

Policy Brief: Supporting ethics assessment in research and innovation

The Stakeholders Acting Together On the ethical impact assessment of Research and Innovation (SATORI) project, funded by the European Commission (FP7 scheme), aims to develop a common framework of ethical principles and practical approaches. It also aims to strengthen shared understandings among actors involved in the design and implementation of research ethics.

Who is this policy brief for?

National and international policy makers and advisors, science academies, national ethics committees, networks of research ethics committees, academic and professional associations, university associations, research funding organisations, civil society organisations.

Why was it prepared?

This policy brief aims at publicising the SATORI ethical impact assessment framework and fostering its widespread adoption to enhance responsible research and innovation.

Share the message.

Please share this policy brief with your networks and contacts.

SATORI website: <http://satoriproject.eu/>

This policy brief was prepared by Research Centre of the Slovenian Academy of Sciences and Arts (ZRC-SAZU) on behalf of the SATORI consortium.



EXECUTIVE SUMMARY

Ensuring that R&I follows high ethical standards by reliable and efficient assessment procedures requires well-functioning national systems of ethics assessment based on internationally harmonised principles, which also facilitate international research collaboration.

Key recommendations:

- National governments can support ethics assessment by providing the legal framework and by establishing and funding the institutional network for ethics assessment.
- Intergovernmental organisations can provide the impetus for the harmonisation of ethical guidelines at the international level.
- National ethics committees, science academies, university associations, professional associations and other stakeholders can contribute to the development of ethical guidelines and assessment procedures in all scientific fields as well as organising trainings and raising awareness on ethical issues in R&I.

INTRODUCTION

The SATORI project promotes a vision of a well-developed practice of ethics assessment at the European level, which seeks to **ensure that the European research and innovation (R&I) community follows high ethical standards**. The project partners have studied ethics assessment practices and principles in different EU and non-EU countries, scientific fields and different types of institutions and have consulted an array of stakeholders through interviews and workshops. Based on the project's findings and consultations, SATORI has developed an ethics assessment framework and proposed a set of recommendations for improving various aspects of ethics assessment.

This policy brief presents an overview of ways in which ethics assessment of R&I can be supported and enhanced. It provides a set of recommendations for different types of actors to implement support structures for ethics assessment in institutional settings.

THE IMPORTANCE AND CHALLENGES OF ETHICS ASSESSMENT PRACTICES

Ethics assessment, as an institutionalised review or appraisal of research and innovation (R&I) based on ethical principles, was established decades ago to safeguard the wellbeing of research participants. Today, the advancement of **R&I continues to raise ethical issues** e.g., related to genetics, big data, environmental protection, etc. Ethics assessment is thus an important part of advancing the beneficial role of R&I in society by ensuring its integrity and social responsibility.

SATORI interviews with various stakeholders identified several problems and challenges with ethics assessment systems and practices. Among the problems most often reported by ethics assessment organisations were: **a shortage of resources** (financial, personnel, time allocation, infrastructure), **an absence of clear and harmonised procedures and guidelines**, **a lack of awareness** of ethical issues, **resistance to ethics assessment** among researchers, insufficient attention to **compliance monitoring**. Other stakeholders voiced concerns over increased **bureaucratisation** and lack of respect of cultural **differences** and the specifics of ethical issues in individual scientific **fields**.

The comprehensive approach of the SATORI project contributed to the realisation that the resolution of these problems and thus the further development of ethics assessment practices **calls for the involvement of an array of actors** who are in a position to make a specific and important contribution. National and international policy makers, academies of sciences, national ethics committees (NECs), networks of research ethics committees (RECs), academic and professional associations, university associations, research funding organisations and civil society organisations all have a role to play in improving ethics assessment.

Figure 1: Actors supporting ethics assessment



TOWARDS A SUPPORT SYSTEM FOR ETHICS ASSESSMENT

Ensuring that R&I follows high ethical standards by reliable and efficient assessment procedures requires well-functioning national systems of ethics assessment based on internationally harmonised principles, which also facilitate international research collaboration. This can only be achieved by establishing and maintaining institutional networks, regulatory frameworks and supportive practices that foster good ethics assessment practices.

Ethics assessment requires a **national institutional network** composed of a national ethics committee to oversee the practice of ethics assessment and of a sufficient number of research ethics committees to carry out the assessments. Adequate **resources** (i.e., funding, time allocation, infrastructure, personnel, etc.) should be provided for the proper functioning of this network.

