

# How to organise the Ethics Advisor & the Ethics Advisory Board?



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# Experience - I

## 1. Lack of Clarity in Task Descriptions:

- **Incomplete Task Descriptions:** Inadequate information provided in the grant agreement or task descriptions from the EC regarding ethical expectations and compliance measures.

## 2. Additional Workload due to Unforeseen Ethical Requirements:

- **Unexpected Requirements:** Discovering post-initiation that certain ethical self-assessment questionnaires or compliance measures were necessary, leading to additional workload for project acceptance.

## 3. Ensuring GDPR Compliance:

- **Data Handling Challenges:** Managing personal data within the context of GDPR compliance, especially when involving non-EU countries, requires careful consideration and potential anonymization measures. Guarantee that non-EU countries do not receive personal data from projects, or, if they need them, measures must be taken. No data should move from EU to non-EU countries without measures. But: Check for each country.

## Experience - II

### 4. **DOW was added to GA by EC just before it was signed:**

- **DOW from EC in our GA has not been complete and it was not clearly written** This has caused problems and delays as we misunderstood the work required and the first deliverables were rejected. We then clarified the required content of the deliverables with the PO and then managed to get heavily revised versions accepted. Fortunately, ILVO has agreed to help with the WP and they have done an excellent job.

### 5. **Ethics Advisor:**

- **We had an Ethics Advisor, but this is perhaps not mandatory (look up GA)** The EA had general experience with ethics requirements. In the meantime the EA is not working for the ERA-NET anymore. Normally it is possible/allowed to do the work without an EA, but it helps.

### 6. **How to find the EAB members:**

- **Ask partners if they know experts who bring different expertise:** We knew three experts who had the necessary experience and knowledge and we asked them and fortunately they agreed to help us – for free! And: they have been accepted by EC.

## | Our advice - I

- **Proactive Communication with Project Officer:**

Engage early with PO to clarify ethical expectations and compliance requirements to avoid unexpected obligations later on.

- **Thoroughly Review Task Descriptions:**

Scrutinize task descriptions and grant agreements to ensure a comprehensive understanding of all ethical obligations and compliance expectations from the EC.

- **Prioritize GDPR Compliance:**

Focus on GDPR compliance by implementing measures to safeguard personal data, especially when shared with non-EU countries, such as anonymization or implementing additional protective measures.

## | Our advice - II

- **Knowledge Sharing and Collaboration:**

Encourage knowledge sharing among project participants and stakeholders to exchange experiences, best practices, and lessons learned in managing ethical aspects, facilitating smoother project execution.

- **Documentation and Proactive Planning:**

Document all ethical considerations, compliance efforts, and lessons learned for future reference and proactively plan for potential ethical challenges to streamline project processes.

- **Do not accept vague answers from EC:**

Be persistent: The first time the deliverable was rejected we asked what was wrong with it and the answer was always "it is not acceptable and needs to be improved", but the PO did not specifically say that the H2020 self-assessment had to be filled in. Our advice: Ask the PO if there are guidelines and a self-assessment questionnaire and if this is sufficient or if even more is required to get the work accepted.

# Why an Ethics Work Package

Ensuring that all research activities funded by the program **align with fundamental ethical principles**, legal frameworks, and contribute to the overall quality, credibility, and societal impact of the research outcomes. The Ethics Advisory Board (EAB) and – if installed – the Ethics Advisor (EA) play a vital role in providing independent and impartial advice on ethical issues that may arise throughout the project lifecycle.



- **Ensures ethical conduct:** help to ensure that research and innovation activities are conducted in an ethical manner and that potential risks and harms are minimized.
- **Promotes public trust:** help to build public trust in research and innovation by demonstrating that researchers are committed to ethical principles.
- **Enhances decision-making:** provide valuable insights and recommendations to researchers helping them to make informed decisions about ethical issues.

# How?

- **Identify Purpose and Scope:**

Define the EAB objectives, roles, responsibilities, and the scope of its influence.

- **Select Diverse Expertise:**

Choose members with diverse backgrounds, expertise in ethics, law, relevant industries, and stakeholder representation.

- **Establish Governance Structure:**

Define roles, responsibilities, meeting frequency, reporting mechanisms, and decision-making processes within the EAB.

- **Maintain Independence and Conflict-Free Participation:**

Ensure EAB members have independence and no conflicts of interest. EA should act independently in advising the EC and project consortium.

- **Regular Communication and Collaboration:**

Facilitate communication between EA, EAB, and project partners, promoting consistency and avoiding duplication of efforts.

# Challenges

- **Navigating Complex Ethical Issues:**

The EAB must have the expertise and capacity to effectively address complex ethical issues.

- **Ensuring Compliance with Multiple Regulations:**

The EAB must ensure that the project's ethical framework complies with all applicable regulations.

- **Balancing Scientific Progress and Ethical Responsibilities:**

It must ensure that the pursuit of knowledge does not come at the expense of ethical considerations.

- **Engaging with Diverse Stakeholders:**

The EAB must effectively engage with stakeholders to address their ethical concerns and foster trust in the project.

- **Managing Conflicts of Interest:**

The EAB must have clear policies and procedures to identify and manage potential conflicts of interest.

# Pitfalls, opportunities

## Pitfalls

- **Tick-box compliance:**

It can be seen as a tick-box exercise, with little real impact on ethical decision-making.

- **Reactive approach:**

EAB often take a reactive approach to ethics, responding to concerns after they arise rather than proactively identifying and mitigating risks.

- **Lack of authority:**

EAB have not the authority to enforce their recommendations, leading to their advice being ignored.

- **Conflicts of interest:**

EAB members may have conflicts of interest that could influence their judgment.

- **Lack of diversity:**

In terms of expertise, perspectives, and backgrounds, leading to blind spots and inadequate guidance.

## Opportunities

- **Enhanced ethical conduct:**

EAB can help to ensure that H2020 projects are conducted in an ethical manner.

- **Mitigated ethical risks:**

Identification and assessment of potential ethical risks associated with projects and help to develop strategies to mitigate those risks,

- **Promoted ethical innovation:**

Encourage researchers to think about the ethical implications of their work and to develop innovative solutions to ethical challenges.

- **Increased stakeholder trust:**

The involvement of an EAB can demonstrate a commitment to ethical principles and enhance public trust in H2020 projects.

- **Improved decision-making:**

Provide valuable insights and recommendations to help researchers make informed decisions about ethical issues.

# Differences between running ERA-Nets and Partnerships

Ethical Advisory Board (EAB) within different collaborative research frameworks like ERA-Nets and Partnerships may exhibit some differences in their focus, scope, and operational mechanism.

**1. ERA-Nets:** Focus on coordinating national research programs. EAB involvement may vary based on the alignment of national ethical standards.

- **Thematic Areas: Focus on specific thematic or fields of research**

**2. Partnerships:** Collaboration between public-private entities. EAB involvement might be very useful due to very different kinds of stakeholders.

- **Broader Research Scope: Focus on addressing societal challenges and innovation in diverse fields.**

**Due to the involvement of diverse stakeholders and multifaceted research aims, ethical considerations might be more complex and varied**

**Thank you for your attention!**



**LET'S KEEP IN TOUCH!**

Please feel always free to reach out to us.

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