Key policy recommendations and policy briefs

Deliverable 9.3

Lead authors: Wessel Reijers, Agata Gurzawska and Emils Birkavs, University of Twente;
Rowena Rodrigues, Trilateral Research;
Rok Benčin, Scientific Research Centre of the Slovenian Academy of Sciences and Arts (ZRC SAZU);
Ingrid Callies, UNESCO

Contributors:
Stéphanie Gauttier, Philip Brey, University of Twente
David Wright, Trilateral Research
Erich Griessler, Institute for Advanced Studies
Andrea Porcari, Associazione Italiana per la Ricerca Industriale (AIRI)
Rossella Cardone, Ericsson Telecomunicazioni
Professor Dr Elmar Doppelfeld, EUREC
Ms Anke Reinhardt, DFG (German Research Foundation)
Ms Chiara Giovannini, ANEC

Contact details for corresponding author:
Wessel Reijers, University of Twente
w.h.m.reijers@utwente.nl

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Contents

1 ABSTRACT

This deliverable offers an overview of the key recommendations that resulted from the SATORI projects. Additionally, it presents six policy briefs that were written to condense the main findings of the SATORI project into short, comprehensive texts that allow for these findings to be translated into actual policy for ethics assessment in research and innovation (R&I). The first part of the deliverable presents the key recommendations according to different thematic foci in the project. The second part of the deliverable provides summaries of the six policy briefs and presents the policy briefs themselves. The final policy briefs are included in the Annex.

2 EXECUTIVE SUMMARY

This deliverable provides short and comprehensive overviews of the key SATORI project recommendations and their translation into six policy briefs. For detailed information about all the recommendations, we would like to direct the reader to the full texts of the SATORI deliverables[1].

Recommendations are the suggested courses of action, in terms of policy making, to be followed based on the results of both the theoretical and empirical work carried out within the SATORI project. They are key outcomes formulated in order to facilitate the uptake of the findings by policy-makers and create real life impact. This deliverable therefore performs a crucial function in the SATORI project.

First, this deliverable starts out with providing an overview of the key recommendations resulting from the work undertaken in the SATORI project. These recommendations for instance focus on organising stakeholder participation, or on guidance for the implementation of the SATORI framework for shared ethics assessment practices.

Second, it discusses how the recommendations were used as input for the policy briefs, and describes how the draft policy briefs were produced, e.g. how the process and review was organised. This deliverable provides summaries of the six policy briefs that were produced, on the topics of "Responsible and ethical governance of research and innovation in the context of globalisation", "Improving the organisation of research ethics committees (RECs)", "Ethical Impact Assessment – enhancing responsible research and innovation (R&I)", "Supporting ethics assessment in research and innovation (R&I)", "Industry and Research and Innovation: Towards Ethical, Responsible and Sustainable R&I" and "Maximising the potential of ethics assessment of research and innovation: a call to research funding organisations".

Finally, this deliverable concludes with discussing challenges encountered during the process of producing the policy briefs and the dissemination strategy of the policy briefs and its impact. It also includes an annex with the final policy briefs that have been published on the SATORI website.

[1] See: SATORI. "All Deliverables". 2017. http://satoriproject.eu/work_packages/comparative-analysis-of-

3 INTRODUCTION

This deliverable provides an overview of the key policy recommendations from the SATORI project. The SATORI project has provided a comprehensive overview of ethics assessment practises in R&I across countries, organisations, scientific fields, and cultures[2]. Based on this overview, it formulated a framework for ethics assessment in R&I in the EU and beyond[3]. Stakeholder engagements and research activities have brought very promising results such as the CEN Workshop Agreement[4] for ethics assessment in R&I, conformity assessment recommendations to support ethics assessment[5], procedures for measuring the impacts of ethics assessment practices[6] and a heritage strategy to ensure the sustainability of the work done in the project[7].

However, the SATORI outputs can only be translated into actual R&I practice once the critical step towards developing supportive policies and implementation is made. For this purpose, the SATORI project has formulated key recommendations (suggested courses of action to be followed based on the results of both the theoretical and empirical work carried out) in the reports it produced, which together can guide the harmonisation of ethics assessment practises in R&I in the EU and beyond, all of which are brought together here.

The development of the SATORI policy briefs, except for the first one[8], involved four distinct steps: (1) agreeing on a general structure for the policy briefs, (2) creating a first draft, based on the SATORI deliverables, (3) conducting an internal review and (4) submitting the final draft to select SATORI Advisory Board members for external review.

This deliverable has two main sections. First, we provide a short overview of the key recommendations formulated in SATORI. Second, we provide a short overview of the policy briefs developed in SATORI and a description of the process involved in their preparation. It also has an annex, in which the final policy briefs are included that were published on the SATORI website.

4 KEY RECOMMENDATIONS OF THE SATORI PROJECT

The SATORI project has produced a variety of recommendations aimed at policy making for improving the organisation and implementation of ethics assessment of R&I. These recommendations have resulted from the thematically organised work packages of the SATORI project. Below, we provide an overview of the key recommendations (which, should be stressed, is not an exhaustive overview of all SATORI recommendations). The key

[2] See: SATORI. "Comparative Analysis of Ethics Assessment Practices". 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/

[3] See: SATORI. "Roadmap for a Common Ethics Assessment Framework". 2017. http://satoriproject.eu/work_packages/roadmap-for-a-common-eu-ethics-assessment-framework/

[4] SATORI, Ethics assessment for research and innovation, CEN Workshop Agreement, May 2017. http://satoriproject.eu/publication_type/standards/

[5] Rodrigues, Rowena, Michael Madary, Andrea Porcari, Elvio Mantovani, *Exploring the potential of conformity assessment techniques to support ethics assessment,* SATORI Deliverable 7.2, February 2017.

[6] SATORI. "Measuring the Impacts of Ethics Assessment". 2017. http://satoriproject.eu/work_packages/measuring-the-impacts-of-ethics-assessment/

[7] SATORI. "Heritage (Sustainability)". 2017. http://satoriproject.eu/work_packages/heritage-sustainability/

[8] The first policy brief was developed in the context of Work Package 3 in 2015 and was not part of the concerted effort to create standardised policy briefs, which is part of Work Package 9 and started in 2016.

recommendations have been selected on the basis of (1) their central role in translating the main findings in the SATORI project into concrete policies and (2) their general nature. The overview of key recommendations has been organised according to general and institution-specific recommendations.

The recommendations proposed by the SATORI project are aimed at a wide range of stakeholders that are engaged in R&I activities. Notably, these are supranational (EU), national and regional governments, research-performing organisations (RPO), research funding organisations (RFO), national science academies, civil society organisations (CSOs), and commercial entities.

4.1 GENERAL RECOMMENDATIONS

A number of recommendations are general in nature, which means that they should be taken up by different types of institutions involved in ethics assessment. These general recommendations are therefore relevant for all actors involved in policy making for ethics assessment.

4.1.1 Raising awareness of ethics assessment

Generally, organisations involved in ethics assessment should be incentivised to engage in continuous awareness raising about the significance of ethics assessment in R&I and of the positive impacts it can have on society. One way that is recommended for addressing this is by identifying communication needs and participatory processes regarding critical themes concerning R&I in society, such as stem cell research. Another way in which this can be achieved is by concretely communicating the positive effects of ethics assessment when it is integrated in R&I processes, such as communicating design interventions or funding decisions. Concerning ways for organising ethics assessment, it is recommended that ethics assessors should be familiarised with the SATORI framework and principles.

4.1.2 Supporting sustainable ethics assessment

National governments and intergovernmental organisations should legally and financially support the institutional networks for ethics assessment and provide the necessary impetus for harmonisation of ethics assessment practices[9]. Another recommendation is that countries in a relatively weak economic position should be supported in setting up proper ethics assessment, not only financially but also through guidance focusing on good practices. In order to ensure the sustainability of the work done in the SATORI project, a temporary secretariat should be established that could support multi-stakeholder collaboration on ethics assessment in R&I[10]. This secretariat should be involved in pilot implementations of the SATORI framework and related standard, experimenting with testing the impacts of practices recommended through the SATORI project, enabling dialogues with cavity society, further developing the SATORI framework and supporting activities aimed at building systemic infrastructures for common European approaches to ethics assessment. Furthermore,

[9] SATORI. "Comparative analysis of ethics assessment practices", 2015. http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/ The countries were selected to enable SATORI to present an international comparison of the ethics assessment infrastructure in the respective countries, with a focus on understanding those structures and agents that comprise the ethics assessment landscape.

