise** is essential to the effectiveness and thoroughness of the performance of the role.

EAs and EAB Members should have expertise in research ethics in general and/or substantive experience in the assessment of ethics issues in the specific topic area of the project. In addition, expertise in applicable law, data protection and privacy may be necessary.

The concept and application of EAs/EABs is well established in the medical and animal welfare area and adequate expertise is usually readily available. However, in other areas of research relevant for ethics (e.g., social science and humanities, digital technologies, new and emerging technologies, artificial intelligence), it can be more challenging to find external experts with adequate expertise. Whenever you need assistance in finding experts, your first point of contact should be the research ethics and integrity officers at your institutions, members of institutional ethics committees, law faculties and philosophy and/or ethics departments at your institution. While members of those committees or departments might not be independent and thus not suitable candidates, they might be able to refer you to other experts in the field.

For projects with EU classified information (EUCI) that require **security clearances**, it should be made clear that the members of the EAB or the EA might also need adequate clearance in order to have access to all relevant information. This should be clarified beforehand to ensure adequate time is given to obtain such clearances and to have a functional EA/EAB at the start of the project.<sup>2</sup>

- 2.3. **Independence and impartiality** will be essential in providing fair ethical judgements and expertise and recruitment practice must take this into consideration. The appointment of an EA/EAB is to assist the beneficiary to address ethical issues. Hence, besides being an obligation, it is in the beneficiary's best interest to ensure the independence and expertise of the EA/EAB.

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<sup>2</sup> For more information, please consult Section 13 of the [Horizon Europe Programme Guide](#) and the Guidance notes [How to handle security-sensitive projects](#) and [Guidelines on the classification of information in Horizon Europe projects](#).

### 3. The Advisory Role

- 3.1. The EA/EAB should assess the ethical merits of the work performed by the Beneficiary/ies, give independent recommendations, and, if required, report to the Commission/Agency/Funding Body on the project's compliance. Where appropriate, the EA/EAB can give advice on approval requirements, risk-benefit assessments, guidance on specific ethical questions and guidance concerning the relevant legal framework and regulatory requirements in the countries where the research takes place.
- 3.2. Importantly, for EAs/EABs required by the **Ethics Review**, the EA and EAB Members **are not and may not** be held responsible for the Beneficiary/ies' compliance with the ethics requirements and the applicable ethical and legal standards.
- 3.3. The **mandate** of the EA/EAB should be clearly defined and outlined in a **Memorandum of Understanding (MOU)**. For EAs/EABs required by the **Ethics Review**, the MOU should accurately reflect the mandate specified in the **Ethics Summary Report (EthSR)**. Specifics can be further negotiated between the EA/EAB Members and the Consortium Management.
- 3.4. Securing the 'best interests' of society is one of the main goals. EAs/EABs exist to **offer, advice, monitoring and recommendations for future work**. EAs/EABs should operate according to the mandate outlined in **MOU** at the beginning of the project –neither dominating the work nor obstructing it unnecessarily. They should be **facilitative**.

However, there are times when EAs/EABs will and must be able to apply mandatory or regulatory powers. To have a real impact, EA/EAB consultation must be incorporated in the key decision-making processes, rather than seeking post factum approval. The EA/EAB may advise the Commission/Executive Agency/Funding Body to initiate an **Ethics Check/Review**.<sup>3</sup> The EA/EAB may do so without any restriction – including for activities conducted outside the EU and/or by non-EU project partners.

- 3.5. EAs/EABs are **resources for advice and guidance** when ethical issues and dilemmas arise during a project's activities. In addition, EABs with oversight functions will check compliance with ethical standards within the relevant research fields.

Therefore, EAs/EABs must maintain an overview of operations throughout a project, helping with preparation in terms of thinking ahead about possible problems and how they can be addressed. Any sense of static, **'tick-box' approvals must be avoided**.

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<sup>3</sup> The objective of the **Ethics Checks/Review** is to monitor during project implementation how ethics issues are addressed by the Beneficiary, assist the Beneficiaries, and, if necessary, to take preventive or/and corrective measures. The **Ethics Check** is an internal check by the project officer or ethics officer who may be supported by ethics experts. The **Ethics Review** is an elaborate review and in-depth procedure carried out by up to 5 external ethics experts. Both procedures are conducted on the basis of the information provided by the concerned beneficiaries. Onsite visits can also be organised during the Ethics Reviews. In case of substantial breach of ethical principles, research integrity or relevant legislation, the Commission can carry out an **Ethics Audit** following the provisions and procedures laid down in the grant agreement. 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.

