SATORI

Policy Brief:
Ethical Impact Assessment – enhancing responsible research & 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.

For whom is this policy brief?

Policy-makers, research organisations, policy advisors, government research and innovation (R&I) departments interested in ethical impacts of research and innovation, private companies, R&I departments, national ethics committees, research ethics committees, researchers.

Why was it prepared?

To publicise the SATORI ethical impact assessment (EIA) framework, foster its widespread adoption and enhance responsible research and innovation (RRI).

Share the message.

Please share this policy brief with your networks and contacts who might be interested in tools to address the ethical impacts of research and innovation (R&I).

SATORI website: http://satoriproject.eu/

This policy brief was prepared by Trilateral Research Ltd. on behalf of the SATORI consortium.

EXECUTIVE SUMMARY

Key recommendations:

- Increase the general use of EIAs.
- Raise awareness of the SATORI EIA framework and its benefits.
- Promote the conduct of good quality and transparent EIAs.
- Support EIA (as a tool to address ethical impacts) as an essential part of the management of an organisation's research and innovation process.
- Facilitate discussion and mutual learning about EIA at the EU and national levels.

INTRODUCTION

Ethical impact assessment (EIA) is a non-prescriptive process of assessing the ethical impacts of R&I activities, outcomes and technologies.[1] Ethical impacts concern or affect human rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good.[2] Specific examples include: negative impact on human rights (e.g., discrimination, inequality), problematic genetic modifications, safety risks, privacy violations resulting from unauthorised collection and processing of personal data, accessibility restrictions, harmful interference with the environment, targeting of vulnerable groups, dual use, misrepresentation of cultural heritage, etc.

The SATORI consortium collaboratively constructed the SATORI EIA framework, in dialogue with a wide range of stakeholders. The framework provides a means to determine and address the ethical impacts of research and innovation activities and outcomes[3]. It is a result of a synthesis of literature on EIA and foresight studies – its final formulation is based on extensive consultation (written and face to face) with ethics and impact assessment stakeholders from several EU countries, scientific disciplines, and organisations. SATORI presented and discussed the EIA framework in five mutual learning workshops in Belgrade, London, Milan, Utrecht and Warsaw in 2016 (after which the framework was refined).

NEED FOR AND VALUE OF EIAs

The need for EIA methods emerges not only from the evolving ethical risks from R&I activities, but also from the increasing focus on responsible research and innovation (RRI) in policy contexts, collaborative efforts by the scientific community to identify and mitigate ethical impacts, and from new (hard and soft) legal thrusts for RRI at the European level. The increasing impact of research and innovation on society and the fast pace of technological advancements calls for a considered reflection, and addressing of such impacts. An EIA can help bridge the gap between ethical principles and actionable guidance to promote the ethical conduct of research.

All research and innovation activities have ethical impacts – to a greater or lesser extent. For example, artificial intelligence (AI) technologies might adversely affect human autonomy (i.e., humans may pass powers on to AI or lose decision-making rights altogether in some respects). Robotics may perpetuate or increase asymmetries of power. Human genome editing carries risks of errors, other unintended effects, or lead to health inequality. Data analytics may have adverse impacts in terms of increasing surveillance of people, or might feed wrongful

1 Wright, David, "A Framework for the Ethical Impact Assessment of Information Technology", *Ethics and Information Technology*, Vol. 13, No. 3, September 2011, pp. 199–226.

2 SATORI, "Ethics assessment for research and innovation — Part 2: Ethical Impact Assessment Framework", CEN Workshop Agreement, SATORI, May 2017.

3 We recognise that while some ethical principles may be shared across countries and scientific disciplines as SATORI research has shown, there are also significant differences in their interpretation and application. EU-level application might differ from national applications. National level requirements and sensitiveness to ethical issues and impacts also varies.

decisions based on inaccurate data. Neuro-enhancement research may support objectionable physical and social changes in human beings. Security research and innovations might be open to misuse and carry a risk of severe harm to human beings. The dynamism and fast-changing nature of research and innovation activities in a project's lifecycle call for a more proactive approach to identify and address on an ongoing basis any ethical risks that might arise.

