SATORI

Policy Brief:

Maximising the potential of Ethics Assessment of Research & Innovation: a call to Research Funding Organisations

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 ethics in research.

For whom is this policy brief?

For all research funding organisations, international, EU-level and at Member State level.

Why was it prepared?

– To promote good practices in research and innovation and enhance responsible research and innovation (RRI);
– To facilitate the work of research funding organisations in setting high ethics assessment standards;
– To publicise the SATORI ethics assessment and ethical impact assessment of research and innovation frameworks, foster their widespread adoption and enhance ethical, responsible and sustainable research and innovation.

Share the message.

Please share this policy brief with your networks and contacts who might be interested in tools for addressing ethical issues and impacts of R&I.

SATORI website: http://satoriproject.eu/

This policy brief was prepared by UNESCO in behalf of the SATORI consortium.

EXECUTIVE SUMMARY

This policy brief focuses on **Research Funding Organisations** (**RFOs**).

Key recommendations relevant to RFOs:

➤ RFOs should adopt the SATORI framework for ethics assessment in R&I activity.

➤ RFOs should generate/promote general awareness of ethics and ethical issues among researchers and innovators.

➤ Improve the capabilities of RFOs to perform ethics assessment.

➤ Enable regular discussion and exchange of information among RFOs at the national and international levels on the good practices in ethics assessment of R&I.

➤ RFOs could insist on the requirement that those who receive funding should adhere to a specified code of ethics.

➤ Standardise the review and audit procedures of SATORI's ethics assessment and ethical impact assessment methodologies as much as possible to decrease the administrative burden on RFOs.

➤ Set adequate criteria and procedures for in-house ethics review and monitoring of proposals and projects.

➤ Train ethics assessors in applying the SATORI framework and principles.

INTRODUCTION

RFOs, especially the European Commission, through their various funding programmes have a major leverage effect on how ethics is addressed in research and innovation. Ethics assessment at the European Union and Member States level has existed for decades in the field of clinical trials on drugs and medical devices. However, this has not been the case in other fields of research and innovation (R&I).

The SATORI project interviewed a range of stakeholders (across organisations (including research-funding bodies), scientific fields, and countries) about their expectations, the need for a shared European framework for ethics assessment (EA) of research and innovation and their support for it. 51.6% of interview respondents thought it would be desirable to have a shared European framework for ethics assessment. An additional 30% of respondents were conditionally positive about the desirability of such a framework.

RFOs do not primarily assess ethics, but fund research with private or public funds. RFOs aim to promote developments in science and innovation.[1] In selecting which proposed research to fund, ethics assessment (or ethics review) plays an important part.[2] Since RFOs evaluate concrete products and procedures of research, SATORI classes them as ethics assessors.[3]

The SATORI EA framework aims to pave the way towards improved consistency in EA procedures within and between scientific fields, different kinds of organisations, and countries. The need of the hour is further development of practices to implement EA in different kinds of organisations. RFOs due to their strategic position are optimally placed to support this.

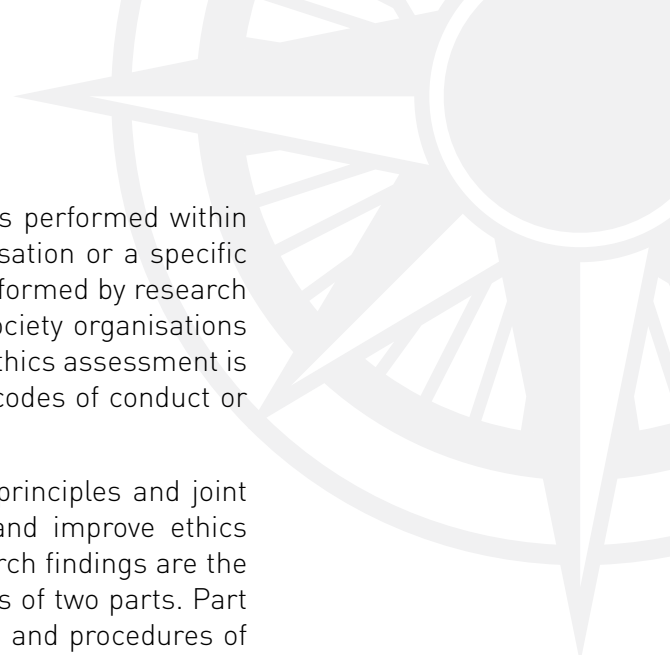## 1.1 A FRAMEWORK FOR BASIC ETHICAL PRINCIPLES AND JOINT APPROACHES AND PRACTICES

The SATORI framework[4] is concerned with **ethics assessment**: that is, an institutional form of applying (primarily) ethical principles and criteria to assess, review, appraise or evaluate research and innovation (R&I) activity. This activity may include basic research, applied research, or product development and testing. It

---

1   Wolfslehner, Doris "Ethics assessment and guidance in different types of organisations. Research Funding Organisations." *SATORI D1.1*, June 2015, p. 15. http://satoriproject.eu/media/3.c-Research-funding-organisations.pdf

2   Some RFOs conduct ethics assessment activities, others require ethics assessment to be carried out to a specified standard by the research performing institution itself.

