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**A COMPREHENSIVE PICTURE OF ETHICS ASSESSMENT IN THE EU NOW AVAILABLE!**

*A major report on the state of the art of ethics assessment in select EU countries, different disciplines and institutions is issued by the SATORI Project, supported by the European Commission through its FP7 funding scheme.*

Research and innovation are becoming more and more “responsible”, and driven by the needs of the society and by ethical principles and norms that many European countries are setting up. The Report on the *Ethical Assessment of R&I: A Comparative Analysis*, presents the results of 18 months of work by researchers from 17 institutions that are partners in the SATORI project. The Report is available and freely downloadable at <http://satoriproject.eu/deliverables> and offers a comprehensive picture of the state of the art of ethics assessment in Europe and beyond (China and USA were also taken into account in the comparative analysis). The research activity underlying this report was led by Trilateral Research & Consulting (UK).

Science-based knowledge and its technological applications provide new opportunities to improve daily life. At the same time they raise concerns about their social, legal and ethical implications. That’s why ethics assessment (the evaluation of actual and future ethical issues related to a research project, a technology or an artifact) is becoming more and more important. The SATORI project focuses on central questions in ethics assessment: what is the specific role of ethics assessment for research and innovation? Who is in charge of it? What do we mean by ethics assessment of research and innovation? Who is in charge of it? Who develops guidelines for this activity and under what kind of principles and norms? What kind of institutions conduct the assessment in the different countries? Is there a difference in quality or frequency of ethical assessment among the different scientific fields?

“This report of more than 100 pages, with 47 annexes covering specific aspects of the topic, answers these questions and offers many opportunities for experts to better understand the framework of ethics assessment in EU and for the journalists to report the development of an ethical approach to science and research, not only in the field of biomedicine but also in engineering, natural sciences, environmental sciences and humanities” explains Philip Brey, professor of Philosophy of technology at University of Twente (NL) and coordinator of the SATORI project.

The emerging notion of responsible research and innovation (RRI) requires a more systematic focus on scientific responsibility, which goes beyond what scientists do to consider the consequences of their actions. Given complex causal pathways of indirect use and impact, it is both important and challenging to establish the specific responsibilities to which individual scientists or scientific institutions are responsible for, and the role that ethical assessment plays in this framework. This report will help achieve this.

## THE STRUCTURE OF THE REPORT



### **The SATORI Project**

The SATORI project is a forty-five month project on ethics assessment of research and innovation (R&I) supported by the European Commission through its FP7 funding scheme. The SATORI project aims to support mutual learning about ethics assessment and ethical guidance in different fields, organisations and countries, and strives to identify best practices, to support harmonisation and shared standards, and, to the extent that it is possible and desirable, develop common principles, protocols, procedures and methodologies for the ethical assessment of research and innovation in the European Union and beyond. The aim of this substantial research effort is to improve ethical assessment practices and strengthen respect for ethical principles in research and innovation.

**For more informations please see: <http://satoriproject.eu>**

## FURTHER DETAILS

### **How is the report structured and what information does it provide?**

The main report summarises the results of 18 months of work and provides a comparative analysis of ethics assessment in different scientific fields, organisations and countries. The 47 report annexes examine ethics assessment in greater depth for different scientific disciplines (i.e. natural sciences, engineering sciences, medical and life sciences, humanities and social sciences) and sub-disciplines, different types of organisations (i.e. research ethics committees, national ethics committees, research funding organisations, national academies of science, universities, government and government funded organisations, civil society organisations, standards and certification organisations), countries (Austria, China, Denmark, France, Germany, Netherlands, Poland, Serbia, Spain, UK, and the USA). The report annexes also study principles and approaches in ethical impact assessment and conventional impact assessment, research integrity, human subjects research, institutional integrity, use of animals in research, dual-use etc. In addition, the report looks at ethics assessment and guidance at the European Union and global levels.

### **How was the research conducted ?**

The report is based on over 230 interviews with representatives of organisations that engage in ethics assessment and guidance, and experts in the field, in Europe, the US and China. It is also based on extensive desk research and literature surveys. The main report introduces basic terminology, discusses major traditions, approaches, principles and issues for ethics assessment, and provides comparative analyses of ethics assessment in different scientific fields, types of organisations, and countries. It also analyses ethics assessment and guidance policies and institutions at the EU and global level.

### **What does SATORI mean by ethics assessment?**

SATORI defines ethics assessment as any kind of institutionalised assessment, evaluation, review, appraisal or evaluation of practices, products and uses of research and innovation that primarily makes use of ethical principles or criteria. The objects of research or innovation that are assessed may include research or innovation goals, new directions, projects, practices, products, protocols, or new fields. There are many organisations engaged in some form of ethics assessment of R&I. Ethics assessors are agents (organisations or individuals) that engage in ethics on a professional basis but sometimes this term is used more broadly, to include agents that engage in any type of ethics assessment, guidance, or awareness raising (e.g. as occurs in the case of civil society organisations). The report also discusses other forms of assessment, including quality assurance, social and environmental impact assessment, valorization and compliance.

### **What are the principles and approaches in ethics assessment?**

The chapter entitled “Issues, Principles and Approaches in Ethics Assessment” offers a discussion of the ways in which research ethics has become institutionalized, mainly in the field of biomedicine, by means of research ethics committees (RECs), national ethics committees, regulations and policies, and other initiatives.