Identifying, assessing and resolving ethical impacts while a project is being undertaken and before project deployment can help an organisation avoid grief (e.g., public backlash, regulatory action, penalties, media censure, rejection of results) downstream. It helps reduce the cost and time needed to fix complex and serious ethical risks. Engaging the right stakeholders in a consultative EIA process can help minimise liability. An EIA can also help an organisation or project avoid reputational damage. It can boost transparency and build end user and public trust. For those carrying out an EIA, it is a good opportunity to reflect and work collaboratively with stakeholders to identify and mitigate ethical risks.

For the policy-making community, an EIA has multiple benefits: First, an EIA makes the goal of responsible research and innovation (RRI) less elusive as it helps implement and document RRI within a project in a systematic, and practical manner. Second, public institutions can better justify the allocation of public money to research and innovation projects because an EIA makes explicit both the benefits and the possible negative risks for society.

For commercial entities, an EIA can provide insights about the potential negative impacts of research and innovation initiatives and consequently allow for an outreach to clients and consumers to show how such impacts have been mitigated.

THE SATORI ETHICAL IMPACT ASSESSMENT FRAMEWORK

As SATORI research has determined, so far, no harmonised framework for conducting EIA has in practice been agreed upon or implemented at the EU-level. Different approaches to EIA exist. However, ethics assessment is increasingly becoming a requirement for obtaining funding in R&I projects. The lack of a structured and harmonised approach to carry out EIAs makes it harder to assess the effectiveness and quality of the current EIAs. The SATORI EIA Framework presents a comprehensive structured methodology for conducting an EIA in research and innovation (R&I) projects, which reflects both the existing literature, and R&I impact assessment practices, tailoring it to the way R&I projects are organised. The Framework lays down clear steps, criteria and options for adapting EIAs to fit various types of R&I projects.

SATORI defines an EIA as **the process of judging the ethical impacts of research and innovation activities, outcomes and technologies, in consultation with stakeholders**.[4] This process involves identifying and evaluating the ethical impacts and developing guidelines or making recommendations for remedial actions to mitigate ethical risks and enhance ethical benefits.

4 SATORI, "Ethics assessment for research and innovation — Part 2: Ethical Impact Assessment Framework", CEN Workshop Agreement SATORI, May 2017.

With the aim of enhancing the overall benefit of research and innovation for society, the SATORI EIA helps determine whether a project raises any ethical risks, identify and evaluate ethical impacts using different methods and tools, and facilitates taking remedial actions to mitigate negative ethical impacts of the project. EIAs may be useful in all fields of research and innovation – both traditional (e.g., medical or engineering research) and emerging (e.g., socio-technical research, human-machine interactions etc.).

The diagram below illustrates areas of potential use for the SATORI EIA framework:

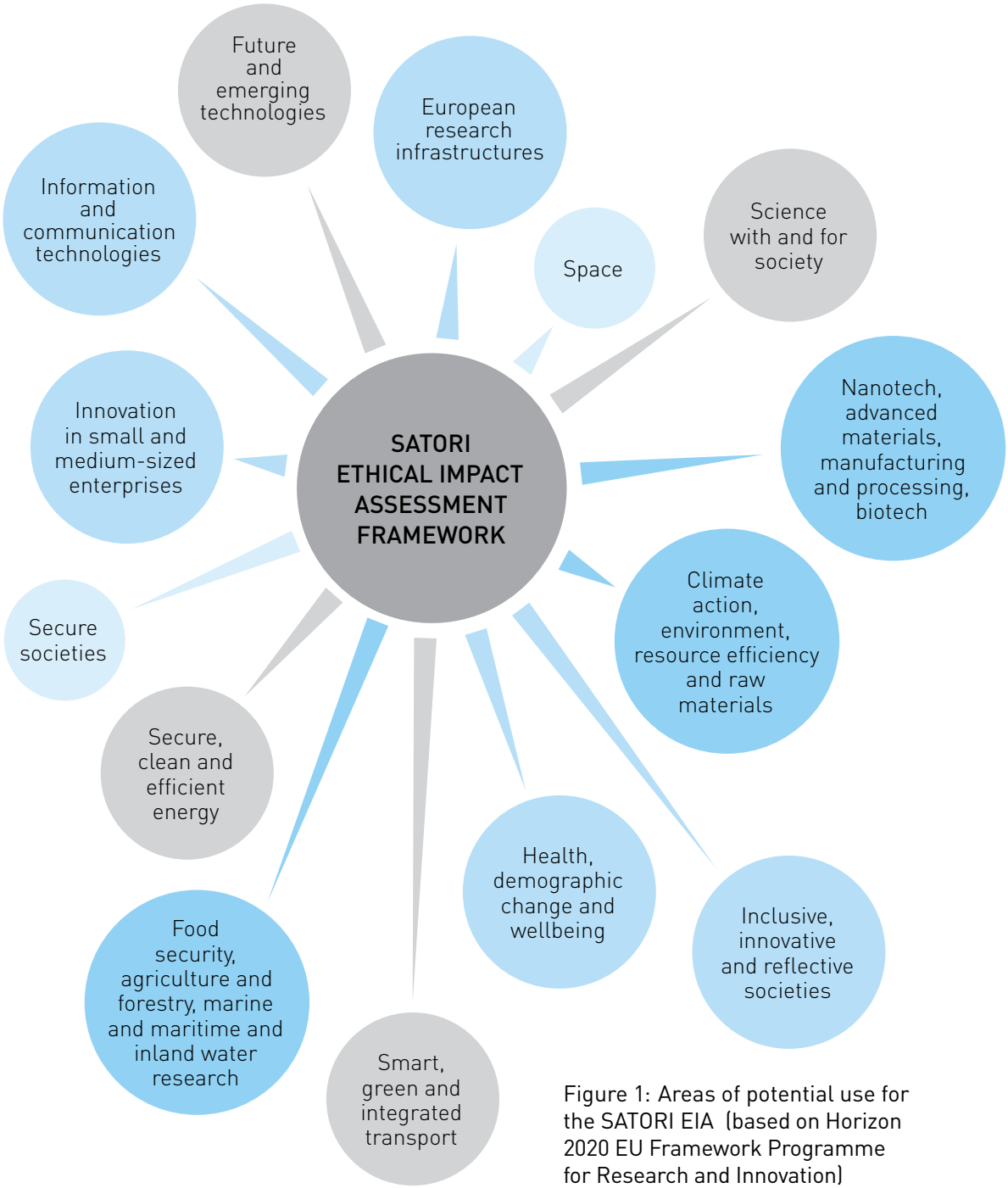


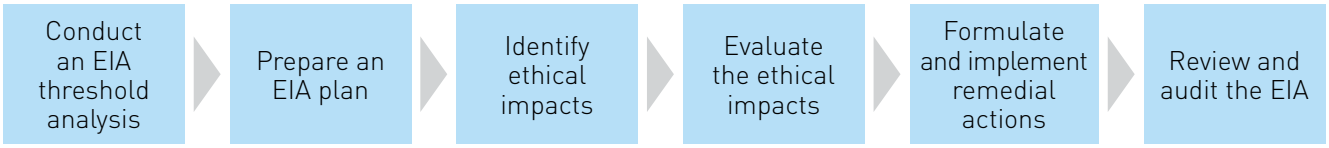
Figure 1: Areas of potential use for the SATORI EIA (based on Horizon 2020 EU Framework Programme for Research and Innovation)

An EIA may be carried out by an individual or team, e.g., administrator(s) at a research institute, project researchers, or independent consultants. The timing of the EIA depends on the nature of the R&I project or activity.