- 3.6. Clarity in all communications coming from the EA/EAB is essential. Advice offered must be understandable by the partners so that appropriate actions can be taken – it must be **pragmatic/workable**. Direct communications between advisors and partners is vital.
- 3.7. **Transparency** and **critical detachment** are important components of ethical advice and oversight. Being open and clear about decision, actions to take and the rationales behind them is good practice.
- 3.8. The EA/EAB 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**, thereby assisting the Commission and its Executive Agencies in ensuring that researchers, research participants nor the general public are exposed, by the work of the project, to activities that would be considered to be ethically unacceptable or even prohibited.

As research activity is dynamic and evolves along unpredicted pathways, advisors must be prepared to tackle new issues and concerns as they arise, and the ethical perspective will need to be revised throughout the lifetime of the project.

- 3.9. Clarification of remit in terms of relevant ethics issues should be carried out at the start of the whole process. **Therefore, the Ethics Summary Report provided by the Ethics Review panel should clearly justify making any recommendations and requirement for an EA/EAB.** Furthermore, the Consortium coordinator should ensure that the Ethics Summary Report (and any subsequent Ethics Check/Review reports) are fully available to partners and that they are acted upon. The EA/EAB should, as far as is possible, ensure there is consistency of advice and practice across all ethics experts.

The partners' actions must be consistent with their responses to the **Ethics Issues Table** contained in the original proposal. Any relevant changes should be reported and explained to the EA/EAB and the Commission/Executive Agency/Funding Body. In some cases, the Grant Agreement (GA) might introduce specific ethics requirements as a result of the Ethics Review or Ethics Check/Review. It is an important function of the EA/EAB to advise the beneficiary on how to ensure compliance with the requirements outlined in the GA. Where differences of opinion, judgment and/or interpretation exist, between the EA/EAB and the Ethics Panels or within the EAB, these should be explained to partners to assist in their application to practice.

- 3.10. EAs/EAB Members cannot work so closely with the Beneficiary/ies or become “part” of the working team. Otherwise, the EA/EAB is no longer external or independent. In cases where the role of the EA/EAB would be closely linked to a technical deliverable (e.g., participation in the development of “Privacy by Design/Default” concepts), it might be worthwhile considering the use of individual work packages and **integration of ethics experts as project partners** as part of the working structure that ensures easier integration of the expertise in the daily research. Similarly, where ethics is integrated and part of the research work packages, including project partners familiar with the legal and ethical requirements might serve the project better than an independent EA or EAB. Nonetheless, to ensure independent judgement in highly sensitive research, the establishment of an EA/EAB should be considered in addition.

## 4. Establishing Working Practices

- 4.1. Working practices should be formally agreed and clarified from the outset. To avoid confusing flows of information, it should be clearly outlined in a **Memorandum of Understanding (MOU)** how the interaction between the consortium and the EA/EAB takes place.

A clear division of tasks between the EAB Members and applied to specific project deliverables according to members' expertise can increase the efficiency of operations. An EAB Chairperson should be elected from the membership and may speak on their behalf.

Ongoing liaison between the EA/EAB and project partners might be optimized by identifying an individual from each of the partners with responsibility for communicating with the EA/EAB. It might be of some help if this individual had some expertise in research ethics, data protection and/or privacy issues – but this is by no means the only way to ensure effective liaison.

It is highly recommended that principal link to the consortium be established between the EA/Chairperson of the EAB and Project Coordinator. This is also important for ensuring consistency of advice and avoiding confusion – as controversial issues might need discussion among all members of the EAB prior to the formulation of clear advice.

In addition, it is important that the EA/EAB keeps up regular contact with any partner bearing work package responsibilities for ethics-related actions and that both know what actions the other is taking and planning. This should ensure consistency and coordination and help avoid any unnecessary overlaps or duplication of effort.

All other project groups (partners and advisors) should be encouraged to raise issues with the EA/EAB knowing they are to be treated with discretion.