[10] SATORI. "Heritage (Sustainability)". 2017. http://satoriproject.eu/work_packages/heritage-sustainability/

SATORI recommends that there is an effort for supporting voluntary collaboration on the evaluation and advancement of the SATORI CEN standard for ethics assessment. More generally, ethics assessment should be recognised as a crosscutting priority for the H2020 and FP9 programs to deal with ethics assessment, research integrity, and other relevant issues.

4.1.3 Embedding ethics assessment in cultural contexts

Generally, policy and legal frameworks should be implemented for supporting the development and implementation of ethics assessment, both at the national and at the EU level. One recommendation for setting up such schemes is that differences in value systems should be taken into account for ethics assessment activities[11]. Most notably, this implies paying attention to differences between traditional and rational-secular values and between informal normative frameworks such as those dominant in Anglo-Saxon countries, and formal frameworks that are more dominant on the European continent. Another recommendation is that economic and political pre-conditions for the harmonisations of ethics assessment policies be considered, such as the need for political stability for the harmonisation efforts to be successful.

4.1.4 Harmonising frameworks for ethics and ethical impact assessment (EIA)

It is recommended that procedures for ethics assessment activities (such as procedures governing the activities of research ethics committees) be harmonised across countries and institutions (e.g. European universities adopting a common standard for the organisation of ethics assessment). For this, government actors should support the use of the SATORI CWA part 1. Generally, SATORI recommends that the use of EIAs in R&I projects is increased by including them in legal and regulatory frameworks, and that policy makers should raise awareness of the EIA framework and the corresponding CWA. SATORI also recommends that an EIA should become an essential part of the management and organisation of R&I processes. Finally, it is recommended that a discussion and a mutual learning process be facilitated about EIA, both at the EU and national levels.

4.1.5 Risk-benefit analysis of ethics assessment

Cost-effectiveness and risk-benefit analyses should be conducted in the context of R&I programs (e.g. the H2020 program)[12]. In line with this, it is recommended that policy makers incentivise assessors to take into account that R&I value chains in Europe span across organisation types, which bear different risks and enjoy different types of benefits. Moreover, it is recommended that the value of systematic analysis should not be overstated, since metrics for evaluation remain ambivalent in most cases. Other recommendations focus on methodology for conducting risk-benefit analyses. In this regard, it is recommended that policy makers provide assessors with a typology of relations between costs and effects of ethics assessment, in order to enable comparability between approaches with similar objectives. Additionally, tools should be offered for assessors to reflect on the risks imposed by their choice of objectives, methods and modes of organisation. Finally, it is recommended

[11] SATORI. "Legal Aspects and Impacts of Globalisation". 2015. http://satoriproject.eu/work_packages/legal-aspects-and-impacts-of-globalization/

[12] SATORI. "Risk-benefit analysis of ethics assessment activities". http://satoriproject.eu/work_packages/risk-benefit-analysis-of-ethics-assessment-activities/

that policy makers ensure that assessors take into account organisational and territorial embeddedness of ethics assessment when considering risks and benefits.

4.1.6 Education and training

In general, more attention should be paid to investing in education and training for ethics assessment and to public outreach to inform people about the importance of ethics assessment of R&I. The need for such education and training should be more intensively discussed at the EU and national levels. More specifically, it is recommended that researchers working in R&I processes are educated in ethics assessment and in ways to conduct EIAs. In line with this, it is recommended that appropriate efforts be directed to the creation of suitable presentations and information materials on the theme of ethics assessment. Also, training activities should be monitored and standards for the organisation and implementation of training activities for ethics assessment should be set up.

4.1.7 Stakeholder participation and engagement

One of the main recommendations for policy makers concerns moving away from participation in ethics assessment understood as consultation towards a broader understanding that focuses on the engagement of stakeholders in the process of ethics assessment in co-constructing the targets of R&I processes and the relevant decision-making. In line with this, the SATORI project recommends that participation be organised in a bottom-up fashion when appropriate, meaning that stakeholders can actively contribute to the goals and design of the participatory process[13]. An important issue to take into account in this respect is the balance between openness (the ease with which stakeholders can access the ethics assessment process) and the formal structure of ethics assessment.

4.1.8 Quality assurance

Quality assurance of ethics assessment should include normative objectives that underscore the political character of assessment practices, and it should be proactive – by assessing the dynamism of assessment practices and improving training opportunities[14]. Furthermore, SATORI recommends that policy makers should adopt methods for assessment of ethics assessment that distinguish between procedural, substantive, transactive and normative effectiveness, that they should be embedded in a broader context – looking at case-to-case particularities and related literature - and that they should make use of shared, weighed assessment criteria. Additionally, it is recommended that ethics assessors be encouraged to use the SATORI methodology to inquire into the impacts of their ethics assessment practices[15]. In general, the transparency, credibility, reliability, and consistency of the ethics assessment and the review process should be improved. For this, it recommends that conformity assessment techniques are used to check, evaluate, or assess adherence to the SATORI CWA standard specifications[16]. A conformity assessment of ethics assessment

[13] SATORI. "Dialogue and Participation". 2014. http://satoriproject.eu/work_packages/dialogue-and-participation/

[14] SATORI. "Measuring the Impact of Ethics Assessment". http://satoriproject.eu/work_packages/measuring-the-impacts-of-ethics-assessment/

[15] Koivisto, R., A. Tuominen, M. Kari, K. Hyytinen, M. Ylonon, D. Douglas, W. Reijers, P. Brey, L. Bitsch, J. Romare, D. Trescher, D. Ovadia. *Report on measuring the impact of ethics assessment.* Deliverable D6.1. 2017.

[16] SATORI. "Standardising Operating Procedures and Certification for Ethics Assessment". 2017. http://satoriproject.eu/work_packages/standardizing-operating-procedures-and-certification-for-ethics-assessment/

should be carried out in a way that simplifies procedures and reduces bureaucracy. Furthermore, it is recommended that the implementation and review of standardisation should allow for different approaches that are case-based - e.g., specific to a certain research performing institution - ranging from simple and fast implementations to detailed and time consuming ones in case the circumstances call for it - e.g., when the ethics assessment practices need to be implemented from scratch.

4.2 INSTITUTION-SPECIFIC RECOMMENDATIONS

The findings of the SATORI project include recommendations to organise a framework for ethics assessment that offers consistent regulation across institutional settings. Bringing the SATORI framework to life requires from governmental actors that they provide or amend the legal statuses of ethics committees and establish policies concerning ethics assessment for a wide range of research-related institutions.

4.2.1 Governmental policies for universities

The role of universities is to ensure proper ethical assessment of the research conducted by their researchers. Governments must incentivize the creation of a research ethics committee (REC) in each university. These RECs should be centralised and interdisciplinary as possible so as to guarantee a high quality of ethics assessment and at the same time to ensure that the specificities of each discipline are taken into account. Further instruments can increase the consistency and quality of ethics assessment across universities at the national scale, such as codes for ethical behaviour. The SATORI list of ethical principles[17] can be used as a basis to develop such codes.

4.2.2 Governmental policies for Research Ethics Committees (RECs)

Government policies on the composition and functioning of the RECs are required in order to guarantee the creation of a consistent system at the national level. First, legal provision should be made for when RECs are to be included in the ethics assessment practice. Second, policies should specify the multidisciplinary character of RECs, the types of expertise required from their members, and how researchers can appeal decisions. However, it is recommended to avoid a juridification of the ethics assessment process itself, as the role of RECs goes beyond checking for legal compliance. When incentivizing the creation of RECs, governments should make provisions for the creation of a network for RECs to exchange experience and solutions.