The report also discusses the approaches of engineering ethics and ethics of technology and innovation. Engineering ethics is a tradition of professional ethics for engineers that has developed in response to health, safety and environmental hazards resulting from engineered products and systems. Ethics of technology is a field that analyses the ethical issues concerning the functioning of technology in society and their potential or actual impacts on society.

Annex 1 of the report contains eight in-depth studies on research integrity, social responsibility, human subjects' research, institutional integrity, the use of animals in research, dual-use in research, ethics and risk, and ethical impact assessment and conventional impact assessment.

### **In which field is ethics assessment more developed?**

The report provides a comparative analysis by scientific field based on a systematised inventory of current practices and principles of ethics assessment in the five major areas: the medical and life sciences, natural sciences, engineering sciences, social sciences, and the humanities. The aim of the analysis was to determine differences and similarities, with a view to determining the feasibility of transferring ethics frameworks, principles and practices from fields with well-developed traditions to other fields.

Ethics assessment exists to different degrees in the five fields especially in medical and life sciences, followed by the engineering sciences, and then the social sciences. EU and supranational organisations have an important role in providing guidance to ethics assessment in the medical sciences, in particular. The humanities have not really managed to establish their own tradition in ethics assessment. Shared concerns of the five fields include research integrity, social responsibility, intellectual freedom, and professional attitudes such as honesty, collegiality and impartiality. In addition, many fields express concerns about the protection of human subjects and the welfare of animals used in experimentation.

Annex 2 contains five in-depth studies of ethics assessment in the major scientific fields previously described. It also contains twelve studies of ethics assessment in disciplines and subfields within these fields: eight in the medical and life sciences, two in the social sciences, and two in engineering.

### **Who is in charge of ethics assessment?**

The report provides a comparative analysis of ethics assessment and guidance by a variety of organisations that are active in this area. The report distinguishes fifteen types of organisations that routinely or professionally engage in ethics assessment : research ethics committees (RECs), associations and networks of RECs, national ethics committees, governmental organisations and councils, universities and research institutes, associations of universities and research institutes, research funding organisations, science academies and associations of science academies, academic and professional organisations in R&I, companies, business and industry associations, civil society organisations (CSOs), standards organisations, certification and accreditation organisations, and academic ethics centres and departments. Each actor performs a significant but different role in ethics assessment. Not all companies or industry associations see a role for themselves in setting or following ethical standards. Not all universities or research funding organisations pay serious attention to ethics assessment. Many organisations see problems in the way that ethics assessment

and guidance are practiced, including a lack of clear procedures and guidelines, of time and resources, of training, of awareness of ethical issues in the organisation and ways of approaching them, and an insufficient ability to recognise and incorporate new issues and challenges.

Annex 3 contains nine in-depth reports on organisations that engage in ethics assessment or guidance, with some reports analysing more than one type of organisation.

### **Is ethics assessment equally taken into account in the different countries?**

The report comprises an analysis of ethics assessment structures and agents in both the public and private sectors in eleven countries, namely eight European Union countries and one candidate for membership (Serbia), the United States and China. The aim of the analysis was to make 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, in addition to their funding and scope.

All countries that were studied are currently expanding their ethics assessment and guidance infrastructure. The expansion of ethics assessment in non-medical areas is especially noteworthy. There are also significant differences in the extent to which ethics of R&I is institutionalised, ranging from limited (Serbia, Poland, China) to extensive (Netherlands, Germany, Austria) institutionalisation. The role of government in ethics assessment and guidance is different, ranging from strong (China) to little regulation and intervention (USA), with EU countries located at different points in between. Governments stimulate corporate social responsibility for industry to different degrees and with different means, and that CSOs engage in informal ethics assessment and guidance in public discussion, and have a role in ethics assessment procedures by other organisations in some countries. Annex 4 contains eleven in-depth reports on Austria, China, Denmark, France, Germany, the Netherlands, Poland, Serbia, Spain, United Kingdom and the United States.

The main report also provides a summary of the ethics assessment landscape at both EU and global levels, specifically with regard to the relation between EU and global counterparts. Annex 5 contains two in-depth reports on ethics assessment and guidance at the EU and global levels, respectively.

### **What are the general conclusions of this report?**

The ethics assessment of research and innovation in Europe faces many challenges: it currently lacks unity, recognised approaches, professional standards and proper recognition in some sectors of society. Stakeholders such as universities, research institutes, corporations and government organisations have flagged the the importance of ethics assessment and developing different initiatives and mechanisms to address ethical issues. The rapid expansion of ethics assessment has not, however, been accompanied by significant efforts to harmonise approaches in different fields and organisations, to raise standards, and to introduce quality assurance. Questions remain about the feasibility of transferring ethics principles and practices from fields with well-developed ethics assessment skills to other fields. While there are certainly specific aspects that can be usefully transferred, some areas such as the social sciences and humanities are faced with the challenge of

dealing with familiar issues, such as informed consent and data protection, and simultanelously novel, and largely unknown, contexts.

There is a need for improvement and coherence in the ethical assessment of R&I in Europe and beyond, and this will be the aim of the future activities of the SATORI Project.

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