- 4.2. Ethical issues can become quite formidable or can be capable of being addressed in a straightforward way – largely dependent on the primary substantive focus of the project and the complexity and severity of the ethics issues involved. In all cases **'proportionality'** is of the utmost importance: EA/EAB practice should be proportionate to the topic in hand.

Hence, the **format and frequency of meetings** should reflect this proportionality, as should **the reporting** function. When justified by the severity of the ethics issues, attendance by the EA/EAB members at relevant project meetings should be possible (whether virtual or face-to-face). Likewise, project partners should be invited to EAB meetings in case specific questions need to be addressed.

Although face-to-face meetings are advantageous in solving complicated issues, it is often not feasible to convene all members together at a certain place and time due to time, financial and health constraints. Alternatives might be e-mail conversation or videoconferences. Nevertheless, face-to-face meetings should take place when feasible to ensure active discussions between the members of the EAB and with the researchers involved in the project.

- 4.3. If there is an additional Oversight Board for the project, then the EA/EAB Chairperson should be *ex officio* a member of the Oversight Board. If there is no Oversight Board, the EA/EAB Chairperson should be allowed, when necessary, to participate (as independent observer/advisor) in Consortium (management) meetings.

When relevant, the EA/EAB Members should be able to attend project meetings, have access to technical reports and papers for publication, and monitor all the authorizations, approvals and licences.

4.4. **Memorandum of Understanding (MOU)** should include, where relevant, a **confidentiality agreement**. However, any such agreement may not prevent the EA/EAB to report ethical misconducts directly to the Commission/Executive Agency/Funding Body.

4.5. EAs/EABs should develop:

- a) **a Program of Work** lasting for the duration of the project that includes, if applicable, reporting deadlines corresponding with the reporting requirements set by the Ethics Review of the proposal performed by the Commission/Executive Agency/Funding Body;
- b) procedures for conducting its work that apply the principles of proportionality, appropriate participation, procedural justice, responsible stewardship, accountability, transparency, effectiveness, and coherence.

The Program should define and shape reporting; the stated procedures should guide the decision-making process and be reflected in all Reports.

4.6. EAs/EAB Members may have to gain some level of familiarity with the technical aspects of a consortium's work and the research field in general, as well as gaining fuller understanding of how the consortium plans to operate. To ensure that adequate expertise can be recruited, and the task is treated in a professional manner, **compensation for the work** must be foreseen.

Funding must be adequate to the task. **Clarity over fees and expenses is vital**. The workload in complicated projects can be very high and may require the commitment of several full working days. The commitment can be substantially higher if the DOW links the advisory work to specific research and/or networking activities.

It is therefore advisable to include this in the project application, to avoid budget reallocation during GAP. Moreover, it may be hard to fully anticipate the budget in advance since the need to address unanticipated issues might occur. This suggests that some room for manoeuvre within the budget is needed.

Importantly, to avoid conflicts of interests and compromising its independence as a result of financial interests, the compensation should not be linked to any specific outcome related to ethics.

4.7. For EABs, the Members should cooperate to work out as much as possible **consensus-based** recommendations. In cases where no consensus can be reached, it is recommended that the EAB provide a transparent overview on its discussion to the project management, detailing why no definitive advice was possible.

All meetings of the EAB should be based on an **agreed agenda to ensure efficient decision-making**. Relevant documents should be circulated beforehand to allow for adequate preparation. Meetings should be co-ordinated by the Chairperson and a report should be prepared for each meeting and communicated to the project management.

In particular for highly significant and/or severe issues, EAs/EABs should include summaries of discussions and issues arising in formal meetings in their regular reports. Other suggestions for items to include in reports are included in [Annex II](#).

- 4.8. 'Conflicts of personalities' can impede effective ethical practice, so the operational mechanisms must be such that personality 'clashes' can be overridden. In all cases a **culture of mutual respect and understanding** of the other's position should be cultivated.

