



Policy Brief: Improving the organisation of research ethics committees (RECs)

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?

For policymakers and other stakeholders who set guidelines for, or make recommendations to research ethics committees.

Why was it prepared?

To foster and support good practices in ethics committees across Europe.

Share the message.

Please share this policy brief with people in your network who might be interested in best practices for ethics committees, and ethics assessment in general.

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

This policy brief was prepared by the University of Twente on behalf of the SATORI consortium.



EXECUTIVE SUMMARY

Ethics assessment in R&I faces many challenges, which impacts the functioning of research ethics committees (RECs). SATORI stakeholders perceived problems such as lack of clarity regarding legal competencies of RECs and inconsistencies in the appointment process of REC members. SATORI proposes how to improve the governance of RECs, harmonise REC procedures, ensure quality control and ensure adequate funding for good practices.

Key recommendations:

- Guidelines should be in place for the composition of RECs, to ensure that REC members have the relevant types of expertise (which may include the expertise of laypersons).
- Guidelines for procedures prior to an assessment should be in place; these should minimally include (a) a standard application for researchers in which crucial information is recorded, and (b) a means for researchers to conduct a self-assessment before being assessed by the REC.
- A system of appeal should be in place for researchers to challenge the decisions made by RECs.
- Countries in a relatively weak economic situation, and looking to harness RECs to facilitate more ethical R&I should be supported not only through finance but good practice guidance.

INTRODUCTION

The SATORI project aims at supporting mutual learning in ethics assessment and guidance across stakeholders, and harmonising ethics assessment in Europe and beyond. Research ethics committees (RECs) form a crucial part of any framework for ethics assessment. Therefore, the SATORI project studied good practices in RECs aims, organisation and procedures across different institutions and jurisdictions.

RECs assess, evaluate and review research activities, on the basis of legal and ethical requirements. They assess research or innovation goals, research project proposals, research practices such as experiments with human subjects, and many other research and innovation (R&I) related practices. They may offer advice for proper ethical conduct, and make decisions about compliance of R&I projects with national and international laws.

However, ethical assessment of R&I faces many challenges. It currently lacks unity, recognised approaches, professional standards and proper recognition in some sectors of society. These problems are relevant for RECs, since the ways in which they are organised differ widely between countries and institutions. In a context of globalising R&I, this situation is increasingly problematic because the work of ethics committees can become ineffective when R&I activities cross borders and have a strong international dimension.

These problems come at a time of rapid expansion of ethics assessment in different sectors of research, particularly the humanities and social sciences. An increasing number of universities and research institutes are instituting RECs in addition to research integrity offices. At the same time, differences across institutions and jurisdictions in how RECs are organised may cause inconsistencies in ethics assessment and incompatibilities between practices. This has an adverse impact on the quality of ethics assessment and reliance upon it to safeguard ethical principles. Therefore, there is a need to draft policies to harmonise the organisation of RECs. In this policy brief, we present some recommendations that can guide the drafting of such policies.

KEY OBSERVATIONS

The SATORI project has been the first of its kind to survey the entire ethics assessment landscape in the EU and beyond, by conducting more than 230 stakeholder interviews and engaging in in-depth and multiple-country case studies of different institutions involved in the ethics assessment process. Of the interviews, thirty were conducted with REC representatives from nine different countries and five with representatives of REC associations. From this comprehensive study, the SATORI project drew several key observations pertaining to the workings of ethics committees.

What are RECs? What challenges do they face?