Ethics assessment can only be carried out in a transparent and efficient way if it is based on a clear **regulatory framework**. This entails a grounding in national legislation, and clear ethical guidelines and assessment procedures. Policy makers, national ethics committees and science academies can support these efforts. In an age of globalised and highly cross-border collaborative R&I, efforts to achieve international regulatory frameworks (or at least harmonise national ones) are most welcome.

The work of research ethics committees should be **overseen** by a national body (most suitably a national ethics committee) to assure the quality and independence ethics assessments. Procedures to **monitor compliance** with ethical guidelines and assessments should also be in place.

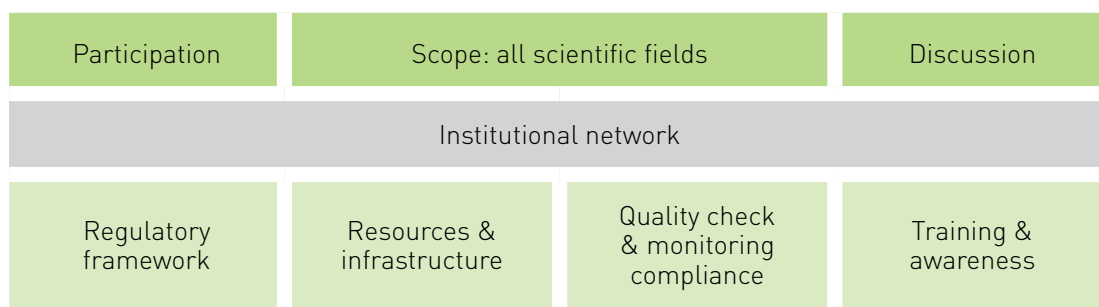
The stakeholders involved in R&I and ethics assessment would benefit from having **platforms for discussion** on recurring and emerging ethical issues. Such discussion forums should operate at several levels: national and international, general and field-specific.

Ethics assessment should be carried out in **all scientific fields** in which ethical issues occur. The ethics assessment procedure should take into account the differences between disciplines.

Trainings for RECs members and the familiarisation of researchers and students with ethical issues in R&I would help improve ethics assessment practices and **raise awareness** of ethical issues.

Ethical issues in R&I have a major societal impact; individuals should thus **participate** in ethical discussions. Civil society organisations can play an important role in raising public awareness of ethical issues in R&I and act as intermediaries in the inclusion of citizens in the ethics debate.

Figure 2: Elements of the support system for ethics assessment of R&I



WAYS OF SUPPORTING ETHICS ASSESSMENT

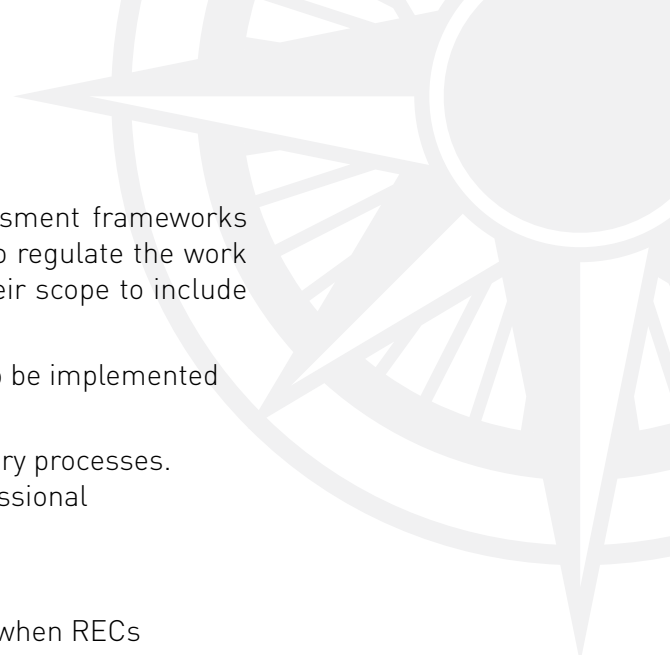
The vision of a well-developed practice of ethics assessment can only be achieved at a system-level by cooperation of various actors. The following recommendations describe the role of individual actors and suggest specific actions they can take to support ethics assessment.

NATIONAL GOVERNMENTS can support ethics assessment by providing the legal framework and by establishing and funding the institutional network for ethics assessment.