## 5. Identifying Appropriate Ethical Best Practices and Criteria to Apply

- 5.1. Ethics advice should incorporate the assurance that EU/national/local laws are complied with, as well as international ‘soft laws,’ and widely accepted ethics codes and guidelines. This position is reflected in the statement that:

*Actions which fall within the scope of the Programme should respect fundamental rights and observe the principles acknowledged in particular by the Charter of Fundamental Rights of the European Union (the ‘Charter’). Such actions should be in conformity with any legal obligation including international law (...), as well as with ethical principles, which include avoiding any breach of research integrity. The opinions of the European Group on Ethics in Science and New Technologies, the European Union Agency for Fundamental Rights and the European Data Protection Supervisor should be taken into account, where appropriate. Article 13 TFEU should also be taken into account in research activities, and the use of animals in research and testing should be reduced, with a view ultimately to replacing their use.<sup>4</sup>*

One of the greatest challenges is to ensure that all advice given is underpinned and justified by the appropriate ethical and/or legal frameworks and principles. EA/EABs should refer to the normative documents they base their advice on in order that their work has legitimacy and is coherent across the board. A non-exhaustive list of relevant documents is included in:

- [How to complete your ethics self-assessment](#)
- [Horizon Europe Programme Guide](#), Section 12

- 5.2. Ethics needs to permeate all parts of the project ‘culture’ to be effective. In the interests of raising and maintaining **ethics awareness**, all aspects of the project’s activities require the maintenance of an ethical perspective. A sound ethics policy requires transparency and balance. Evidently some risks of harm for any project can be anticipated, but by no means all.

One way of maintaining ethics awareness is to establish a set of ‘core values’ or ‘principles’ to be signed up to by all partners. Additionally, an ethics checklist to act as an aide memoire and modified to apply specifically to the project in hand can be a focus for ethical practice. Application of the checklist can highlight misunderstandings of terminology and conceptual problems associated with the rationales that lie behind conventional ethical principles. A basis for core values and principles are outlined in Article 19 (1) of the [Horizon Europe Regulation](#), and Article 14 and Annex 5) of the [Grant Agreement](#). This together with applicable legal provisions, codes of conduct and guidance documents provided by the European Commission should form a base for the work of any EA/EAB.

- 5.3. EU-funded research and related activities must comply with ethical principles and relevant European, national and international legislation, including the EU’s Charter of Fundamental Rights and the European Convention on Human Rights and its Supplementary Protocols.<sup>5</sup> When research or related activities are conducted outside the EU, however, it may be the case that local standards diverge from

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<sup>4</sup> [Horizon Europe Regulation](#), Recital 71.

<sup>5</sup> Article 19 of the [Horizon Europe Framework Programme and Rules for Participation Regulation \(EU\) 2021/695](#) (OJ L 170, 12.5.2021)

the best practice standards set by the EC. In such instances, there may be an important role for the EA/EAB to ensure that appropriate EU standards are met.

- 5.4. The **societal implications** of any EU-funded projects might be considered to be relevant to ethics oversight. EAs/EABs might be tasked with including some assessment of societal implications and/or risks as part of their duties.
- 5.5. Some degree of flexibility is of benefit when thinking through both ethical and societal impact issues. The combination of partner ethics, independent expertise and the potential to draw upon a breadth of experience across an EAB allows for a balance of 'interests' and could help ensure that no 'vested interests' dominate.



## 6. Liaison with other relevant EU-funded projects and resources

- 6.1. EAs/EABs should be aware of and, when appropriate, liaise with other relevant EU-funded projects. Many EU-funded projects have faced and continue to face very similar ethical issues. It is therefore strongly recommended to reach out to and liaise with other projects on ethics, to avoid duplication of effort, which is a waste of resources and impedes the building of foundational work that could enable more rapid and widespread ethical awareness. Information about all projects and funding programs is available on [CORDIS](#).
- 6.2. EU-funded projects that have established ‘codes of conduct’ or other relevant ethics guidances could provide the basis for similar ethics progress elsewhere. Some interesting examples are:
- [TRUST Code of Conduct for research in resource-poor settings](#)
  - [SHERPA Guidelines for Use and Developments of AI or big data system](#)
  - [SIENNA Ethical guidance for Research with a Potential for Human Enhancement](#)
  - [Human Brain Project Opinion and Action Plan on ‘Data Protection and Privacy’](#)
  - [iConsent Guideline for Tailoring the Informed Consent Process in Clinical Studies](#)

The ‘official’ status of such codes can vary greatly – the main point is to be aware of foundational advice they contain and perhaps view them as ‘helpful tools’.