4.2.3 Governmental policies for National Ethics Committees (NECs)

Policy should be formulated to coordinate RECs at the national level, through a National Ethics Committee (NECs). Establishing a pan-European system to expand ethics assessment to other disciplines requires a series of actions. First, NECs need to be established where they do not yet exist. Second, NECs need to be provided with legal statuses that widen their scope to sciences beyond life sciences, and that underline their independent, multidisciplinary, and pluralist character. An equal gender representation should be compulsory. The structure of NECs must reflect its multidisciplinary character. Sub-committees for different disciplines

[17] Jansen, P., W. Reijers, D. Douglas, A. Gurzawska, A. Kapeller, P. Brey, R. Bencin, Z. Warso. *A reasoned proposal for shared approaches to ethics assessment in the European context*. Deliverable D4.1. 2017.

must be established, and a platform to discuss ethics related issues between disciplines and stakeholders must be established. Third, the scope of work of NECs should include the elaboration of procedures to be followed by RECs, as well as procedures for monitoring RECs activities. Fourth, the national level can serve as a court of appeal of decisions formulated by RECs, a mechanism for which legal provisions need to be made. Where national governments set up NECs, it is recommended that they require NECs to engage different stakeholders in the ethics assessment process. This involves the creation of a temporary sub-committee to investigate how to best include citizens, civil society organisations, external experts and possibly other groups in ethical decision-making process. NECs must develop organisational structures that allow for the consultation of citizens, civil society organisations, external experts and possibly other external groups based on the investigation results. Finally, NECs would benefit from exchanging their findings through an international platform.

4.2.4 Governmental policies for National Science Academies (NSAs)

National governments should be establishing compliance officers for NSAs, as a measure meant to monitor the compliance to ethics assessment across universities. Governments should provide sufficient funding for this and ensure the participation of NSAs in international exchange platforms.

4.2.5 Governmental policies for Research Funding Organisations (RFOs)

RFOs play an important role in incentivizing the compliance with ethics assessment. As such, government policies should aim at improving the capabilities of RFOs to perform ethics assessment should be improved. This means that provisions should be made for RFOs to acquire the institutional organisation necessary to perform ethics assessment, establishing independent, multidisciplinary and pluralist ethics committees to perform ethics assessment. Second, RFOs capabilities would be reinforced by regular discussion and exchange of information among RFOs at the national and international levels on the topic of ethics assessment of new and emerging technologies. Government policies needs to consider organising such forums.

4.2.6 Governmental policies for Industry

Generally, it is recommended that ethical behaviour in the private sector be strengthened by more precise rules and legal regulations. Regular consultations with companies, industry associations and other relevant stakeholders should be organised to discuss the relevance of ethics assessment of R&I and EIA. SATORI also recommends that its framework be, as far as possible, integrated in already existing CSR (corporate social responsibility) frameworks and that SMEs and start-ups are specifically supported in organising ethics assessment.

4.2.7 Governmental policies for Civil Society Organisations (CSOs)

In order to organise the voice of civil society as a stakeholder to ethics and research, SATORI recommends that government take measures for the development and funding of an independent CSO that would focus on assessing public research and innovation agendas and cooperate with other CSOs in developing strategies of their own. Other CSOs should be encouraged to from dedicated working groups or ethics assessment related networks. These networks could vary in terms of structure, level of interdependence, and aims. The purpose

of networking would be to exchange information (knowledge and experience) and learn from each other (through sharing best practices, coordinating activities, obtaining common funding, organising advocacy campaigns, influencing the adoption of new regulative acts, etc.). CSOs performing ethics assessment should be trained to do this. National policies, but also European funded projects that concern Ethics in R&I and RRI could organise this training. At the internal level, CSOs should take measures improve their expertise in ethics assessment by engaging experts in the EA procedures, establishing expert groups and engage in ethics capacity building.

5 POLICY BRIEFS

The SATORI partners have written six policy briefs that capture the breadth of the work done in the SATORI project. The aim of these policy briefs is to make the extensive work carried out in the project accessible to policy-makers who can help turn the proposals of the SATORI project into concrete solutions that enhance ethics assessment of R&I in the EU. The SATORI policy briefs, therefore, cover aspects such as: how do we support the implementation of the SATORI ethical impact assessment framework? How do we support the harmonisation of good practices for ethics committees? What are the challenges that need to be addressed in EU-level ethics assessment? All the policy briefs are available on the SATORI website[18].

The following characteristics summarise the main structure of the policy briefs and the way in which they were drafted.

- **General structure:** the general structure of the policy briefs, except for the first policy brief that was drafted at an early phase in the SATORI project, was based on the EU document "Communicating Research for Evidence-Based Policy Making"[19] of the European Commission. Each policy brief has an introduction of the theme, covers and main challenges and/or provides a description of the topic, followed by a section with key observations based on the SATORI deliverables, and a final section with recommendations for policy-makers and a presentation of the project identity.
- **Getting to the first draft:** We assigned each policy brief to one SATORI partner who was responsible for putting together a first draft, which contained skeletons of texts of the main sections. The responsible partner consulted the relevant SATORI deliverables and condensed the findings from those deliverables in an easy-to-understand format.
- **Conducting an internal review:** Once the responsible SATORI partner finished the first draft, it was sent for internal review. First, all partners working on the policy briefs reviewed the draft, provided feedback on the structure and main findings of the policy brief and made suggestions for textual changes, where appropriate. Second, the responsible partner amended the draft.
- **Submitting the final draft for external review:** After a policy brief was internally reviewed and a final draft prepared, it was sent to several SATORI partners and members of the SATORI Advisory Board for additional feedback and comments. Some feedback was also provided during the SATORI workshop held in Brussels on

[18] http://satoriproject.eu/publication_type/policy-briefs/

[19] European Commission Directorate General for Research, *Communicating Research for Evidence Based Policy Making*, 2010. http://bookshop.europa.eu/en/communicating-research-for-evidence-based-policymaking-pbKINA24230/

23 May 2017. The feedback was addressed during the final revision of the policy briefs.

In the following sections, we provide a short overview of the six SATORI policy briefs. Additionally, we discuss challenges encountered during the process of writing the policy briefs and elucidate the dissemination strategy applied and its potential impact.

5.1 SUMMARIES OF SATORI POLICY BRIEFS

This section presents short summaries of the six policy briefs.

5.1.1 Policy brief: Responsible and ethical governance of research and innovation in the context of globalisation

This policy brief contextualises the work done in the SATORI project in the setting of global research and innovation (R&I) practices. It addresses six central issues in globalised R&I: (1) responsible supply chain governance, (2) scientific misconduct, (3) respect for traditional and indigenous knowledge, (4) the outsourcing of emissions of greenhouse gasses, (5) the "brain drain" of skilled scientists and (6) standards for clinical research and trials. For each of these key issues, the policy brief offers recommendations.

This policy brief is publicly available at the following link: http://satoriproject.eu/publications/policy-and-legal-options-for-developing-research-ethics-within-the-context-of-globalisation/

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

This policy brief provides guidelines for drafting policies that support the harmonisation of good practices concerning the organisation of RECs. It, first, discusses what RECs are, and what key challenges they face, such as dealing with shortages of resources and dealing with personal biases of REC members. It also discusses challenges with regards to globalisation of R&I, such as the strong influence of economic and political circumstances on the functioning of RECs and cross-cultural agreement about moral limits of R&I. It, finally, offers recommendations for (1) the proper governance of RECs, (2) the harmonisation of procedures for RECs, (3) ensuring quality control of RECs and (4) ensuring adequate funding for RECs.

This policy brief is publicly available at the following link: http://satoriproject.eu/publications/improving-the-organisation-of-research-ethics-committees-recs/

5.1.3 Policy brief: Ethical Impact Assessment – enhancing responsible research and innovation (R&I)

This policy brief provides guidance for the process of Ethical Impact Assessment (EIA), which is a non-prescriptive process of assessing the ethical impacts of R&I activities, outcomes and technologies. It provides for a rationale for implementing an EIA, which

centres around the increasing impact of R&I on society and the fast pace of technological advancements. It presents the SATORI EIA framework, illustrating its use in different contexts and outlining its key steps: (1) the threshold analysis, (2) the preparation of an EIA plan, (3) identification of ethical impacts, (4) ethical impacts evaluation, (5) formulation and implementation of remedial actions, and (6) the review and audit of the EIA. It discusses some on-going challenges for the implementation of the EIA, related to the compatibility between the EIA framework and other legal, ethical and social methods for ensuring ethical R&I. Finally, it presents recommendations to support and incentivise the implementation of EIAs.

This policy brief is publicly available at the following link: http://satoriproject.eu/publications/maximising-the-potential-of-ethics-assessment-of-research-innovation-a-call-to-research-funding-organisations/

5.1.4 Policy brief: Supporting ethics assessment in research and innovation (R&I)

This policy brief provides guidance for supporting and enhancing ethics assessment. It first discusses the importance and challenges of ethics assessment, underlining the need to deal with new ethical issues related to R&I activities and amongst other the problem of a lack of awareness of ethical issues. It then lays out requirements for a support system for ethics assessment, which are: (1) a national institutional network, (2) sufficient resources, (3) a clear regulatory framework, (4) proper oversight, (5) platforms for discussion and (6) trainings for REC members. Finally, it provides recommendations to support ethics assessment for different stakeholders: national governments, supranational and inter-governmental organisations, national ethics committees, research ethics committees and other stakeholders.

