Initiatives and policy developments at local, national, and European levels

Deliverable 9.1

Lead authors: Rowena Rodrigues, Trilateral Research Ltd; Faridun Sattarov, University of Twente

Contributors: David Wright, Michael Madary, Trilateral Research Ltd
Andrea Porcari, Airi- Italian Association for Industrial Research
Zuzanna Warso, Helsinki Foundation for Human Rights
Emils Birkavs, Stéphanie Gauttier, Wessel Reijers, University of Twente
Dino Trescher, Daniela Ovadia, European Union of Science Journalists' Associations
Raija Koivisto, Mika Kari, VTT Technical Research Centre of Finland Ltd
Erich Griessler, Institute for Advanced Studies
Ingrid Callies, UNESCO
Signe Annette Bøgh, Danish Standards
Rok Benčin, Scientific Research Centre of the Slovenian Academy of Sciences and Arts (ZRC SAZU)

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Contact details for corresponding author:
Rowena Rodrigues, Trilateral Research Ltd.
rowena.rodrigues@trilateralresearch.com

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LIST OF CONTRIBUTORS

Global level	Ingrid Callies
EU level	Rowena Rodrigues, David Wright
Austria	Erich Griessler
Finland	Raija Koivisto, Mika Kari
France	Stéphanie Gauttier
Germany	Dino Trescher
Italy	Daniela Ovadia, Andrea Porcari
Netherlands	Emils Birkavs
Poland	Zuzanna Warso
Russia	Faridun Sattarov
UK	Rowena Rodrigues
USA	Rowena Rodrigues
Discussion of developments	Andrea Porcari, Zuzanna Warso, Rowena Rodrigues
Introduction and conclusion	Rowena Rodrigues, Faridun Sattarov
Methodology	Rowena Rodrigues, Michael Madary
Reviews	Stéphanie Gauttier, Signe Annette Bøgh, Rok Benčin, Mika Kari, David Wright

Contents

Abstract

This report focuses on policy initiatives and policy developments at the global, European, and national levels related to ethics assessment of research and innovation (R&I), covering the period 2014-2017. It primarily draws on the research and findings of the SATORI policy watch and policy engagement activities and the project's comparative analysis of ethics assessment practices.

The report identifies *key policy actors* at the global, EU and national levels and presents overviews of policy developments impacting ethics assessment of R&I at these levels. It outlines *major policy developments* in the following countries: Austria, Finland, France, Germany, Italy, Netherlands, Poland, Russia, UK and USA. It discusses *good practice developments and the opportunities, challenges and barriers* to introducing and using the SATORI ethics assessment framework. It also contains recommendations for policy-makers to strengthen ethics assessment of R&I.

Executive summary

This report focusses on initiatives and policy developments at global, European and national levels related to ethics assessment of research and innovation (R&I) during 2014-2017, drawing on the research and findings of SATORI work package 9 *Policy watch and policy recommendations* and work package 1 *Comparative analysis of ethics assessment practices*. The report identifies key policy actors at the global, EU and national level. It presents overviews of policy developments relating to ethics assessment of R&I at the global and EU levels. It outlines major policy developments in the following countries: Austria, Finland, France, Germany, Italy, Netherlands, Poland, Russia, UK and USA, and discusses good practice developments, opportunities for SATORI intervention and potential challenges and barriers to introducing and using the SATORI ethics assessment framework. It also presents the report of the SATORI policy workshop held in Brussels on 23 May 2017.

Methodology and scope

The monitoring of policy developments (global, EU, and national sources) took place on a frequent basis between May 2016 to April 2017 (some sources were monitored daily, others were accessed once or twice a week). The countries actively monitored were: Austria, Finland, France, Germany, Italy, Netherlands, Poland, Russia, UK and the USA. The most relevant items were presented via the SATORI newsletter.[1] The means used included: monitoring of international and national developments using institutional sources; Google alerts and news feed monitoring; monitoring of Twitter feeds etc.

Role of policy-makers in ethics of R&I

Policy-makers include global, EU and national governmental institutions and agencies that set up, support ethics policies, create conditions to support ethics assessment of R&I by establishing standards, codes, declarations, and other soft-law instruments; capacity-building for regional ethics assessment; providing forums for international collaboration and reflection; and providing advisory services.[2]

Policy-makers can help give concrete shape to ethics in R&I by **promoting responsible practices of R&I**. Based on its findings and results, SATORI envisages various roles for policy-makers in supporting ethical R&I, as illustrated in the figure below:

[1] See http://satoriproject.eu/publication_type/newsletters/
[2] Rangi, Sudeep, Siya Bhatt, "Ethics Assessment and Guidance at the Global Level", SATORI, 2015, p 4. http://satoriproject.eu/media/5.b-EA-and-Guidance-at-the-Global-level.pdf

Fig: Role of policy-makers in supporting ethical R&I

Key policy actors at the global, EU and national level

There are various types of policy actors influential in ethics of R&I at the **global level** e.g., Council for International Organizations of Medical Sciences **(**CIOMS**),** Organisation for Economic Co-operation and Development (OECD), United Nations (UN), UNESCO, World Health Organization (WHO). The institutions often have specific committees or commissions dedicated to ethics.