The [Embassy of Good Science](#) also contains a significant number of resources on research ethics and research integrity, such as codes of conduct and ethics guidelines from publishers, academic societies, national research agencies and funders. Relevant knowledge on best practices and guidelines can be shared via this platform. Other relevant networks are The European Network of Research Ethics Committees ([EUREC](#)), The European Network of Research Integrity Offices ([ENRIO](#)) and All European Academies ([ALLEA](#)), the European Federation of Academies of Sciences and Humanities.

- 6.3. Any liaison activities between EAs/EABs directly related to project actions should be discussed and agreed with the project management in advance, to ensure that no confidential, project-specific information is exchanged between competing research consortia.

## Conclusion

This document is intended to draw some initial observations and recommendations. The Working Group<sup>6</sup> is seeking to establish some guidance for best practice and ground rules that outline what the Group believes should be the framework of operation of the Ethics Advisor and/or Ethics Advisory Board.

In certain respects, the role of EA/EAB can be seen as the Commission fulfilling obligations that arise from the funding of emerging, innovative (often weakly governed) research to ensure that the most appropriate standards are applied and met, whilst admitting that some standards that develop in a complex innovative environment can only be provisional best practices. Meeting the challenge of making the EU the most competitive and dynamic knowledge economy in the world requires that innovative research be funded, but it is precisely such research that may pose the most complex ethical challenges.

Nevertheless, it is required that proposals/projects do not merely pay lip service to the advisory function but recognize how seriously it is to be taken throughout the life of a project. Any attempt to simply use the EA/EAB to satisfy the Commission concerns while ensuring that EA/EAB do not inhibit or interfere with the main direction of the research is to be strongly resisted. The EA/EAB must not simply become a symbolic cipher without any effective power to influence the ethical terms and references of the research activities or the methodology that will be used.

The advisory role is a proactive one. The cultivation of mutual understanding between the EA/EAB and project partners can see differences resolved through diplomacy and clear communications. Problems can be forestalled through cooperative endeavour and a culture of collaborative working.

There is no doubt that serving as an EA/EAB Member on a major project is a very challenging and demanding job and requires a great deal of dedication, experience, commitment and enthusiasm. It is essential to master the details of the research, keep up to date with the latest developments in the field whilst at the same time keeping pace with developments in the ethical opinions and legislation. It also requires the patience to win over what may initially be a critical group of researchers, enthuse them with the concept of ethical probity and demonstrate that the EA/EAB has something positive to contribute to the project. It should be clear from the foregoing that the Working Group sees it as imperative that the forms and functions of EAs/EABs are strengthened in recognition of the vital service performed by Ethics Appraisal Process, the public protections it affords and the checks and balances on the massive investment of public funds.

When seeking to formulate good practices in the area of ethics the uncertainty that often surrounds emerging, innovative science may give rise to further aspects of ethics uncertainty. It is thus suggested that a strong focus should be on developing procedures for deciding what should be done, applying the principles of participation, procedural justice, responsible stewardship, accountability, transparency, effectiveness, and coherence.

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<sup>6</sup> This document was originally produced in 2012, by a Working Group of the following ethics experts: Nicola STINGELIN, Guido VAN STEENDAM, Johannes RATH, James A HOUGHTON, Joseph SCHMUCKER VON KOCH, and Ron IPHOFEN (coordinator).

## Annex I: Quick Reference List of “Do’s” And “Don’ts” for Beneficiaries and EA/EAB Members

### Recruitment/Appointment of EA/EABs

	<b>Do’s</b>	<b>Don’ts</b>
Expertise	Select advisors on the basis of their known competence in the field of concern	Assume all ethics advisors have same expertise/experience
Range	Cover the range of expertise relevant to the project	Merely look for ‘breadth’ of coverage
Complementarity	Ensure the advisors’ expertise and experience match project needs and fit with each other	Neglect to examine CVs to determine expertise
Adequacy	Check for relevant expertise/experience	Assume all ethics advisors have same expertise/experience
Independency, Conflict of Interest	Recruit independent professional experts	Ask your best friend for a favour or recruit your EA/EAB from the project partners or their home institutions