This policy brief is publicly available at the following link: http://satoriproject.eu/publications/supporting-ethics-assessment-in-research-and-innovation/

5.1.5 Policy brief: Industry and Research and Innovation: Towards Ethical, Responsible and Sustainable R&I

This policy brief provides guidance for the organisation of ethics assessment for R&I performed by commercial entities. It discusses the current lack of means for integrating ethics responsibility and sustainability in business R&I contexts and introduces how SATORI addresses this problem. It presents some key statistics, which show that a large share of R&I is performed by companies, making them crucial stakeholders in responsible R&I. It presents key findings of the SATORI project concerning ethics assessment of R&I and CSR (corporate social responsibility) policies, the institutional setup of ethics assessment in companies and the procedures for ethics assessment in industry. The brief discusses some core challenges and drivers for ethics assessment in industry, which finally culminate in an overview of recommendations for policy-makers – such as sharing of good practices and setting up a learning portal for ethical impact assessment.

This policy brief is publicly available at the following link: http://satoriproject.eu/publications/ethical-impact-assessment-enhancing-responsible-research-innovation/

5.1.6 Policy brief: Maximising the potential of ethics assessment of research and innovation: a call to research funding organisations

This policy brief provides guidance for improving ethics assessment in the context of research funding organisations (RFOs). It discusses the most relevant aspects of the SATORI framework for the harmonisation of ethics assessment practices. It discusses the use of tools and training to advance ethics assessment. The brief offers recommendations based on the SATORI roadmap, concerning (1) system-level capabilities, (2) professional norms, (3) use of the SATORI framework, (4) promotion of ethics assessment tools and the framework and (5) the promotion of professional attitudes and norms.

This policy brief is publicly available at the following link: http://satoriproject.eu/publications/industry-and-research-and-innovation-ri-towards-ethical-reponsible-and-sustainable-ri/

5.1.7 Challenges with drafting the policy briefs

The process of drafting and reviewing the policy briefs encountered some challenges, i.e.,

- Adjusting the language of the SATORI deliverables to be more generally accessible to non-specialist audience.
- Summarising findings of lengthy SATORI deliverables without losing crucial information therein.
- Structuring the policy briefs in a way that is easy for the readers to understand and access the most crucial information in a glance.

The SATORI partners developing the policy briefs worked hard to ensure these difficulties were addressed and mitigated, in dialogue with one another.

5.1.8 Dissemination strategy & impact

In this section, we briefly discuss the dissemination strategy and the expected impact of the policy brief, in terms of number of relevant people reached.

Target audiences

For most of the policy briefs, we targeted a broad range of stakeholders – most of which overlapped with the SATORI stakeholders. These were policy-makers, science academies, research funding organisations, national ethics committees, and others. For some policy briefs, the target audience was more specific. E.g., the target audiences for the policy brief on responsible R&I in business are commercial entities engaged in R&I activities; the target audiences for the *Maximising the potential of ethics assessment of research and innovation* policy brief are research funding organisations.

Dissemination strategy

Our dissemination strategy consists of publication of the policy briefs in different places and by means of different communication channels:

- Publication of the policy briefs on the SATORI website.[20]

[20] http://satoriproject.eu/publication_type/policy-briefs/

- Presentation at SATORI events: workshops in Ljubljana (January-February 2017), policy workshop at UNESCO, Brussels (23 May 2017) and the final conference in Brussels (18-19 September 2017), which features a range of stakeholders (international, EU and national).
- Distribution of the briefs to the SATORI mailing list, policy briefs contact list and the SATORI partner networks.
- Publicity of the policy briefs in the SATORI newsletters.
- Link to the policy briefs and publicity via SATORI and partner social media feeds e.g., Twitter and Facebook.

Achieving impact

At the time of writing this report, the full impact of the policy briefs cannot be completely determined, though they seem to have been well-received based on feedback from the Brussels policy workshop. The SATORI consortium will strive to achieve the following impacts:

- Education and awareness of policy-makers
- Sensitisation to results of SATORI
- Sensitisation to the need to enhance ethics assessment in R&I
- Wider engagement with ethics of R&I
- Better acknowledgement of ethics assessment in R&I policy making. Feeding into policymaking, further impetus to supporting ethics in R&I.

As feasible, between the date of writing and the close of the project, the consortium will continue to make efforts to support good impact for the policy briefs.

6 CONCLUSION

This deliverable provided an overview of the key recommendations that resulted from the SATORI project. Additionally, it provided an overview of the policy briefs that have transformed the SATORI results into policy documents. It summarised the policy briefs and provided an overview of their drafting process. The final policy briefs, as they were published on the SATORI website, are included in the annex.

7 ANNEX: THE SATORI POLICY BRIEFS

List of the policy briefs displayed below:

1. **Improving the organisation of research ethics committees (RECs)**
2. **Ethical Impact Assessment – enhancing responsible research and innovation (R&I)**
3. **Supporting ethics assessment in research and innovation (R&I)**
4. **Industry and Research and Innovation: Towards Ethical, Responsible and Sustainable R&I**
5. **Maximising the potential of ethics assessment of research and innovation: a call to research funding organisations**
6. **Responsible and ethical governance of research and innovation in the context of globalisation**

SATORI

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, werecommend 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.

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/

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:

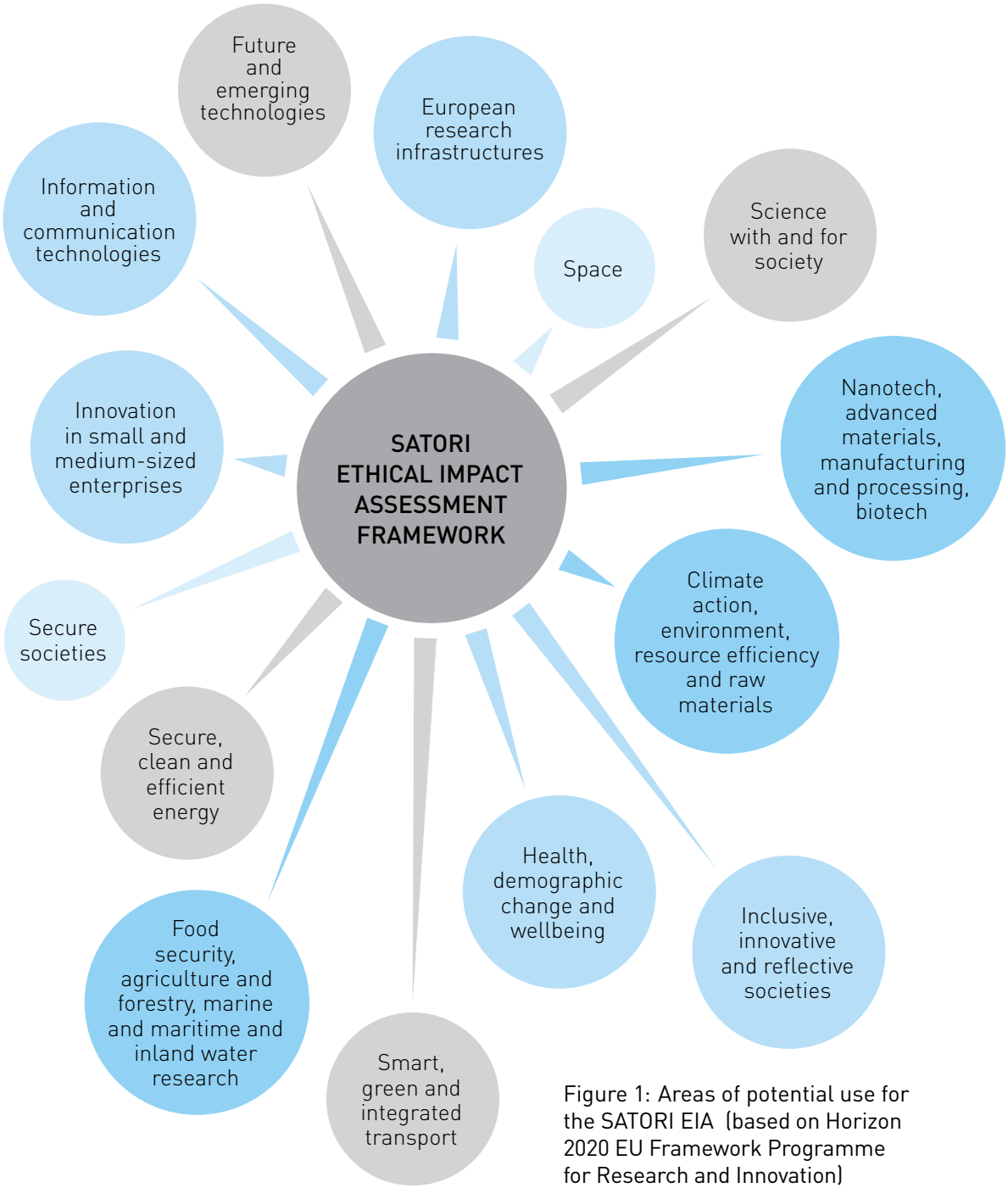


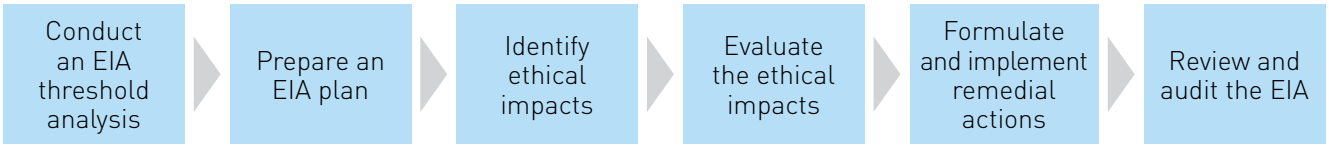
Figure 1: Areas of potential use for the SATORI EIA (based on Horizon 2020 EU Framework Programme for Research and Innovation)

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/

SATORI

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.

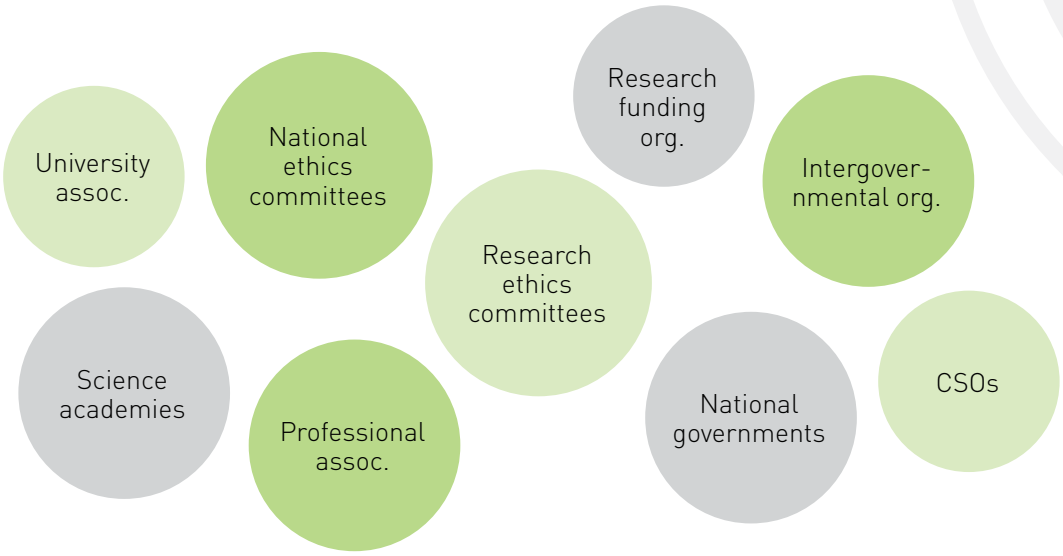
THE IMPORTANCE AND CHALLENGES OF ETHICS ASSESSMENT PRACTICES

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.

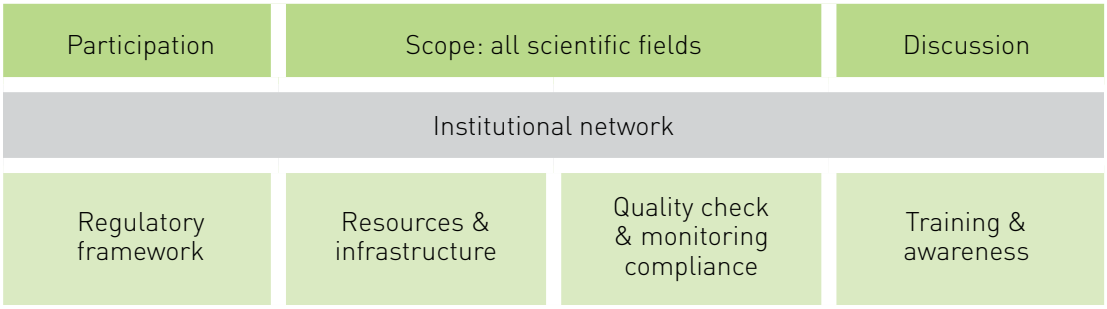
The stakeholders involved in R&I and ethics assessment would benefit from having **platforms for discussion** on recurring and emerging ethical issues. Such discussion forums should operate at several levels: national and international, general and field-specific.

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 principleswith 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.

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/

SATORI

Policy Brief:

Industry and Research and Innovation (R&I): Towards Ethical, Responsible and Sustainable R&I

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, policy advisors, government R&I departments interested in research and innovation (R&I), private companies, industry associations, CSR and sustainability officers and departments.

Why was it prepared?

To publicise the SATORI frameworks for ethics assessment and ethical impact assessment of R&I, foster their widespread adoption and enhance ethical, responsible and sustainable R&I.

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 University of Twente, on behalf of the SATORI consortium.

EXECUTIVE SUMMARY

Despite various efforts, SATORI findings show that ethics, responsibility and sustainability of R&I in the business context, have not yet been sufficiently addressed by policy makers and industry. Building on this, this policy brief:

- discusses implications and suggests to policy-makers how to improve the design of deployment policies and navigates businesses in policy-induced markets,
- provides tools to help policy-makers and industry to foster ethical, responsible and sustainable R&I in industry, namely ethics assessment (EA) and ethical impact assessment (EIA) of R&I.

INTRODUCTION

Industry is focusing on research and innovation (R&I) to improve its financial performance and market share. At the same time, companies are increasingly improving their corporate social responsibility (CSR) practices to gain greater social acceptance of their activities. However, the processes of innovation are not necessarily governed by ethics assessment. While the EU sees opportunities in R&I to contribute valuable solutions to societal challenges, such as the climate change, demographic change and wellbeing, energy security, and food safety, it also strives for R&I that is ethically acceptable and socially desirable[1].

The **issue** is that the concepts of ethics, responsibility and sustainability of R&I in industry are not necessarily embedded in tangible procedures. This can lead to societal and environmental issues, which in turn can drain economic resources and decrease the competitive advantage of European companies.

The SATORI project investigated the forms of assessment carried out and identified directions in which policy is needed.

The main **recommendations** of the SATORI project are for policy-makers to:

- Raise **awareness** and **use** of the SATORI Ethics Assessment (EA) and Ethical Impact Assessment (EIA).
- Promote good quality and transparent procedures of EA and EIA
- Facilitate dialogue about them to make them part of management practices

1 See e.g.: Science With And For Society (SWAFS) and Responsible Research and Innovation (RRI): http://ec.europa.eu/research/swafs/index.cfm?pg=home

FACTS AND NUMBERS

R&D

Research and development (R&D) is a major driver of innovation. R&D expenditure and intensity are two of the key indicators used to monitor resources devoted to science and technology worldwide.

Science and technology contribute new innovations that are essential to Europe's international competitiveness.

The EU strives for R&I that takes societal expectation into account with the aim to foster the design of inclusive and sustainable R&I.

64%

The business enterprise sector in EU is the main sector in which R&D expenditure is spent, accounting for 64% of total R&D condudted in 2014.

INDUSTRY PLAYS A CRUCIAL ROLE IN THE EU EFFORTS TO BETTER ALIGN BOTH THE PROCESS AND OUTCOMES OF R&I WITH THE VALUES, RULES, NEEDS AND EXPECTATIONS OF EUROPEAN SOCIETY.

79%

Some 79% of companies that introduced at least one innovation since 2011 experienced an increase of their turnover by more than 25% by 2014.

Industry is crucial for EU competitiveness, and research and innovation (R&I) is a key factor in this regard.