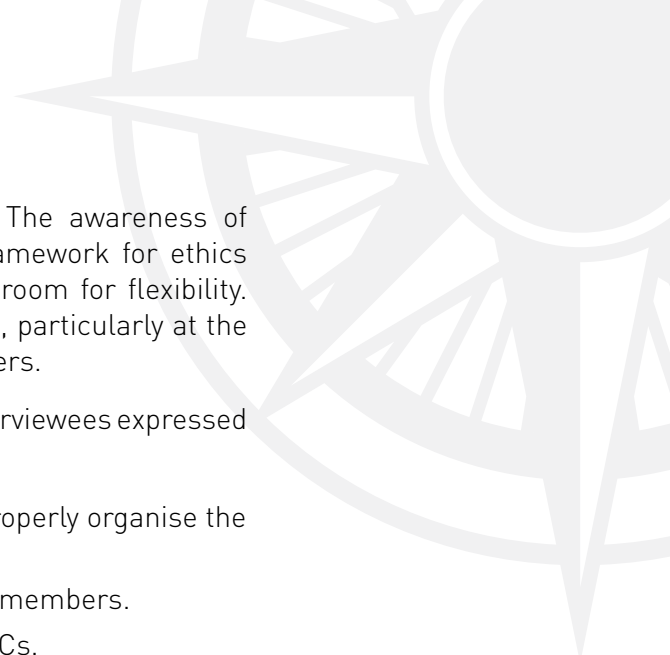
RECs are usually multidisciplinary, independent groups of individuals that are chosen or appointed to assess ethical issues in R&I. They are, for instance, present in universities where they assess the ethical acceptability of proposals for human subject experiments. RECs are important actors in some research funding organisations, and they assess whether research proposals should be funded or not, based on ethical considerations. The SATORI project identified the following types of RECs:

- ▶ Local RECs are linked to research performing institutions, such as universities and hospitals, and assess R&I activities within these institutions.
- ▶ Regional RECs are instituted by different regional bodies (regional authorities, medical associations, etc.) and assess R&I activities within a certain geographical area.
- ▶ National RECs supervise local and regional RECs, assess specific types of R&I activities, and may serve as appeal bodies.

RECs have been established in the field of biomedical research in the 1950s, and since that time, have been extensively regulated. For RECs in this field, the European Commission has been active in setting guidelines that complement national regulations. Additionally, the Steering Committee on Bioethics of the European Council has published a “Guide for research ethics committees”, which specifically addresses RECs for biomedical research.

During the last years, however, RECs expanded their scope to many other fields of R&I such as the engineering sciences and computer science. This rapid expansion is accompanied by a growing need for guidance and harmonisation of practices of RECs. Additionally, it presents a need for improved training of REC members and quality assurance.

SATORI REC interviewees expressed that we need RECs amongst others to “ensure that research is in line with national and international standards”, “to offer ethical guidance to researchers”, “to ensure the safety of research subjects” and to make ethical behaviour “part of the everyday routine” of researchers. According to a significant number of interviewees, the biggest obstacles for harmonisation of ethics assessment are differences between countries, cultures, ethical values



and philosophies, and differences between scientific fields. The awareness of these differences led to the conclusion that any proposed framework for ethics assessment should be of a general nature and should leave room for flexibility. Nonetheless, the wish for harmonisation of ethics assessment, particularly at the European level, is shared across most of the SATORI stakeholders.

In dealing with the harmonisation of ethics assessment, REC interviewees expressed they face a variety of problems, such as:

- Perceived shortages of resources, which are needed to properly organise the work of RECs.
- Inconsistencies in the conditions for appointment of REC members.
- The lack of clarity regarding the legal competences of RECs.
- The narrow scope of ethics assessment in certain cases, where focus is only on compliance and no allowance is made for ethical reflection.
- The difficulty of dealing with personal bias in the work of RECs.
- The limited mandates of RECs, which often leads to fragmentary ethics assessment.
- The lack, for some RECs, of any clear procedural structure.
- The general lack of (self-) evaluation of RECs.

RECs in a globalising world of R&I

R&I has become a global endeavour, with research projects being carried out at the multi-national level and cross-cultural collaborations flourishing. Accordingly, ethics assessment and the organisation of ethics committees needs to keep up with this trend. For this reason, the SATORI project conducted an in-depth comparison of value-systems of different cultures and of regulatory systems across the world.