### Establish EA/EAB procedures

Security clearances	Define clearly for whom and from whom security clearances are needed and request such clearances in advance	Wait until project starts to think about security clearances
Confidentiality agreements	Clarify what can be ‘shared’ outside the project and allow for direct interactions with Commission/Executive Agency/Funding Body representatives	Assume advisors know what can be shared
Handling of confidential information	Provide clear guidance on what constitutes project confidential information or security-sensitive information and provide adequate platforms for sharing such	Assume advisors know how to handle confidential information

	information	
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### Relationship to Consortium

	Do's	Don'ts
Memorandum of Understanding	Agree terms of working relationship	Believe that it works anyway
Points of contact	Make sure advisor(s) have point(s) of contact for project management/coordinator and all project partner(s) with responsibility for ethics	Fail to formalize liaison arrangements
Participation in Consortium Meetings	Involve ethics advisor(s) throughout the project, at all stages to completion	Side-line advisors
Independence v. integration	Ensure partner representatives attend EAB meetings if necessary and requested by the EAB.	Compromise independence

### Within EAB

Nominate a Chairperson	Elect the Chair from the EAB members	Accept an appointee from the consortium
Decision-making procedure	Clarify decision-making within EAB	Be vague about how decisions are to be taken
Meeting protocol	Set agenda and record discussions, decisions and actions	Allow meetings to be informal 'conversations'

### EA/EAB Powers

Oversight	Maintain comprehensive vigilance over the whole project	Assume all recommendations will be followed
Contractual approval obligations	Be clear about what is allowed (in ethical/legal terms) and be willing to apply contractual powers if necessary	Approve if full information is not given. Hesitate to act due to 'personal' concerns
Guidance	Be clear and precise about actions to	Leave room for doubt

	be implemented	
Whistleblowing clause	Encourage disclosure of problems	Accept complaints at face value
Budgetary control	Ensure adequate resources for whole project	Devalue the work of ethics advice

### External relationships (obligation and responsibilities)

	Do's	Don'ts
European Commission	Follow-up contractual ethics obligations included in the Grant Agreement or other ethics reports <sup>7</sup>	Fail to use Commission expertise
National Data Protection Agencies, Radiation safety authorities, Biosafety Authorities, RECs with legal authority (e.g., animal welfare, clinical trials)	Follow-up compliance with national/local ethical and legal requirements <sup>8</sup>	Duplicate the work of responsible authorities
Institutional RECs with 'local' jurisdiction	Find out the limits to jurisdiction, obtain and implement their advice	Upset or ignore local institutional RECs

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<sup>7</sup> EA/EABs are never responsible for the ethics compliance of the project. The responsibility rests solely with the beneficiaries.

<sup>8</sup> Ibid.

## Annex II: Reporting Guidance for EAs/EABs

1. EAs/EABs should recall that:
  - The reports and advice offered be **pragmatic/workable, clearly explained and justified** (with reference to the principles, criteria, approached 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 by the EA/EAB 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 of the EA/EAB included in the **Ethics Summary Report**.
  - An EAB should aim to give **consensus-based** recommendations. In cases where no consensus can be reached, it is recommended that the EAB provides a transparent overview on its discussion to the project management, detailing why no definitive advice was possible.
  - The main role of the EA/EAB is to provide guidance to the beneficiary on how to best address the ethics issues with the aim of facilitating the beneficiary's/consortium's ethics compliance. The report should demonstrate how these challenges have been met and what was the role/interaction of the EA/EAB with the beneficiary/ies.
2. There is **no mandatory template** for the report of the EA/EAB and each project is free to choose their own form.

The EA/EAB report may include:

- Context of work/methodology/involvement of the EA/EAB (e.g., number of meetings/interactions with beneficiaries, timeframe);
  - Main research activities with ethical implications and their timetable;
  - Work progress – evidence of compliance;
  - If applicable, an assessment on how the ethics requirements have been addressed;
  - Recommendations, if appropriate (to the coordinator/ a specific consortium partner, to the Commission/Executive Agency/Funding Body) and ethical issues to be followed up
  - Comments for the Commission (if needed)
-  When the appointment of an external independent EA/EAB has been included as an **ethics requirement** in the GA, **the EA/EAB should use the template provided** by the Commission/Executive Agency/Funding Body.