Sources: Eurostat, innobarometer, http://ec.europa.eu/growth/industry/innovation_en
http://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation

BASIC TERMS

SATORI claims that ethical aspects or implications of R&I should be assessed and evaluated with the goal of influencing R&I processes to make them more ethical, and to ensure that they have more ethical outcomes, for the benefit of society and the greater good. Different forms of assessment exist and can be defined as follows:

- **Ethics assessment (EA)** is any kind of assessment, evaluation, review, appraisal or valuation of research or innovation that makes use of ethical principles. Ethical principles are criteria that aim to determine whether certain actions or developments are right or wrong. They define individual rights e.g., rights to freedom and privacy, and include principles of justice and principles that say that harms to individuals and society should be avoided and benefits for them should be promoted.
- **Ethical guidance** is different from ethics assessment in that it does not concern an evaluation of practices and products of R&I that have already occurred, but rather presents rules, codes, and recommendations to which future scientific practices, innovation practices, and developments in science and technology are expected or recommended to adhere.
- **Ethical impact assessment (EIA)** is a non-prescriptive process of assessing the ethical impacts of R&I activities, outcomes and technologies. Ethical impacts concern or affect human rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good. Specific examples include: negative impact on human rights (such as discrimination, inequality), problematic genetic modifications, safety risks, and privacy violation.

KEY FINDINGS

The SATORI findings and results are based on an extensive inventorisation of ethics assessment practices, literature reviews of ethics and CSR policies and codes of conduct. Additionally, they are based on interviews focusing on ethics assessment of R&I with 25 representatives of multinational corporations (different branches, including e.g., pharmaceutics, ITC, nanotechnology, automotive industry), SMEs, consultancy firms, chambers of commerce, national and international organisations and non-governmental organisations (NGOs) engaged in human rights. The interviewees came from ten different countries and at the EU and global international level (Austria, France, Germany, the Netherlands, Poland, Serbia, Spain, the United Kingdom, the US and China).

Ethics assessment of R&I by industry: Prevalence and aims

- Companies are increasingly using structured approaches to monitor economic, environmental and societal impacts of their activities, taking

into account ethical principles and values acknowledged by stakeholders and society. These approaches are broadly known as Corporate Social Responsibility (CSR)[2].

- Most corporations have policies, and officers, or divisions, for CSR. A CSR policy is intended to function as a self-regulating mechanism for business to ensure its compliance not just with laws, but also with the spirit of the law, with international norms, and with ethical standards.
- Small and medium sized enterprises (SMEs) typically do not have CSR structured strategies. SMEs are constrained by the lack of financial and human resources, which lead them to have relatively short-term and profit-oriented goals and impairs their ability to undertake research and development as well as their and potential commercialisation of innovation.

Ethics assessment of R&I and CSR

- CSR strategies and activities can be perceived as a form of ethics assessment or ethics guidance. However, CSR is broader than ethics assessment of R&I. It is because CSR does not exclusively relate to companies' R&I activities.
- CSR covers all aspects of a company's activity, including R&I. CSR is, in large part, a form of ethics assessment and ethics guidance that emphasises impacts on the society and environment.
- Companies that also conduct human subjects research and/or biomedical research often carry out additional ethics assessment of such research: an ethics committee or ethics officer evaluates ethical considerations and measures
- In practice, ethics assessment of R&I in companies is either part of CSR, or a combination of that part of CSR that is concerned with R&I and ethics assessment for biomedical or human subjects research.

Procedures for Ethics Assessment

- Companies use the term "ethics" in a narrow context referring to a professional behaviour e.g., anti-corruption. Companies do not use the term "ethics assessment". Preferably, they refer to responsibility, responsible behaviour, sustainability, and sustainable behaviour. Companies often refer to "innovating and doing research in a responsible way". The assessment conducted by companies is not however strictly an "ethics assessment", but it rather focuses on applicable CSR instruments. Through CSR initiatives, companies also engage in ethics guidance.

2 European Commission, *Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of Regions: A renewed EU strategy 2011-14 for Corporate Social Responsibility,* Brussels, 25 October 2011, COM(2011) 681 final.

- The most common assessment procedure that companies implement is impact assessment (IA). IA is a process of identifying the future consequences of a current or proposed action (impact prediction/ forecasting), and an assessment of the social significance of those impacts (impact evaluation).[3] The IA may concern the effects of actions on environment, society, or more specifically on ecology, biodiversity, human rights, health, culture, gender, etc. Companies therefore use different types of impact assessment, e.g., environmental impact assessment (EIA), human rights impact assessment (HRIA) and social impact assessment (SIA).

Institutional setup of ethics assessment of R&I

- The level of institutionalisation of ethics assessment in industry varies greatly across different countries, and companies and industry sectors.
- The ethics assessment and ethical guidance of R&I in the context of industry relates to companies CSR strategies. CSR tools include standards, principles, codes of conduct, and reporting initiatives to provide quantitative data on CSR performances.
- Multi-stakeholder initiatives play a key role in the diffusion of CSR policies in industry. In the last two decades, these have supported the development of shared practices and methodologies (standards) to define, apply, measure and report CSR actions and performances.
- Standardisation plays an important role in companies' activity, as it provides clear requirements on development and implementation of management strategies. The advantage of the standards system is its compatibility and applicability in every organisation regardless of sector or size.[4] See e.g. ISO 26000 on social responsibility; Social Accountability 8000; OHSAS 18001 regarding health and safety of employees and minimizing the risk of accidents; ISO 14001 and Eco-Management and Audit Scheme (EMAS) on environmental management.
- EU policy initiatives aim to stimulate companies to endorse CSR initiatives such as *the United Nations Global Compact*; *the United Nations Guiding Principles on Business and Human Rights*; *ISO 26000 Guidance Standard on Social Responsibility*; *International Labour Organization Tripartite Declaration of Principles concerning Multinational Enterprises on Social Policy;* and *the OECD Guidelines for Multinational Enterprises*.[5]

3 The International Association for Impact Assessment, http://www.iaia.org/iaiawiki//History.aspx?Page=impactassessment&Revision=1

4 Konstantinos Iatridis, "Identification of CSR tools related to RRI principles", published 27 March 2015, Deliverable for the Responsible Industry Project, http://www.responsible-industry.eu/dissemination/deliverables

5 http://ec.europa.eu/enterprise/policies/sustainable-business/corporate-social-responsibility/index_en.htm

Implementation of ethics assessment of R&I

➤ Companies and industry associations have various roles in the implementation of ethics assessment of R&I.

- First, they engage in the regulation and guidance through CSR policies intended to function as a self-regulating mechanism for business.
- Second, they carry out ethics assessment of R&I (e.g., internal CSR officers or divisions and external CSR consultancy).
- Third, they engage in dissemination and awareness raising of CSR, e.g., business and industry associations and Chambers of Commerce facilitate networking, knowledge-sharing and collaboration among companies.

CHALLENGES AND DRIVERS

SATORI has identified challenges and drivers for industry in performing assessment of ethical, societal and environmental impacts of their activities. These help us understand the industry's perspective and will help create effective policies and incentives to enhance ethical, responsible and sustainable R&I.

CHALLENGES	DRIVERS
• Additional bureaucracy, eventual extra costs • Heterogeneity in approaches and guideline implementation (variety of CSR initiatives and standards) • Lack of awareness of ethics issues • Lack of structured approaches • Lack of resources (financial, human, time, knowledge, particularly for SMEs) • Inability to implement non-binding guidelines (failures of self-regulation) • Problem accepting ethical criteria in the R&I community (beyond what is provided for by law) • Possible slowdown of innovation • Additional ethical constraints may limit creativity • Ethics is culture-sensitive (requirements might change depending on context)	• Improve product sustainability, desirability and acceptability, quality, safety and reliability • Increase customer satisfaction • Positive effect on quality of life and health of customers • Create value, build corporate image and reputation, give competitive advantage • Motivate workers, improve health and safety standards • Improve community relations • Reduce environmental impacts • Reduce costs (e.g., use of resources, efficiency of the decision-making process) • Market penetration • Profit, access to financial support, minimisation of the risk of lower financial performances • Compliance with regulations

To respond to these challenges and drivers, there should be an incentive structure and the mechanisms in place taking into account the interplay between regulations, voluntary actions, incentives and sanctions. CSR global initiatives, standards and principles can successfully support responsible R&I among companies. At the same time, there is a need for tools that are better tailored to the specific character of RRI.