At the **EU-level**, key policy actors include the Council of Europe, Bioethics committee (DH-BIO), European Commission, European Data Protection Supervisor (EDPS), European Group on Ethics in Science and New Technologies (EGE), European Parliament, specifically Science and Technology Options Assessment (STOA). Such policy-makers directly engage with topics of R&I ethics or have committees, branches or fora specifically devoted for the purpose.

At the **national levels**, policy engagement with ethics of R&I takes place via parliaments, science technology, industry or field-specific ministries, departments, regulatory authorities (such as data protection authorities), agencies, advisory committees, boards, commissions, and councils set up specifically to regulate ethical aspects. Countries vary in their set-ups, role and, influence of such actors.

Key findings from the analysis of policy developments impacting ethics assessment of R&I at the global level

The analysis of policy developments impacting ethics assessment of R&I at the global level shows:

- An increased presence of, and interactions between global ethics assessment bodies, discussions, and development of standards,
- Increasing harmonisation and debates on proper and viable ethics assessment practices,
- The establishment (and revision) of internationally recognised standards, codes, declarations and other soft-law instruments to support ethics assessment,
- Capacity-building for regional ethics assessment,
- Creation of forums or platforms for international collaboration, dialogue and reflection,
- A rise in collaborative efforts between ethics committees from different regions,
- Potential challenges and barriers include varying implementation of global standards, lack of capacities to perform ethics reviews due to local deficiencies, and other practical barriers to international ethics assessment compliance
- Global harmonisation of ethics assessment must consider the significant differences in institutions, values, legal frameworks, and cultural practices that exist between different regions and countries, and there should be flexibility in the formulation and interpretation of international standards.
- The SATORI ethics assessment framework which is generalisable across disciplines, countries and institutions could be a good model for wider application at the global-level.

Key findings from the analysis of policy developments impacting ethics assessment of R&I at the EU level

At the EU-level too, there have been several **good policy developments** in ethics of R&I e.g., proposals for regulations and regulatory amendments; issue and publication of hard or soft guidance, official decisions and opinions and expert group/committee reports; adoption of bilateral agreements; public stakeholder consultations; organisation of events; commissioning of research; and scientific and technical research reports.

There are some **potential challenges or barriers** to be overcome in introducing the SATORI ethics assessment framework at the EU-level. Some of these are common, while others are more specific to the different parts of the framework. These include: **need to improve the visibility** of the framework through multi-lingual translations; **finding the political will** to support the use and implementation of the framework; **financial costs**; **political challenges** to any mandatory, top down prescriptions of the framework; **shortage of resources**; **national and local differences**; **scope of ethics assessment activities and limited mandates; infantile and ad hoc nature** of ethical impact assessments (EIAs); **lack of institutional support and positive attitudes** to EIAs; **ineffective implementation** of EIA recommendations; **lack of sharing** of EIA good practice.

Key findings from the analysis of policy developments impacting ethics assessment of R&I at the national level

The survey of policy developments at the national level showed some key **good practice developments** at the national levels concerning policy developments in ethics of R&I, i.e., creation of new laws, and institutions, amendments of existing laws, review of ethics codes and guidance, increasing engagement of stakeholders and increasing ethical awareness. These developments while good, need to be supported and sustained. Further, while ethics assessment is explicitly addressed at the policy level in the medical field and on specific science and research topics (e.g., integrity of research), initiatives related to ethical assessment of scientific research and technology development are increasingly being considered, at least by some countries. EIA seems quite a novel aspect for most of the organisations and institutions

working on ethics at country level – this presents a definite opportunity for the SATORI EIA framework to find a niche of operation.