## Annex III: Determining the mandate of the external independent Ethics Advisor or Ethics Advisory Board

### Guidance for ethics evaluators

During Ethics Screening or Ethics Assessment, the external ethics experts performing the mandatory Ethics Review of all proposals for funding may request the appointment of an external independent Ethics Advisor or an Ethics Advisory Board (with a minimum of three experts), reporting periodically to the Commission/Agency/Funding Body.

When determining the need for appointing an external independent Ethics Advisor or an Ethics Advisory Board, defining their mandate, and the scope of their reporting duties, the ethics evaluators should consider the following points:

1. The appointment of external independent Ethics Advisor or an Ethics Advisory Board **should be clearly justified in light of the number, severity and complexity of the ethics issues raised by the proposal and the capacity of the Applicant/Beneficiary to address the ethics issues appropriately.** In any case, the Ethics Summary Report provided by the Ethics review panel should clearly justify making any requirement for an EA/EAB.
2. **As a general rule, the choice between an Ethics Advisor and Board should reflect the size of the grant and the number, severity, and complexity of the ethics issues raised by the proposal.**

In practice, 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 number of researchers, institutions and or research activities, however, it may be impossible for one single advisor to properly oversee the project. What is more, when there is a broader variety of ethics issues raised by the activities of the beneficiary, multiple areas of expertise might be needed to ensure proper advice and monitoring of the ethics issues.

3. If the appointment of an external independent EA/EAB is requested, **the reasons and mandate of the EA/EAB must be tailored to the specific needs of the project, and clearly explained and justified in the Ethics Summary Report.**

The description of the mandate must include, among others:

- A succinct description of the ethics issues that require further follow-up
- A list of relevant (sub-)topics on which the Applicant/Beneficiary must be advised
- The expertise that is required for the EA/EAB Members.
- A clear indication of the **periodicity and timing of the reports** that must be submitted to the Commission/Executive Agency/Funding Body. Please note that, unless otherwise specified, the EA/EAB will be expected to start working at the beginning of the project, even when reports are not yet due.

E.g., *'The applicant has not shown adequate awareness of the ethics concerns related to research involving children. Therefore, the advisor must advise the beneficiary on measures of risk mitigation to ensure their interests are adequately protected and the consent procedures appropriate. In addition, the advisor has to submit a yearly report, covering the ethical aspects of all human involvement and personal data processing.'*

4. The **number of months after project start when the EA/EAB should submit the first report** must be indicated. For ethics issues that must be addressed at the beginning of the project, before the commencement of certain activities (e.g., recruitment of study participants) may warrant requesting the submission of a first report early on (e.g., month 3 or 6). If there is no such specific justification, a single or periodic (annual, bi-annual, or at the end of each reporting period) reports may suffice.
5. The appointment of an **Ethics Mentor** can be **recommended** for proposals that are cleared at screening stage. Please include the following text in the box where the mandate of the ethics advisor/board can be described:

*It is recommended to appoint an ethics mentor to advise the project participants on ethics issues and to keep a report on the activities on file.*

Alternatively, the appointment of an Ethics Mentor can be included as an ethics **requirement** during the ethics assessment stage.



## Annex IV: Glossary

**Beneficiary** – Any legal entity receiving EU-funding

**Conditional ethics clearance** – Possible outcome of the proposal Ethics Review. When a proposal received conditional ethics clearance, *specific* ethics requirements are added to the Grant Agreement (GA) as contractual obligations.

**Coordinator** – Beneficiary of EU-funding that coordinates the project Consortium

**Description of Work (DOW)** – Part of the Grant Agreement (GA) that describes all project's activities, generally divided in work packages (WP)

**Ethics Appraisal Process** - Refers to the entire ethics process, from self-assessment (by the applicant) to proposal review (e.g., ethics screening and assessment) and monitoring during project implementation, e.g., by Ethics Advisor or Board or by Ethics Check/Review/Audit.

**Ethics Assessment** – Stage in the Ethics Appraisal Process, involving an elaborate in-depth proposal Ethics Review, for proposals that raise serious or complex ethics issues or involve the use of human embryonic stem cells or human embryos. The Ethics Assessment can result in the inclusion of *specific* ethics requirements as obligations in the grant agreement.