SATORI offers a new tool for 'Ethical Impact Assessment (EIA)' which brings together the variety of ethical issues and methods of impact assessment to enable an organisation mitigate negative ethical impacts of it R&I activities and better manage the R&I process. The use of this tool needs to be incentivized by policy-makers.

SATORI ETHICS ASSESSMENT AND ETHICAL IMPACT ASSESSMENT (EIA)

Ethics Assessment

The SATORI Ethics Assessment provides common basic ethical principles and joint approaches and practices with the objective of harmonising and improving ethics assessment practices of research and innovation. The SATORI ethics assessment makes recommendations for the composition, role, functioning and procedures of ethics committees. Ethics committees include, but are not limited to, research ethics committees, institutional review boards, ethical review committees, ethics boards, and units consisting of one or more ethics officers.

The full ethics assessment framework is documented in the SATORI CEN Workshop Agreement *Ethics assessment for research and innovation — Part 1: Ethics committee and the SATORI report A reasoned proposal for set of shared ethical values and principles for ethics assessment in the European context*.[6]

While the SATORI ethics assessment may not be fully applicable to companies due to the private character of their activities, it can assist policy-makers and companies in developing specific R&I mechanisms in industry to enrich general CSR instruments. This is because SATORI ethics assessment provides common basic ethical principles and definition of these principles, such as scientific freedom, conflict of interests or dual use. Therefore, SATORI ethics assessment can help companies strengthen and/or improve the ethics assessment of their R&I projects.

Ethical Impact Assessment (EIA)

SATORI defines an EIA as the process of determining and addressing the ethical impacts of research and innovation activities, outcomes and technologies in consultation with stakeholders. With the aim of enhancing the overall benefit of research and innovation for society, the **SATORI EIA** assists in determining whether an R&I project raises any ethical risks, helps identify and evaluate ethical impacts

6 See http://satoriproject.eu/publications/cwa-part-1/

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 research) and emerging areas (e.g., human-machine interactions).

The full EIA framework is documented in the SATORI CEN Workshop Agreement *Ethics assessment for research and innovation — Part 2: Ethical impact assessment framework*.[7] SATORI has also published a policy brief on EIA: enhancing responsible research & innovation[8].

Policy makers and companies can use SATORI EIA as a tool for determining and addressing the ethical impacts of industrial R&I activities, outcomes and technologies. It can be part of companies CSR strategies. The advantage of EIA in the industry context, is its comprehensiveness. While there is a variety of tools and methods that help to address impact of the activities of companies, SATORI EIA is a comprehensive methodology for addressing a whole range of ethical impacts that concern or affect human rights and responsibilities, benefits and harms, justice and fairness, well being and the social good.

CALL FOR ACTION

SATORI RECOMMENDATIONS	WHAT POLICY-MAKERS CAN DO
Raise awareness about the SATORI Ethics Assessment and Ethical Impact Assessment (EIA) frameworks and their benefits in research and innovation (R&I) contexts.	• Organise consultations with companies (including SMEs), industry associations and other stakeholders to discuss the relevance, use of the ethics assessment of R&I and EIA frameworks and how it could complement existing CSR frameworks. • Share industry experiences and good practices for ethical, responsible and sustainable R&I.
Increase the general use of ethics assessment and EIA	• Create soft law for ethics assessment (general or specific guidelines, policy declarations or codes of conduct). • A model for ethics assessment and guidance in industry should be integrated within already exciting CSR framework (CSR global initiatives, standards and principles). • Include ethics assessment and EIA as criteria in R&I procurement policies and grant funding conditions, or subsidies.

7 See http://satoriproject.eu/publications/cwa-part-2/

8 See http://satoriproject.eu/publication_type/policy-briefs/

SATORI RECOMMENDATIONS	WHAT POLICY-MAKERS CAN DO
Promote the conduct of good quality and transparent ethics assessment and EIA	• Incentivise the certification of socially responsible R&I and accreditation of certification bodies or agencies certifying ethics assessment and EIA of projects. • Organise European Awards for ethical, responsible and sustainable R&I and ensure recognition and visibility for these awards. Put a special focus on SMEs and start-ups • Encourage publication of ethics assessment and EIA reports (or summaries) as part of companies' non-financial reporting.
Support ethics assessment and EIA (as tools to address ethical issues and impacts) as an essential part of the management of a company's R&I process	• Integrate ethics assessment and EIA into research management and/or corporate social responsibility procedures and practices. • Dedicate resources (human, financial, time) for carrying out ethics assessment and EIAs and their review. Pay a special attention to SMEs and start-ups. • Encourage publication of ethics assessment and EIA reports (or summaries) as part of companies' non-financial reporting.
Facilitate discussion and mutual learning about ethics assessment and EIA at the EU and local levels	• Set up an ethics assessment and EIA mutual learning portal or community at EU and/or national level. • Create a platform to discuss and exchange experiences between EU institutions that are responsible for business, economy, finance and Research and Innovation. • Develop ethical, responsible and sustainable R&I guidance in the industry context based on the results of SATORI.

FURTHER READING

- Callies, Ingrid, et al, *SATORI Outline of an Ethics Assessment Framework*, V.1.1, Deliverable 4.2, December 2016.
- Gurzawska A., Porcari A., *A reasoned proposal for a set of shared ethical values and principles for ethics assessment in European context; Annex 7: Models for ethics assessment and guidance in industry*, Deliverable 4.1., March 2016, available online: http://satoriproject.eu/media/D4.1_Annex_7_Industry.pdf
- Gurzawska A., et al., *Ethical Assessment of R&I: A Comparative Analysis; Annex 3h: Ethics Assessment In Different Types of Organisations: Industry*, Deliverable 1.1, June 2015, available online: http://satoriproject.eu/media/3.h-Industry.pdf
- SATORI, *CEN Workshop Agreement Ethics assessment for research and innovation*, CWA SATORI, May 2017.. Please add the current weblink where the CWA is downloadable from
- SATORI, *Ethics assessment for research and innovation — Part 1: Ethics committee*, Secretariat, NEN, 2017.
- SATORI, *Ethics assessment for research and innovation — Part 2: Ethical Impact Assessment Framework*, Secretariat, NEN, 2017.
- Trilateral Research Ltd., *Policy Brief: Ethical Impact Assessment: enhancing responsible research & innovation*, May 2017.

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/

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.

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Consortium:

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

Website: https://satoriproject.eu/

Policy Brief: Responsible and Ethical Governance of Research and Innovation in the Context of Globalization

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.

Now in month 20 of the four-year project, the SATORI consortium of 17 partners has collected empirical insights to help formulate proposals for improved and more harmonised ethics assessment within scientific fields and among different kinds of ethics assessors and countries. The consortium is paying particular attention to ethics assessment in the context of globalisation.

In June 2015, consortium partners, leading authorities and experts met at a conference at UNESCO Headquarters in Paris to deliberate on the project's findings so far and to develop policy and legal options for developing ethics assessments for research and innovation within the context of globalisation. The conference generated recommendations in six areas:

Responsible Supply Chain
Scientific Misconduct
Traditional and Indigenous Knowledge
The Outsourcing of CO_2 Emissions
"The Brain Drain"
Clinical Research and Trials

http://www.satoriproject.eu

September 2015

Introduction

In recent decades, research and innovation have become global enterprises. Emerging economies have invested heavily in R&I, there has been a significant outsourcing of R&I activities from high-income to middle- and lower-income countries, and research organizations and firms have have developed global alliances or have become multinational themselves. These developments have benefited R&I overall, but there are also significant social, ethical and regulatory challenges that still have to be met. Research and innovation practices in different countries and regions are subject to divergent, or altogether lacking, regulatory and governing standards and practices, and burdens and benefits of the globalisation of research and innovation are being unequally spread across the globe. In this context, the globalization of R&I raises important ethical issues that should be addressed by all involved parties. These issues concern how the practice and impact of globalized R&I could and should respect civil and human rights, promote well-being, economic development and sustainability, and involve a just distribution of benefits and burdens, both within countries and between higher, middle and lower income countries. We hold that all parties involved – governments, industry, public research institutions, civil society, as well as individual scientists and engineers, have a responsibility to promote and uphold the ethical conduct of research innovation in a global setting – all the way from agenda setting to research, innovation, production and sales. We call on all parties to ensure procedures and mechanisms by which ethical issues are considered in globalized R&I activities, in particular respect for civil and human rights, protection of the environment, and sharing the benefits of research and innovation between peoples and nations.