KEY STEPS IN THE SATORI EIA

There are six key steps in the SATORI EIA, as illustrated in the figure below:

Figure 2: Steps in the SATORI EIA



The threshold analysis determines whether an EIA is needed. The EIA plan sets out the scale of the EIA, budget, team composition, criteria for EIA review, criteria for re-visiting the EIA, and plans for stakeholder consultation. The ethical impact identification stage aims to identify and describe the ethical impacts of the R&I project and place these impacts in a temporal perspective, anticipating short, medium and long-term impacts. It includes an identification of potential (future) ethical impacts through literature reviews of the ethical impacts in similar projects, and further specification and identification of additional potential ethical impacts via the use of foresight methods and ethical impact analysis methods. The ethical impact evaluation stage assesses the relative importance, the likelihood of occurrence and the possible value conflicts of ethical impacts that have been determined in the ethical impact identification stage. Both the ethical impact identification and evaluation steps might be done in consultation with stakeholders. The remedial actions stage, involves the formulation of remedial actions to minimise and overcome any negative ethical impacts. The review and audit stage ensures independent evaluation of the EIA process and, if necessary, independent intervention to ensure its goals are met. The full EIA framework is documented in the SATORI CEN Workshop Agreement *Ethics assessment for research and innovation — Part 2: Ethical impact assessment framework* and the SATORI report *Outline of a common ethics assessment framework* (Deliverable 4.2).[5]

ONGOING CHALLENGES

While an EIA is a good tool to support the R&I community in stimulating ethical thought and action, its application faces challenges, which must be considered in the design, use and implementation of EIAs. The challenges (along with the nature of the R&I) have a bearing on whether methods other than an EIA, e.g., a broader ethical, legal, social analysis (ELSA), should support ethical research and innovation and how the EIA framework could be made compatible with other frameworks in use.

5 See http://satoriproject.eu/work_packages/

One major challenge is that EIAs are still in their infancy – as it stands, EIAs are used on an ad hoc basis to address ethical impacts in R&I. While this can be considered normal for a process that is still in development, it is far from ideal as it impacts their generalisability and adaptability. This challenge will become less significant with the wider use of EIAs and sharing of good practice. However, new research methods and technologies will continuously introduce new ethical issues and thus any EIA framework will need to be continuously updated and adapted.

Another challenge is institutional support and attitudes to EIAs. A good level of support from institutional management is necessary to enhance and optimise EIAs. Support from management can help ensure that an EIA exercise is not taken lightly, adequate resources are allocated to it, the process is well supported (its quality is assured and it is not mismanaged), and the results are implemented. Sometimes there is resistance to the idea of an EIA – because it is perceived as a mere formality, its purpose and benefits are not understood, and/or EIA assessors are not trained in the process but charged with the responsibility of conducting one.

Another challenge for EIAs is the effective implementation of its recommendations – i.e., measures to mitigate ethical impacts. The danger is that many a times the results of a EIA might become mere tick-box exercises and the EIA itself might become a 'paper tiger'. To avoid this, the recommendations of an EIA should have an owner (responsible party), and there should be a monitoring mechanism to check whether the recommendations are being considered. Here independent review and audit becomes critical.

Yet another challenge is the lack of sharing ('closed doors') of ethical impact assessment good practice. Researchers, academics, and private consultants carry out different forms of ethical impacts analysis[6] in EU or national R&I projects. Each of these may adopt different, yet valuable practices (depending on scope of their analysis and sector of application), yet often what is missing is a common portal or means of cross-project and actor sharing of good practices and procedures to advance the process. Making EIA reports (or their redacted summaries) publicly available could go some way to address this challenge and advance the future use of EIA. Policy-makers should aim to take actions to support transparency in EIAs.