The comparison of legal systems mainly revealed an inconsistent application of international standards of ethics assessment across jurisdictions. This again shows the urgent need for harmonisation efforts. The main conclusion from the comprehensive comparison of value-systems is that there are no differences in values between global value systems that would categorically hinder harmonisation of practices in ethics assessment. However, some important observations were made that should guide the harmonisation process of ethics committees:

- More horizontal forms of organisation of ethics committees could lead to more responsible behaviour from members.
- Due to the general support of democratic values across cultures, decision-making processes in ethics committees would benefit from an incorporation of democratic principles.
- Economic and political circumstances have a strong influence on the value-system in which ethics committees operate.
- In the EU, people generally agree that certain moral limits should apply to scientific research, especially in the field of biotechnology. This indicates that the work of ethics committees is generally welcomed.

RECOMMENDATIONS FOR POLICY MAKERS

Based on the key findings in of the SATORI project, we present a number of recommendations for promoting good practices in RECs. Policy makers can utilise these recommendations to improve the functioning of RECs and to harmonise the organisation of RECs across institutions and countries.

Proper governance of RECs:

We recommend that policy makers set certain guidelines for the proper governance of RECs. This pertains to the composition of RECs, the appointment of members and their training. To ensure proper governance of RECs, we recommend that:

- Guidelines are in place for the composition of RECs, to ensure that REC members have the relevant types of expertise (which may include the expertise of laypersons).
- Policy makers should also encourage RECs to include non-experts in their decision-making processes, to make sure that broader views in society are taken into account.
- Proper guidelines are in place to ensure that REC members are appointed in a transparent and democratic manner.
- Adequate training is provided for the REC members to enable them to be sufficiently capable of dealing with the relevant type of ethics assessment.

Harmonisation of procedures of RECs:

We recommend that guidelines be set up to harmonise the working of RECs across institutions and countries. This would imply that a minimum set of guidelines are proposed, that should be followed. Good practices that surpass these minimum requirements should be encouraged. Regarding these minimum requirements, we recommend that:

- Guidelines for procedures prior to an assessment are in place; these should minimally include (a) a standard application for researchers in which crucial information is recorded, and (b) a means for researchers to conduct a self-assessment before being assessed by the REC.
- Guidelines for procedures that shape the actual assessment are in place, which should minimally include (a) appropriate decision-making procedures and (b) an appropriate transparency of decision-making.
- Guidelines for procedures after the assessment, ensuring proper follow-up, which should minimally include (a) a written judgement that is send to the researchers in a timely manner, (b) an appeal procedure and (c) a follow-up mechanism that ensures that the decision of the REC is respected.

Ensuring quality control of RECs:

Finally, we recommend that guidelines for quality control of RECs should be put in place. These guidelines would ensure that RECs that are not functioning optimally or sub-optimally, can take appropriate remedial actions. To ensure quality control in RECs, we recommend that:

- A supervising body is in place, which should preferably be an independent body to prevent bias in the quality control process.
- A plan for remedial actions is in place, which would ensure that the functioning of an REC could be improved when this is deemed unsatisfactory.
- A system of appeal is in place for researchers to challenge the decisions made by RECs.
- The value of the work of RECs is shared with the general public.

Adequate funding for good practices and harmonisation:

We recommend that policy makers responsible for setting guidelines for RECs should ensure adequate funding and support is made available. Adequate funding is needed to facilitate better organisation and good practices in RECs. Some of the SATORI REC interviewees indicated very clearly that a lack of funding obstructs the proper functioning of RECs and stated that negative socio-economic pressures can have a negative effect on RECs. Thus, we recommend that:

- Policy makers should garner and make adequate funding available to support the work of, and good practices in RECs .
- Policy makers should specifically attend to the needs of institutions that do not have established REC mechanisms
- Countries in a relatively weak economic situation, and looking to harness RECs to facilitate more ethical R&I should be supported not only through finance but good practice guidance.

FURTHER READING

- SATORI, Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries, 2015. http://satoriproject.eu/media/D1.1_Ethical-assessment-of-RI_a-comparative-analysis.pdf
- SATORI, A reasoned proposal for shared approaches to ethics assessment in the European context, 2016.

PROJECT IDENTITY

Project name:

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



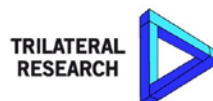
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