The analysis of country studies indicates **several challenges** (which need to be addressed at different levels and by a variety of ethics assessment stakeholders) to implementing the SATORI ethics assessment framework at national levels. These include:

Fig: National-level challenges

The report has also identified a **significant number of opportunities** for intervention at the national level. All these require further funding, support and encouragement by policy-makers at the EU and national level. To add to this, countries face various challenges in the use and implementation of ethics assessment. These too need to be considered and addressed through dialogue, resource allocation and good practice sharing across countries (potentially supported by an EU-level institution, if deemed appropriate). Additional key take-away messages for policy-makers based on the work underpinning this report and the SATORI policy workshop discussion, include the need to:

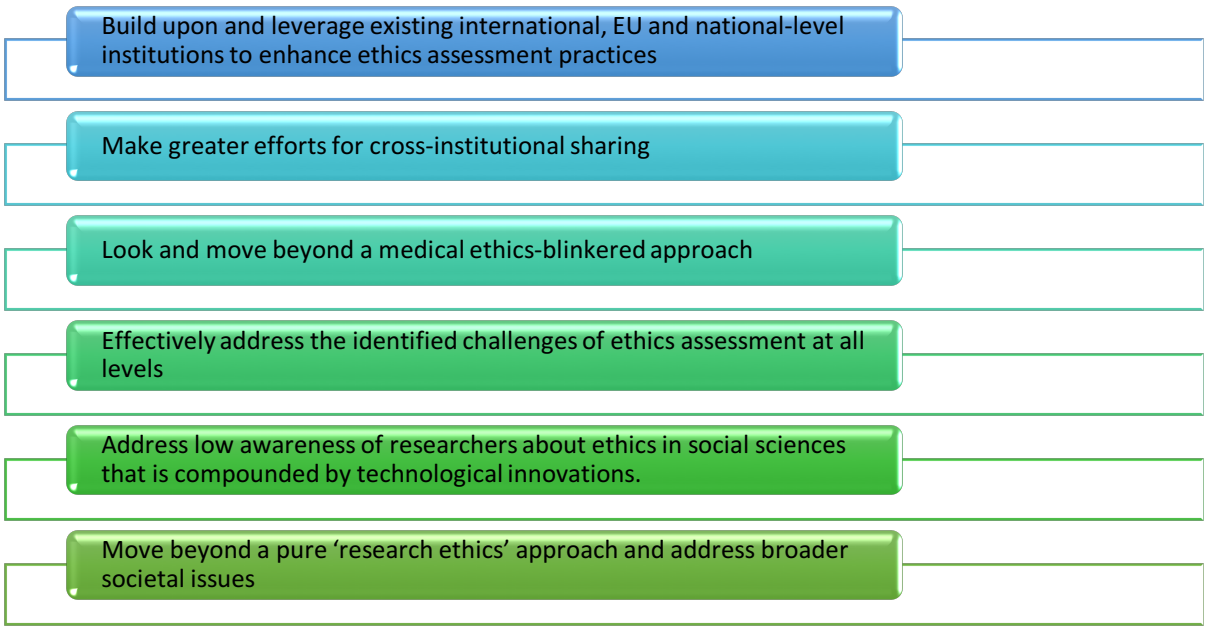

Fig: SATORI key take-away messages for policy-makers

Glossary

Term	Definition
Ethics assessment	Institutionalised assessment, evaluation, review, appraisal or valuation of plans, practices, products and uses of research and innovation that makes use of ethical principles or criteria [SATORI Deliverable 1.1, 2015]
Ethical impact assessment	Process of judging the ethical impacts of research and innovation activities, outcomes and technologies that incorporates both the means for a contextual identification and evaluation of these ethical impacts and the development of a set of guidelines or recommendations for remedial actions aimed at mitigating ethical risks and enhancing ethical benefits, typically in consultation with stakeholders [SATORI CEN Workshop Agreement, 2017]
Policy-makers	Persons or entities responsible for, or involved in creating, setting and making policy, especially in government. [SATORI CEN Workshop Agreement, 2017]

1. Introduction

The aim of this deliverable is to report on ethics initiatives and policy developments at the global, European and national levels, and to determine where there appears to be a utility in introducing or promoting the SATORI ethics assessment framework. It will draw on the research and findings of Task 9.1 of the project[3], for a thematic description and analysis of the most salient issues for SATORI and make relevant recommendations for future EU and national strategic priorities.

Scope

In the context of this deliverable, "policy-makers" refer to persons or entities responsible for, or involved in creating, setting and making policy, especially in government. The scope of this deliverable is limited; it covers policy making at the global, EU and national levels for the period 2014-2017 with a view to determining how the SATORI ethics assessment framework can be further promoted and implemented.

The SATORI ethics assessment framework

Based on research into existing practices and in consultation with a variety of stakeholders, the SATORI project has developed a framework for common basic ethical principles and joint approaches and practices with the objective of harmonising and improving ethics assessment practices of research and innovation (R&I). The SATORI ethics assessment framework, as outlined in the SATORI CEN Workshop Agreement (CWA)[4] comprises two parts.

