

## **Towards a Common Approach to Ethics Assessment in European Research and Innovation**

*A SATORI follow-up project to continue mobilization and mutual learning*

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### **Concept Note**

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- **From 2014-17 the SATORI project has laid the groundwork for a common approach to ethics assessment in European research and innovation**
  - **The major results of the project include: extensive mapping of the field; a proposal for a common European ethics assessment framework; an early-stage standard for organizing ethics assessment units and for assessing ethical impacts of research and innovation; recommendations for improvement of the H2020 ethics appraisal system; and a roadmap towards a fully implemented common European approach to ethics assessment**
  - **These results – if taken up by the appropriate stakeholders – may supplement and support the advancement of already ongoing developments in the field, such as the Guideline for Ethics Integrity, the H2020 ethics appraisal system, and others.**
  - **Nevertheless, the results of SATORI still need attention and work to fully mature and to become integrated in existing ethics assessment strategies and practices.**
  - **We therefore invite you to join this call for the launch of a collaborative follow-up project to SATORI by signing the Letter of Support and indicating your level of commitment to such a follow-up activity.**
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This concept note provides:

- Background information on SATORI
- Overview of the major results of SATORI
- Outline of a SATORI follow-up project

## Background

The SATORI project was launched in 2014 with the purpose of developing a common European approach to ethics assessment of research and innovation and exploring the possibility of standardization. The framework developed in the project aims to facilitate *aspiration to common standards* rather than regulatory harmonization. This approach allows for mutual learning based on respect for cultural differences across Europe while providing a common language and field of practice for ethics assessment.

The development carried out in the project has been based on extensive empirical studies as well as dialogues with experts and stakeholders.

## Major results of SATORI

### Extensive empirical mapping and comparison

The first major result of the SATORI project is an extensive library of reports mapping of ethics assessment approaches, practices and forms of organization<sup>i</sup>. The scope of this mapping has been very broad. Beyond the field of ethics assessment proper, SATORI has mapped and compared *de facto* approaches to ethics assessment found in impact assessment, research integrity guidance, social responsibility policies, human subjects research, institutional integrity management, animal ethics, dual use, and risk assessment. Beyond ethics assessment practice in the medical and life sciences, SATORI has also mapped such practices in the natural sciences, engineering, the social sciences, and humanities. Beyond research ethics committees (RECs) and national ethics committees (NECs) SATORI has mapped forms of organization around ethics assessment in research funding organizations (RFOs), national science academies, academic and professional organizations, universities, governmental and government-funded organizations, civil society organizations, standardization and accreditation organizations, and industrial organizations. This mapping exercise is unique in European ethics assessment by way of its scope and depth, and will hopefully serve as a stepping stone for future research in the area.

### A reasoned proposal for a common ethics assessment framework

The second major result of the SATORI project is a proposal for a European framework for ethics assessment of research and innovation in the EU member states<sup>ii</sup>. Based on an analysis of stakeholders' expectations from such a framework, this framework is presented as a starting point for further dialogue and bottom-up initiatives. The framework outlines *generally shared ethical principles* that apply to issues of professional conduct, research practice, and societal impact management across all disciplines and innovation areas. The framework furthermore outlines *ethical issues of specific pertinence* to particular areas of research and innovation. In addition, the framework makes recommendations for quality assurance in the 'ethics assessment unit', i.e. any type of body – independent or sub-organizational – that carry out ethics assessment of research and innovation. Finally, the SATORI framework includes proposals for the design of institutional structures of ethics assessment bodies in the European Union and its member states.

### Early-stage standards for ethics assessment units and ethical impact assessment

The third major result of SATORI is an early-stage CEN standard – a so-called CEN workshop agreement (CWA) in two parts<sup>iii</sup>. One part of the CWA sets standards for the composition, role, functioning and procedures of an *ethics assessment unit*. The other part of the CWA provides researchers with guidance on the performance of an *ethical impact assessment*. The CWAs are currently being finalized and will then be publically available for use by all interested organizations. The agreement, which the CWA represents, was

reached through a number of stakeholder dialogue sessions with 100+ experts or stakeholders contributing to its development and refinement under the guidance of the Dutch standardization organization (NEN). The CWA will be revised no later than three years from publication to decide whether they remain relevant; a process to which all stakeholders are able to contribute.

### **Recommendations for the revision of the European Commission's H2020 ethics appraisal system**

A fourth major result will be a set of recommendations for ethics assessment under H2020 and beyond, which are still underway<sup>iv</sup>. Based on the SATORI framework, the SATORI project has carried out a case study of the European Commission's ethics appraisal system, which supports the assessment and management of ethical issues in relation to H2020-funded research and innovation. These recommendations serve as inputs to internal reflections in the Commission on how to achieve ongoing improvement of the appraisal system; both from the point of view of ethics assurance and from the point of view of researchers and innovators.