- Pass and implement legislation and regulations that clarify the status and responsibilities of research ethics committees and individuals and organisations that carry out R&I.
- Establish and support (with the necessary funding, resources and impetus) national level institutions (e.g., national ethics committee, national science academies) with a clear mandate to develop ethics assessment guidelines, procedures and awareness activities.
- Support the procurement of R&I products and services that have undergone ethics assessment

SUPRANATIONAL AND INTERGOVERNMENTAL ORGANISATIONS can provide the impetus for the harmonisation of ethical guidelines at the international level.

- Establish (multi-stakeholder) international platforms to harmonise ethical guidelines and discuss emerging ethical issues and responses to them.



NATIONAL ETHICS COMMITTEES can develop ethics assessment frameworks and advise on emerging ethical issues. NECs could do more to regulate the work of individual research ethics committees as well as expand their scope to include ethical issues in non-medical scientific fields.

- Develop ethical guidelines and assessment procedures to be implemented by individual RECs.
- Encourage multi-stakeholder discussions and participatory processes. (Consider cooperating with national academies and professional associations.)
- Coordinate and monitor the work of RECs.
- Provide advice to RECs; act as a court of appeal in cases when RECs decisions are being disputed.
- Broaden the scope of ethics assessment to include all scientific fields; institute special sub-committees for different disciplines.
- Organise debate on emerging ethical issues. (Consider cooperating with national academies and professional associations.)
- Consider organising ethics training for REC members.
- Develop procedures for monitoring of compliance with ethical advice, guidelines and RECs' decisions.
- Join or establish international networks to harmonise ethical guidelines and discuss emerging issues.

RESEARCH ETHICS COMMITTEES carry out ethics assessment of R&I. By networking, RECs can exchange good practices and provide bottom-up solutions for ethics assessment frameworks.

- Join, establish or liaise with national and international networks to discuss good practices and propose bottom-up solutions for ethics assessment frameworks based on day-to-day practices.
- Encourage dialogue with researchers to ease resistance to ethics assessment and promote the benefits of ethics assessment for the excellence of research.

NATIONAL SCIENCE ACADEMIES can develop ethical guidelines and raise awareness by organising public discussions on ethical issues in R&I.

- Develop ethical guidelines and advise on emerging ethical issues.
- Encourage multi-stakeholder discussions and participatory processes. (Consider cooperating with national ethics committees, professional associations and civil society organisations.)
- Organise public discussions on ethical issues in R&I;
- Organise and disseminate awareness raising activities and materials.



ACADEMIC AND PROFESSIONAL ASSOCIATIONS can develop ethical guidelines for their field and raise awareness of ethical issues among their members.

- Associations active in specific scientific fields or disciplines should encourage reflection on ethical issues among professional peers and develop discipline-specific ethical guidelines.
- Liaise with international, regional, and national ethics guidance bodies for mutually beneficial learnings in ethics assessment

UNIVERSITY ASSOCIATIONS can play a big role in supporting ethics assessment by adopting ethical frameworks and policies to be implemented by member universities.

- Develop an ethics assessment framework to be implemented by member universities. (Consider cooperating with NECs, national academies and professional associations.)
- Encourage the establishment of RECs and research integrity boards at member universities.
- Include reflection on ethical issues in university curricula to raise awareness among young researchers
- Consider organising trainings for academics and researchers.

RESEARCH FUNDING ORGANISATIONS have an important role in ensuring that the research they fund is ethically assessed.

- Consider ethical issues of the funded research and encourage reflection on ethical issues as an integral part of research projects.
- Ensure that the funded research goes through a process of ethics assessment; to this end, liaise with ethics committees or consider conducting your own ethics assessment procedures.

CIVIL SOCIETY ORGANISATIONS can play an important role in bridging the gap between society and R&I by being more involved in ethics assessment practices.

- Become more involved in research ethics committees as representatives of a specific vulnerable group (e.g., consumers, or patients, children) or spokespersons for a specific cause (e.g., animal welfare, environment, rights of minorities).
- Establish networks to build internal structures for ethics assessment.
- Identify further needs for ethics assessment in R&I and monitor compliance with established ethical principles with established ethical principles.

FURTHER READING

- Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries, SATORI D1.1, 2015. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf
- A reasoned proposal for shared approaches to ethics assessment in the European context, SATORI D4.1, forthcoming 2017.

PROJECT IDENTITY

Project name:

SATORI: Stakeholders Acting Together
On the ethical impact assessment of
Research and Innovation.



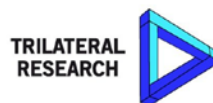
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