3   Shelley-Egan Clare "Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries" *SATORI D1.1*, March 2016, p. 6.

4   Callies Ingrid and Philip Brey (Editors), 2016. "Outline of an Ethics Assessment Framework". Part of the SATORI D4.1. p36; Jansen, P., W. Reijers, D. Douglas, A. Gurzawska, A. Kapeller, P. Brey, R. Benčin, and Z. Warso, "A reasoned proposal for shared approaches to ethics assessment in the European context". *SATORI D4.1*, December 7, 2016, p 182. http://satoriproject.eu/media/D4.1_Proposal_Ethics_Assessment_Framework.pdf; CWA SATORI-1:2016. "Ethics assessment for research and innovation — Part 1: Ethics assessment unit", A CEN draft, NEN 2017.

is an institutionalised or formal method of assessment as it is performed within an institutional setting, with defined procedures, by an organisation or a specific unit within a larger organisation. Such assessment may be performed by research ethics committees (RECs), universities, industry, RFOs, civil society organisations (CSOs), or other organisations with an interest in R&I activity. Ethics assessment is distinct from ethics **guidance** which seeks to produce advice, codes of conduct or guidelines for ethical behaviour.

The SATORI project developed a framework for basic ethical principles and joint approaches and practices with the objective to harmonise and improve ethics assessment practices of research and innovation. These research findings are the basis of a CEN Workshop Agreement (CWA). The CWA[5] consists of two parts. Part 1 sets recommendations for the composition, role, functioning and procedures of **ethics committees**. Organisations can use part 1 to strengthen and/or improve the ethics assessment of their research and innovation projects. Part 2 provides researchers and organisations with guidance on **ethical impact assessment** - a comprehensive approach for ethically assessing actual and potential mid and long term impacts of research and innovation on society. Researchers and ethics committees will find this information useful as it describes ethical impact assessment in different stages of the ethical assessment. Part 2 is applicable to all researchers and innovators, regardless of the context they are working in, or research and innovation area.

The most important aspect of the institutional perspective is to create the system-level capabilities for a systematic and harmonised implementation of ethics assessment structures and procedures. The SATORI project contributes to this outcome by finalising an Ethics Assessment (EA) standard (in the CWA), which is a strong starting point in building the capabilities. The standard promotes a harmonised understanding of EA of R&I across disciplines, countries and actors, and is aimed at improving its various (institutional) structures and procedures.

The SATORI framework aims to pave the way towards improved consistency in EA procedures within and between scientific fields, different kinds of organisations, and countries. Further development of practices to implement ethics assessment in different kinds of organisations is needed. This is especially the case for organisations, such as RFOs, performing ethics assessment that are not research ethics committees.[6]

1.2 USE OF TOOLS AND IMPROVED SKILLS IN ETHICS ASSESSMENT

Training is another means to improve the consistency between different fields and kinds of actors. Systematic and continuous training is necessary to generate proper

---

5   CWA SATORI-1:2016. Ethics assessment for research and innovation — Part 1: Ethics assessment unit. NEN 2017. P 35 and 37; CWA SATORI-2:2016. Ethics assessment for research and innovation — Part 2: Ethical impact assessment framework. NEN 2016. p37.

6   Leinonen, Anna ¨Roadmap towards adoption of a fully developed ethics assessment framework¨, *SATORI D4.3*, June 2017. p24.
http://satoriproject.eu/work_packages/roadmap-for-a-common-eu-ethics-assessment-framework/

skills in EA among different actors, particularly the ones that do not have established committees, or well-developed processes and procedures. Furthermore, the need for ethics training in general should be discussed at the EU level and at the national level: the survey in SATORI[7] revealed that the meaning of ethics in practice is unclear especially in engineering and business environments even though it is taken into consideration under different names.

In the long run the research community has accepted the respect for new criteria called for by RFOs if they have been well introduced to the community and have been accompanied by training measures.[8] RFOs have therefore a major role to play with regard to training.