### **Roadmap towards a common European culture of ethics in research and innovation**

A fifth major result is the SATORI roadmap. Produced through a dialogue-based process, the SATORI roadmap outlines how the SATORI ethics assessment framework can be continually developed and implemented in practice<sup>v</sup>. The timespan of the roadmap is 10 years. Centering on a vision of a common approach to ethics assessment being achieved through ongoing mobilization and mutual learning, the steps of the framework are fleshed out in the form of recommendations and associated actions that need to be taken by various stakeholder groups that are involved in ethics assessment of research and innovation if such a vision is to be achieved.

### **Outline of a follow-up project**

Along the way, the SATORI project has confirmed in a myriad of ways that there is both a need and a wish among stakeholders for greater coherence and better coordination in ethics assessment of research and innovation. To take active steps to facilitate a structured search for such coherence and coordination is therefore the logical next step; not only for the European Commission, but for a range of interest groups as well. The elements of such actions have been articulated and debated with relevant stakeholders in two connected workshops during the first half of 2017.

To ensure the activation of the SATORI results beyond the end of the project, the SATORI consortium proposes that a follow-up project be initiated. The purpose of the follow-up project will be two-fold. On the one hand, the follow-up project will test, evaluate and revise the SATORI CWAs in order to prepare the ground for a decision by interest groups whether or not to formally recommend the adoption of the CWAs by their member organizations after its revision no later than 2021. On the other hand, the follow-up project will also seek to establish routine communication between the different actors in European and international R&I, which the SATORI roadmap has identified as centrally positioned to push the culture of ethics in R&I towards greater voluntary harmonization.

Possible elements of such a follow-up project are outlined below.

#### **Establish a temporary secretariat function**

The secretariat function must have dedicated time, staff and means to facilitate coordinate the follow-up project, arrange dialogue events and gather lessons learned in shared reports. The secretariat can be funded by the European Commission (through FP9 or a tendered service), the interest groups participating in the project, or both. The secretariat function can be performed by an independent actor, an existing

European or international organization or network, or as a networked function shared between parties to the project.

### **Promote and coordinate pilot CWA implementations and evaluations by R&I organizations**

The partners involved in the follow-up project as well as the secretariat will invite research performing institutions and companies and innovation performing organizations in industry and business to carry out pilot implementations of the SATORI CWAs and to evaluate their usefulness; as standards for practice; and as tools for conformity assessment. The secretariat will develop a pilot implementation and evaluation template in dialogue with the parties to the follow-up project (template provided in D7.3 and D8.1). The secretariat will gather and process feedback from pilots.

### **Support CEN's CWA revision process**

By gathering and analyzing evaluation results from pilot implementations and from dialogues between the parties of the follow-up project, the secretariat will help to prepare the engagement of the parties to the project in the CWA revision process. This process will take place in 2021 at the latest. The parties of the follow-up project will have a central say in determining whether the CWAs will be taken up for revision and maturation into full standard status. The support of temporary secretariat will provide support, which some organizations will need in that connection.

### **Host annual strategy dialogue events between central R&I ethics actors and projects**

The purpose of these dialogues is to a) discuss, evaluate and revise the SATORI framework and roadmap with respect to their usefulness to the inter-organizational cooperation between central R&I actors, especially those who are the parties to the follow-up project and b) provide a platform for coordination of ethics projects in H2020 and ethics strategies among central actors and networks. The output of these meetings could be, on the one hand, consensus statements about how the framework and roadmaps should be changed to best support inter-organizational cooperation and, on the other hand, to explore and establish specific avenues of cooperation among European and global actors.

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<sup>i</sup> See: [http://satoriproject.eu/work\\_packages/comparative-analysis-of-ethics-assessment-practices/](http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/)

<sup>ii</sup> See: [http://satoriproject.eu/media/D4.2\\_Outline\\_of\\_an\\_Ethics\\_Assessment\\_Framework.pdf](http://satoriproject.eu/media/D4.2_Outline_of_an_Ethics_Assessment_Framework.pdf) as well as <http://satoriproject.eu/publications/framework-video/>.

<sup>iii</sup> See: <https://www.cen.eu/News/Workshops/Pages/WS-2016-010.aspx> as well as: <http://satoriproject.eu/the-satori-cwa-implications-for-research-and-innovation-policy/>. Final versions will be available from the SATORI website under a separate 'standards' tab.

<sup>iv</sup> Watch this space: [http://satoriproject.eu/work\\_packages/measuring-the-impacts-of-ethics-assessment/](http://satoriproject.eu/work_packages/measuring-the-impacts-of-ethics-assessment/)

<sup>v</sup> See: [http://satoriproject.eu/media/D4.3\\_SATORI\\_Roadmap.pdf](http://satoriproject.eu/media/D4.3_SATORI_Roadmap.pdf)