**Ethics Audit** – Stage in the Ethics Appraisal Process, involving an elaborate in-depth evaluation of the ethics compliance of a project, during project implementation or after project completion.

**Ethics Check** - Stage in the Ethics Appraisal Process, involving the monitoring of the ethics issues and how these are addressed, during project implementation, by EC/Agency staff (the Project Officer/Ethics Officer), if necessary, assisted by one or two ethics experts.

**Ethics Clearance** - Possible outcome of the proposal Ethics Review. A proposal received ethics clearance when no ethics issues are identified, or all ethics issues have already been satisfactorily addressed by the applicant. No *specific* ethics requirements are added to the Grant Agreement (GA), other than the *general* ethics requirement applicable to all Grants:

*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.*

**Ethics expert** – External independent ethics expert contracted by the Commission/Executive Agency/Funding Body to participate in Ethics Panel carrying out the proposal Ethics Review (Ethics Screening, Ethics Assessment), Ethics Check, project Ethics Review or Ethics Audit.

**Ethics monitoring** – All activities that follow-up the ethics compliance of a project during project implementation. Includes the work of the external independent Ethics Advisors and Ethics Advisory Boards, and the Ethics Checks/Reviews/Audits initiated by the Commission/Executive Agency/Funding Body.

**Ethics officer** – Staff member of the Executive Agency/Funding Body responsible for ethics-related aspect of project management.

**Ethics recommendation** – Non-binding advice on ethics included in the Ethics Summary Report (or reports resulting from Ethics Check/Review)

**Ethics requirement** – Contractual obligation related to ethics included in the Grant Agreement (GA) For all Grants, general obligations on ethics are included in Article 14 and Annex 5. In addition, *specific* ethics requirements may be added during GAP as a result of proposal Ethics Review or during project implementation as a result of an Ethics Check/Review/Audit. Some ethics requirements may result in Ethics Deliverables that have to be submitted.

**Ethics Review** - Refers *as a general term* to the ethical evaluation of research, e.g., by university ethics committee (commonly known as IRB or REC). Within the Horizon Europe Ethics Appraisal Process, a Ethics Review can refer to a proposal Ethics Review (before the Grant Agreement is signed) or to a project Ethics Review (during project implementation).

**Ethics Screening** - Stage in the Ethics Appraisal Process, involving the identification of the ethics issues raised by a proposal and the selection of those proposals raising serious or complex ethics issues necessitating an Ethics Assessment.

**Ethics Self-Assessment** – Identification of the ethics issues, and, where relevant, a description of how these will be addressed, provided by the applicant when submitting their proposal.

**Ethics Summary Report (EthSR)** - The ethics report generated after the completion of the proposal Ethics Review, based on the Ethics Consensus Report prepared by the Ethics panel. Informs the applicant of the ethics issues raised by their proposal, and the relevant ethics requirements and recommendations.

**Ethics supporting documents** – All relevant documentation of ethics compliance (e.g., copies of local ethics approvals, training certificates, informed consent templates, etc.)

**Grant Agreement (GA)** – Contract between the Beneficiaries and the Commission/Executive Agency/Funding Body containing all the specific terms and conditions for receiving EU-funding

**Grant Agreement Preparation (GAP) phase** – Phase between proposal evaluation and selection and signature of the Grant Agreement (GA), involving exchange of information between the (prospective) Beneficiaries and the Commission/Executive Agency/Funding Body. Exceptionally, certain ethics requirements have to be met during GAP, before the GA can be signed.

**Institutional Review Board (IRB)** - Local or institutional ethics committee

**Project officer (PO) or Project Advisor** - Staff member of the Executive Agency/Funding Body responsible for project management.

**Project Ethics Review** - Stage in the Ethics Appraisal Process, involving the monitoring of the ethics issues and how these are addressed, during project implementation, by a Panel of 5 ethics experts.

**Proposal Ethics Review** - Part of the Ethics Appraisal Process that takes place before the signature of the Grant Agreement, i.e., Ethics Pre-Screening, Ethics Screening, and/or Ethics Assessment.

**Research Ethics Committee (REC)** – Local or institutional ethics committee

**Work package (WP)** – Part of the Description of Work (DOW) included in the Grant Agreement (GA). During GAP, a WP dedicated to ethics may be added as a result of the ethics requirements set.