

Implementation Guide

implementing and improving research
ethics governance structures at Higher
Education Institutions (HEIs) and
Research Performing Organizations
(RPOs)

the irecs implementation guide what, for whom and why

This guide is aimed at leaders of Higher Education Institutions (HEIs) and Research Performing Organizations (RPOs) interested in implementing a comprehensive research ethics governance structure at their institutes. It outlines a framework to guide local efforts in a flexible manner. The implementation guide includes several mechanisms that can be tailored to an institute's needs and context, alongside guiding questions and practical examples that exemplify the framework.

A comprehensive research ethics governance structure enables research institutions and individual researchers to meet ethical demands posed by both the academic system and the society. As such, it also helps strengthen responsibility and trust in science. However, a strong research ethics governance structure often requires the activation of various instruments at multiple levels of an organization. This implementation guide offers a pragmatic way to organize such efforts by means of a four-pillar framework.

The EU-funded irecs project aspires to improve research ethics expertise and competencies to ensure reliability and trust in science. During the project, three universities, members of the irecs consortium, took steps to improve research ethics governance in their respective institutional contexts. With the further support of the European University Association (EUA), this guide incorporates their experiences and lessons learned.

our framework at a glance



the 3 pilot universities

Maastricht University (UM)

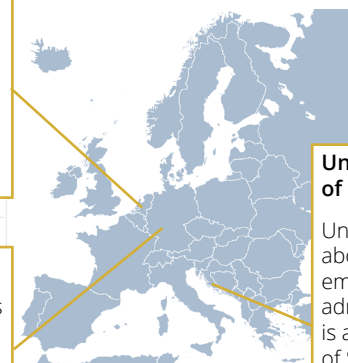
UM has approximately 23.000 students and employs nearly 2.500 academic staff, including 411 doctoral researchers. It consists of six faculties that host 71 research institutes.

University of Bonn (UBO)

UBO employs 699 professors and 5.399 scientific staff, teaching more than 38.000 students, including more than 6.500 doctoral students.

University of Split School of Medicine (MEFST)

University of Split enrolls about 20.000 students and employs 1750 academic and administrative staff. MEFST is a part of the University of Split, functioning as a separate legal entity but collaborating with other University constituents.



pillar 1

Ethics by training

Offer trainings in research ethics, including the ethics of emerging technologies

Education, starting at an early stage and continuing throughout all career stages, enhances both the researchers' capability to integrate ethics into their practice and their appreciations of the importance of ethics for their work



how-to?

Want to offer a training? These questions can guide your planning:

- Who will be trained?
 - Students
 - Early career researchers
 - Advanced career researchers
 - Research Ethics Committee (REC) members
 - Other
- Which mode of instruction is appropriate for the target group and available resources?
 - Self-paced training
 - Interactive exercises
 - Lectures
 - Other
- What group size can be expected?
- What is their academic discipline?
- What is their level of prior knowledge on the topic?
- Is a specific focus needed or an introduction to research ethics?
- How much person power and other resources are available?
- Are qualified trainers available?
- Should the training be on-site or remote?
- Is the training mandatory or optional? Part of the curriculum, of a (PhD) school, or a stand-alone event?

The experience of Maastricht University (UM)

At UM, we used the irecs training materials to train participants at different levels: undergraduate, postgraduate, PhD, junior REC members. Depending on their level and discipline, each audience had varying interests in different sections of the irecs materials.

A tailored, pick-and-mix approach to training is essential to meeting different needs.

lessons from the pilots

irecs training modules

A comprehensive resource to train individuals on research ethics. Stage-1 modules address the basics of research ethics and research integrity. Stage-2 modules focus on four emerging technologies (AI in health, Biobanking, Genome Editing, Extended Reality) and cover both technology basics and ethical issues. Six case studies complement the modules and deepen learning. All materials are published free to use for all on [ENERI classroom](#) and [The Embassy of Good Science](#).

irecs training instructions

Templates for various modes of instruction, from interactive lectures to roleplays. They are published free to use for all on [The Embassy of Good Science](#).

resources



how-to?

Want to organize administrative support? These questions can guide your planning:

- How aware are the researchers of ethics issues in general and in relation to the project they are planning? How much basic training is needed?
- How many applicants need support?
- Is the use of support services mandatory or voluntary?
- Which resources are available to be invested?
- What level of support can be sustained realistically with the available resources, person power and investment?
- Who can provide the support services?
 - Cross-faculty Research Ethics Committees (RECs)
 - Legally required (medical) RECs
 - Department-specifics RECs
 - Profession-specific RECs
 - Contact points on data protection
 - Contact points on dual use
 - Other
- How may the provided services be scaled up to meet future increases in demand for support?

pillar 2

Ethics by design

Provide administrative support for research ethics, with clear division of responsibilities

Pragmatic, transparent, and supportive ethics guidance—whether from advisory services or relevant committees—enables researchers to embed ethical considerations throughout the entire research and innovation cycle



irecs policy briefs

Emerging technologies pose significant challenges to the work of research ethics committees. In four policy briefs, we identify such challenges with respect to four emerging technologies: [AI in health](#), [Biobanking](#), [Genome Editing](#), [Extended Reality](#). Needs and gaps in the ethics review process are further examined in our report “[D2.4- Proposals for adaptation of ethics review processes](#)”.

resources

The experience of University of Bonn (UBO)

To provide researchers with accessible, quick and field-specific ethics reviews, UBO is implementing a new cross-faculty Research Ethics Committee. The committee will offer ethics reviews of projects of all UBO researchers; these reviews are an offer researchers can take advantage of on a voluntary basis.