Decision-makers should also address the quality of an EIA. A good quality EIA benefits the organisation conducting it (i.e., via increased awareness of ethical impacts, adoption of good ethical practices) and the party that relies on it – i.e., it promotes good decision-making, supports responsible R&I and boosts public trust. EIAs of questionable quality demonstrate one or more of the following shortcomings: they lack transparency and openness; they do not adequately identify ethical risks and appropriate resolutions; risk resolutions lack specificity; or they do not consider the views of affected stakeholders, etc.

The recommendations in the next section aim at tackling and addressing these challenges.

6 E.g., some of such activities are classed under ELSA.

SUPPORTING AND INCENTIVISING EIAs: CALL TO ACTION

There are many ways in which policy-makers and private R&I organisations can support and facilitate the wider use of EIA. The following table outlines the SATORI recommendations and actions.

Table 1: How policy-makers can support the SATORI EIA

SATORI recommendations	What policy-makers can do
Raise awareness about the SATORI EIA framework and its benefits in R&I contexts	• Publish the SATORI EIA framework in official communication channels • Organise consultations with stakeholders to discuss the relevance, use of the framework and how it could complement existing ethical frameworks • Share experiences in using the framework
Increase the general use of EIAs	• Mandate EIAs via inclusion in legal frameworks • Specify legal criteria for mandatory EIAs • Create opportunities, embody in soft law (general or sectoral guidelines, policy declarations or codes of conduct) • Include conduct of EIA as a criterion in R&I procurement policies and grant funding conditions, or subsidies.
Promote the conduct of good quality and transparent EIAs	• Support independent peer review and audit of EIAs • Incentivise the certification of EIA and accreditation of certification bodies or agencies certifying EIA of projects • (Regular) training for ethical impact assessors • Encourage publication of EIA reports (or summaries) • Create a registry of ethical impact assessment reports • Set up EIA peer review publication platform[7]
Facilitate discussion and mutual learning about EIA at the EU and local levels	• Set up an EIA mutual learning portal or community at EU and/or national level • Create a registry of ethical impact assessment reports • Develop EIA guidance based on the results of SATORI.

7 As recommended in SATORI Deliverable 7.2. Rodrigues, Rowena, et al., *Exploring the potential of conformity assessment techniques to support ethics assessment*, SATORI Deliverable 7.2, 2017.

Table 2: How private R&I organisations can support the SATORI EIA

SATORI recommendations	What private R&I organisations can do
Support EIA (as a tool to address ethical impacts) as an essential part of the management of an organisation's R&I process	• Integrate the framework into research management and/or corporate social responsibility procedures and practices • Set up internal procedures for conducting an EIA[8] in R&I projects • Dedicate resources (human, financial, time) for carrying out EIAs and their review.
Encourage and facilitate the use of the SATORI EIA	• Download and circulate copies of the SATORI EIA to R&I teams. • Provide guidance and support to the R&I teams planning to use the SATORI EIA.
Support the further development of the SATORI EIA (and cross-organisational learnings)	• Provide feedback to the SATORI CWA Secretariat relating to the use of the SATORI EIA • Publish EIA reports.

FURTHER READING

- Callies, Ingrid, et al, *SATORI Outline of an Ethics Assessment Framework*, V.1.1, Deliverable 4.2, December 2016.
- Jansen, Philip et al, *A reasoned proposal for shared approaches to ethics assessment in the European context*, Deliverable 4.1, December 2016.
- Reijers, Wessel, Philip Brey, Philip Jansen, Rowena Rodrigues, Raija Koivisto and Anu Tuominen, *A Common Framework for Ethical Impact Assessment*, SATORI, Deliverable 4.1, Annex 1, October 2016.
- Rodrigues, Rowena et al., *Exploring the potential of conformity assessment techniques to support ethics assessment*, SATORI Deliverable 7.2, 2017.
- SATORI, "Ethics assessment for research and innovation – Part 1: Ethics committee", CEN CWA SATORI, 2017.
- SATORI, "Ethics assessment for research and innovation – Part 2: Ethical Impact Assessment Framework", CEN CWA SATORI, 2017.

8 See SATORI project website: http://www.satoriproject.eu/

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/