1.3 SATORI ROADMAP[9] RECOMMENDATIONS FOR RESEARCH FUNDING ORGANISATIONS

The aim of the SATORI roadmap process was to work out how the SATORI ethics assessment framework can be implemented in practice. The timespan of the roadmap was set at 10 years. First, it formulates a vision of a future in which the SATORI framework can be implemented. Theories about the implementation of new social practices were subsequently studied, and a model for the implementation of the SATORI framework was constructed. This model was then used to identify steps (or outcomes) that need to be taken to realise the vision. Finally, these steps were fleshed out by listing recommendations and associated actions that need to be taken by various stakeholder groups that are involved in ethics assessment of R&I. We list here the recommendations relevant to RFOs.

1.3.1 Recommendations for system-level capabilities

➤ Improve the capabilities of RFOs to perform ethics assessment: Large RFOs should have the institutional capacity necessary to perform regular in-house ethics review of research proposals (or assess the quality of ethics reviews) submitted to them. They should establish independent, multidisciplinary and pluralist ethics committees to perform ethics assessment.

➤ Enable regular discussion and exchange of information among RFOs at the national and international levels on the (good practices in) ethics assessment of R&I (including new and emerging technologies).

---

7   Shelley-Egan, C., P. Brey, R. Rodrigues, D. Douglas, A. Gurzawska, L. Bitsch, D. Wright and K. Wadhwa, "Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries", *SATORI D1.1* including 5 annexes, June 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/

8   Wolfslehner, Doris "Ethics assessment and guidance in different types of organisations. Research Funding Organisations." *SATORI D1.1*, June 2015, p. 15. http://satoriproject.eu/media/3.c-Research-funding-organisations.pdf

9   Leinonen, Anna "Roadmap towards adoption of a fully developed ethics assessment framework", *SATORI D4.3*, June 2017. http://satoriproject.eu/work_packages/roadmap-for-a-common-eu-ethics-assessment-framework/

1.3.2 Recommendation for stronger professional norms

➤ Recognise responsibility for ethical professional behaviour:

  ➢ Universities and companies should implement codes of conduct and practice for their students and employees. RFOs could insist on the requirement that those who receive funding should adhere to a specified code of ethics (and take into account the SATORI ethics assessment framework).

1.3.3 Recommendations for use of SATORI ethics assessment tools and framework

➤ Standardise the review and audit procedures of SATORI's ethics assessment and ethical impact assessment methodologies as much as possible to decrease the administrative burden on RFOs.

  ➢ This can be done, for instance, by creating an online submission system that the assessor can use to submit his or her findings from the ethics assessment or ethical impact assessment process.

➤ Set adequate criteria and procedures for in-house ethics review and monitoring of proposals and projects:

  ➢ Establish detailed procedures for in-house ethics review and monitoring (based on SATORI's ethical impact assessment methodology set out in the CWA Part 2).

    – These criteria and procedures must go beyond ethics assessment as required by law, and should also include aspects relating to research integrity, and scientific misconduct.

  ➢ Integrate established ethics review and monitoring procedures in RFOs' proposal selection procedures.

1.3.4 Recommendations for the promotion of the use of ethics assessment tools and frameworks

➤ Train ethics assessors in applying the SATORI framework and principles:

  ➢ Institution and coordination of training programs

    – Training programs for ethics assessors should be developed on how to properly apply the SATORI framework and general ethical theories and principles.

    – Develop easy-to-understand online resources for training programs.

➤ Adopt the SATORI framework for ethics assessment in R&I activity.

1.3.5 Recommendations for the promotion of positive attitudes and professional norms

➤ Generate/promote general awareness of ethics and ethical issues among researchers and innovators:

> ➢ Set up programs to educate researchers on the ethical implications of their research through presentations and information materials.

> ➢ Provide information on the ethical implications of R&I and possibilities for ethics assessment online.

FURTHER READING

- Leinonen, Anna "Roadmap towards adoption of a fully developed ethics assessment framework", *SATORI D4.3*, June 2017. http://satoriproject.eu/work_packages/roadmap-for-a-common-eu-ethics-assessment-framework/

- CWA SATORI-1:2016. Ethics assessment for research and innovation — Part 1: Ethics assessment unit. NEN 2017.

- CWA SATORI-2:2016. Ethics assessment for research and innovation — Part 2: Ethical impact assessment framework. NEN 2016.

PROJECT IDENTITY

Project name:

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

Coordinator: Philip Brey

Consortium:

Funding Scheme:

European Commission's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 612231

Duration: 01/01/2014-01/09-2017

For more information: p.a.e.brey@utwente.nl

Website: https://satoriproject.eu/