Implementing a new acting body is a complex and time-consuming procedure so it is imperative that the initiative enjoys the support of all parties, including the institution's leadership, the faculties, and—as applicable—any other group affected by the new Research Ethics Committee.

lessons from the pilots



how-to?

Want to integrate research ethics research in your governance? These questions can guide your efforts:

- Are there specific problems or roadblocks with regard to research in your institution? Could (the right) research find solutions to these issues? How would that have to be?
- Could research help develop smoother processes?
- Which guidelines need to be clarified, improved or updated? Where did the reality of research change, now calling for different approaches?
- Is it possible to give clear guidance for grey areas? What would they have to be like?
- Is it possible for researchers to flag up emerging areas of concern?
- Is there sufficient interaction between research ethics researchers and other disciplines in the organisation?

pillar 3

Ethics by scientific discourse

Conduct (and exploit) research on research ethics

Developing new concepts of research ethics advances the field and lays a strong scientific foundation for research ethics governance efforts, including up-to-date guidelines and administrative procedures



Research ethics research at the pilot universities

UBO: Several groups and institutes dedicated to Research Ethics research, such as DRZE, IWE, Centre for Life Ethics, Institute of Philosophy, Dept. of Law, Dept. of Moral Theology

UM: Research ethics researchers integrated at research institutes across the organization

MESFT: Independent dedicated unit (research group), in close collaboration with other University schools

lessons from the pilots



how-to?

Want to facilitate interdisciplinary exchange? These questions can guide your planning:

- Which specific actors should be involved? Are they national or international?
 - Like-minded colleagues
 - Early career researchers
 - Members of the target groups
 - Policy makers
 - Research support staff
- What information content will be shared within the network? Are there concerns about confidentiality and privacy?
- Who will be the contact point between the different actors?
- Is an online collaborative platform needed?
- Does someone in your organization have some established contacts or is part of an already established network?
- Are there pre-existing networks in your context that meet your specific information needs?
- Do the benefits of a European or international network outweigh the challenges of navigating diverse legal and ethical requirements across countries?

established networks

in the EU context, EARMA, EUA, EUREC are established networks to build partnerships with.

irecs e-communities

irecs foster e-communities to enhance research ethics expertise; these communities are open for qualified others to join.

- For early career researchers: Join [our LinkedIn group](#) or our ENERI community [on SINAPSE](#).
- For research ethics trainers: Become a certified irecs trainer and join our community of research ethics trainers on The Embassy of Good Science.

resources

The experience of University of Split School of Medicine (MEFST)

At MESFT, we reached out to established networks in our national context. We closely collaborate with the Croatian Network for Reproducibility and Integrity Network, where we have established contact with the Croatian Science Foundation, the main public research funding body in Croatia, and the Agency for Mobility and EU Programmes.

lessons from the pilots

pillar 4

Ethics by exchange

Establish pathways for interdisciplinary exchange on research ethics

Effective communication pathways and exchange networks enable actors to avoid repeating mistakes, adopt proven best practices and generate added value as well as new learning opportunities



putting the framework into practice

Higher Education Institutions (HEIs) and Research Performing Organizations (RPOs) come in many sizes and shapes. They operate in different (cultural and regulatory) contexts, follow varying organizational arrangements, pursue growth and academic excellence based on own strategic planning, and serve the professional needs of different student populations.

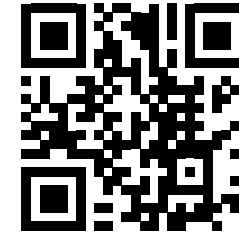
The four pillars of the irecs framework can guide an organization's efforts to implement or improve research ethics governance in their local settings. The four pillars are mutually supportive to each other; it is likely, however, that each pillar will be nurtured to a different degree depending on the organization's profile.

All four pillars need to communicate with each other as well as the university's faculties to ensure that the actual prevailing needs are addressed and met.

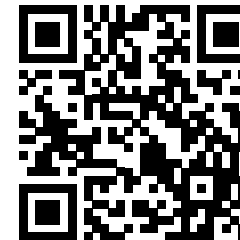
This includes taking into consideration:

- What is needed
- What is already available (at which level)
- Which offers work or do not
- Who provides what (and in which case)

irecs resources



Visit the irecs website: irecs.eu



Check the irecs training materials at the [ENERI classroom](#)

about irecs

The irecs project (*Improving Research Ethics Expertise and Competencies to Ensure Reliability and Trust in Science*) was a 3-year EU-funded project aiming to advance research ethics expertise and competences in new and emerging technologies. The project focused on four emerging technologies (AI in health and healthcare; Extended reality; Genome editing (human/non-human); Biobanking) and developed, implemented and disseminated training material for research ethics reviewers and (early career) researchers.

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Consortium: 18 organizations from 11 countries



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