We have identified six key issues in the globalised R&I for which we have developed specific recommendations.

All texts, including background documents listed below, are available for viewing and download at http://www.satoriproject.eu/deliverables

Responsible Supply Chain Governance

European industry often makes use of global supply chains that involve organizations and resources in many different countries. It is increasingly recognized that supply chains should be governed to address morally problematic issues, such as environmentally unsustainable practices, child labour, repression of freedom of association and collective bargaining, and unfair wages and price levels. Serious efforts are therefore needed for responsible supply chain governance.

Two models of responsible supply chain governance are the following:

Government dominates one model. In the other, industries regulate themselves (self-regulation). In the first case, the government would establish the standards and expect companies fulfil them. If a company did not comply with the standards, the government would take appropriate action.

However, the models are problematic: Today, there are various standards and tools which confuses industry. Industry (and other stakeholders) prefer harmonization of these different frameworks.

We recommend that governments create a multi-stakeholder platform on a global level, in which the UN, OECD, and the EU could collaborate in pursuit of a harmonized ethics assessment framework for ethical supply chains.

Conference participants noted that the EU needed both hard and soft law to remove excesses in the marketplace and to be the basis of standards.

The EU should base its actions on the EU Charter of Fundamental Rights and EU Regulations, but can also reference the principles of other organisations (e.g., UN, OECD).

Taking into consideration policy coherence, the EU should include the responsible supply chain governance and the proposed platform on its corporate social responsibility (CSR) agenda.

The EU can motivate companies not only by adopting a "naming and shaming approach", but also by creating incentives for responsible companies (tax allowance, responsibility awards).

The EC could put more attention on consumer awareness and capacity building in regard to ethical values and ethical impact assessment.

Education is crucial in two ways. First, there is a need to include training on responsible supply chain management in the university curricula. Second, education is a part of the supply chain, for example, as manifested by citizens of developing countries who come to Europe or the USA, and then return to their countries where they use the acquired knowledge. There is a responsibility to ensure the knowledge is gained and shared in the native countries.

Background reading available at http://satoriproject.eu:
SATORI Responsible Supply Chain Case Study
SATORI Responsible Supply Chain Background Document

September 2015

Scientific Misconduct

Scientific misconduct is increasingly recognized as a global problem with great economic costs and harms to society. It is in the interest of EU countries to develop a global approach to scientific misconduct that recognizes the global practice and organization of research.

Capacity-building at an early stage is critical to long-term ethical research conduct; thus specific provisions must be included at the local level to include positive mentoring of good ethical scientific standards.

The European Commission and the European Research Council policies on "Ethics for researchers" and "A comprehensive strategy on how to minimise research misconduct and the potential misuse of research.

Temper the pressure for rapid "cutting-edge" publications as a prerequisite for funding and job status, which can place an undue influence leading to scientific misconduct. Instead, promote the focus on ethical science. The European Commission should consider ways that existing guidelines can be better promulgated.

Background reading available at http://satoriproject.eu:
SATORI Scientific Misconduct Case Study
SATORI Scientific Miscondut Background Document

Traditional and Indigenous Knowledge

It is increasingly recognized that R&D should respect and reward the traditional & indigenous knowledge and biological resources from indigenous communities and ensure that commercial exploitation that draws from indigenous knowledge and resources is not exploitative but beneficial to the group in question. Not enough is done yet, however, to ensure that such exploitation does not occur.

The European Commission should develop a framework directing ethical conduct specifically for EU researchers who are involved with or conducting research or trials related to traditional knowledge of the groups that possess this knowledge.

Background reading available at http://satoriproject.eu:
SATORI Traditional and Indigenous Knowledge Case Study
SATORI Traditional and Indigenous Knowledge Background Document

September 2015

The Outsourcing of CO_2 Emissions

The outsourcing of CO_2 emissions by high-income countries to low- and middle-income countries is increasingly recognized as an impediment to solutions for global warming. To address these problem, we make the following recommendations:

Governments should take responsibility for addressing the outsourcing of CO_2 emissions:

- Governments are responsible for providing a framework that requires inclusion of the carbon footprint in each part of the supply chain.

- The EU should encourage other countries to reduce emissions by requiring companies to include offshore emissions in other countries in mandatory government reporting.

Companies have a responsibility to encourage their suppliers to reduce CO_2 emissions:

- Companies should benchmark the reductions in emission levels.

- Government and industry should establish an authority to regulate CO_2 emission outsourcing that is sector-specific, independent and has oversight over such outsourcing. This authority should be transparent and provide information about the regulatory process.

Government and industry should consider harmonisation with existing institutions.

On the EU Level:

- The EU should introduce a regulatory framework that requires companies to consider their entire car bon footprint, including that of their suppliers.
- The outcome of the Paris climate change negotiations may assist these efforts.
- Companies need incentives, for example:
    - o Tax allowances and trade allowances.
    - o Base awards and competitions on strict criteria (Eco-Design is a good example to follow).
    - o Provide 'greening taxation', including higher taxation for non-green activities and lower taxation for green activities.
    - o Establish clear, unified benchmarks (like Eco-labels)
    - o Certify environmentally friendly products and services (like Fair Trade certification)

Background reading available at http://satoriproject.eu:
SATORI The Outsourcing of CO_2 Emissions Case Study
SATORI The Outsourcing of CO_2 Emissions Background Document

September 2015

The "Brain Drain"

The emigration of highly skilled scientists and engineers from low- and middle-income countries outside the EU to the EU, where they have better employment possibilities, deprives countries of origin of human capital that cannot be easily replaced. Extra efforts are required to halt or compensate for such "brain drain":

EU policy-makers should make research more attractive in specific countries in order to address the "brain drain" and retain skilled individuals. International funding bodies can help these countries build and maintain a scientific infrastructure.

Policy-makers should remove hurdles in soft law that affect the brain drain, for example, citing fair access to research as a framework for immigration.

Policy-makers should promote global research exchanges (for example, Erasmus catered to a North-South bridging policy) as well as gender-focused programmes.

Policy-makers could support programmes for young researchers that include a strong foundation of training, so that the researchers can engage creatively in "giving back". Funds from global foundations should include provisions to encourage beneficiaries to return to their countries of origin.

The EU should promote policies aimed at ensuring that there are appropriate jobs for individuals when they return to their countries of origin.

The EU should facilitate double professorships, whereby individuals can have a position at a university in their home country and in an institution in another country as a way to facilitate trans-national contact, engagement and collaboration. The EU could incentivise teaching staff to teach abroad, which the EU can encourage through grant stipulations and other incentives. Non-European countries should also institute these policies to minimise the brain drain.

Background reading available at http://satoriproject.eu:
SATORI "Brain Drain" Case Study
SATORI "Brain Drain" Background Document

September 2015

Clinical Research and Trials

The conduct of clinical research and trials by EU researchers in non-Western countries involves delicate questions regarding the ethical standards that are put in place.

International soft law as well as regional laws address clinical ethics trials; thus, however, policy-makers need to streamline and optimise existing policies. When policy-makers develop new policies, they should take into account global perspectives on clinical ethics. Intergovernmental bodies (responsible for framework development, training and capacity-building) and national level regulators to apply a globally cohesive framework of ethics evaluation This must also involve better communication between. Collaboration should also involve public and private funders of the research, whose discretion can ensure that ethically-sound research is allowed to proceed, as well as individual researchers who can ensure that their own research is adherent to ethical protocol.

We suggest policies that focus on educating people about the process of reviewing research while keeping in mind the relevant values of the research. Communities, with support from the EU, should put emphasis on capacity-building, specifically building preparedness infrastructure for health crises. Policies should also shift to ethics monitoring, rather than ethics review. In this way, ethics will be engaged throughout the research process. Furthermore, the responsibilities to the subject population post-trial, such as equitable access to treatments, should also be at the forefront of policy application.

The EU and other stakeholders should support generalised training for ethics regulators and one-on-one ethics training in parallel with efforts to achieve best outcomes. Furthermore, SATORI partners and stakeholders could benefit from concrete tool, such as a checklist, to ensure a competent review of ethical issues. The EU, the SATORI consortium, international research partners and other stakeholders should find a common ground for developing a globally consistent ethics policy. This must be done judiciously, however, without "over legislating".

Background reading available at http://satoriproject.eu:
SATORI Clinical Research and Trials Case Study
SATORI Clinical Research and Trials Background Document

This policy brief was compiled by UNESCO, a partner in the SATORI consortium.

September 2015