Part 1, makes recommendations for the composition, role, functioning and procedures of **ethics committees**.[5] Organisations can use it to strengthen and/or improve the ethics assessment of their research and innovation projects. Part 1 of the CWA is applicable to all ethics committees, regardless of their size, scope, or R&I area.

Part 2 provides researchers and organisations with guidance on **ethical impact assessment (EIA);** a comprehensive approach for ethically assessing the actual and potential mid-range and long-term impacts of research and innovation on society.[6] It presents a comprehensive methodology for conducting an EIA in R&I projects. Part 2 is applicable to all researchers and innovators, regardless of the context they are working in or their research and innovation area.

Structure

The report first identifies key policy actors at the global, EU and national level. Next, it presents overviews of policy developments impacting ethics assessment of R&I at the global and EU levels. It also outlines major policy developments in the following countries: Austria, Finland, France, Germany, Italy, Netherlands, Poland, Russia, UK and USA and discusses good practice

[3] Identification and inclusion of relevant EU strategic priorities and policy developments.
[4] Documented in Bøgh, Signe Annette, Katrine Bergh Skriver, Marlou Bijlsma and Thamar Zijlstra*, Report on standardizing operating procedures in ethics assessment, Deliverable 7.1,* SATORI, May 2017. The CWA will be available for download from the SATORI website.
[5] SATORI, Ethics assessment for research and innovation - Part 1: Ethics committee, CEN Workshop Agreement, May 2017.
[6] SATORI, *Ethics assessment for research and innovation — Part 2: Ethical impact assessment framework*, SATORI CEN Workshop Agreement, CWA 17145-1, May 2017.

developments, opportunities for SATORI intervention, and potential challenges and barriers to introducing and using the SATORI Framework. Finally, it presents the report of the SATORI policy workshop (Brussels, 23 May 2017) and its results.

2. Role of policy-makers in ethics of R&I

Ethics assessment of R&I has increasingly become an activity that involves many actors beyond researchers and ethics committees; it also takes place at the policy-level in various ways. It is increasingly recognised, for example, that agenda setting in research by policy-makers, funding agencies, industry and other actors, already involves moral choices. Ethics assessment may result in policy recommendations that become enshrined in laws, or lay bare moral or practical problems and issues with certain legal regulations. Procedures and arrangements of ethics assessment may themselves be subject to various legal regulations that guide and constrain it. Given these interactions, it is vital that any mutual learning about ethics assessment considers also its political contexts and legal environment. Specifically, the rapid growth of legislation and regulation at the European level must be considered, and its consequences for ethics assessment must be further explored.[7]

Policy-makers can help give concrete shape to ethics and responsible practices of R&I. They can convey the SATORI findings, and more vitally, the SATORI framework to each other, and take legislative or regulatory actions (hard or soft) they deem appropriate to support ethical research and innovation. Additionally, policy-makers can stimulate public debate of the issues of concern to the consortium. Based on its findings and results, SATORI envisages various roles for policy-makers in supporting ethical R&I. These include:

- Increasing stakeholder participation and public debate about ethics assessment in R&I,
- Incentivising ethical and responsible research and innovation (RRI), particularly at the small and medium entreprise (SME) level,
- Monitoring whether ethics assessment in R&I is achieving its objectives and taking corrective measures,
- Supporting existing ethics committees in the exercise of their tasks
- Setting up ethics committees with defined roles and responsibilities (in sectors where these are missing),
- Promoting the use and implementation of the SATORI ethics assessment framework at the EU and Member State levels,
- Supporting future research and the development of the SATORI ethics assessment framework.

3. Methodology

The policy developments monitoring (of global, EU, and national sources) took place on a frequent basis between May 2016 to April 2017 (some sources were monitored daily, others were accessed once or twice a week) and using the means outlined below. The most relevant items were presented via the SATORI newsletter.[8]

[7]SATORI, Description of Work, 2014.
[8] See SATORI. http://satoriproject.eu/publication_type/newsletters/

Monitoring of international and national developments

Monitoring of international, EU and national developments was carried out using various sources such as websites and documentation (e.g., newsletters) of government bodies and agencies dealing with R&I (particularly those identified as relevant in the SATORI comparative analysis of ethics assessment practices and the study of legal aspects and impacts of globalisation) national ethics committees, research ethics committees, and the local press. The countries covered in this report and actively monitored include: Austria, Finland, France, Germany, Italy, Netherlands, Poland, Russia, UK and the USA. In addition to this, other countries were monitored on an ad-hoc basis.

Google alerts and news feed monitoring

Google alerts were set up to monitor policy developments using one or more following key words: "ethics", "ethics assessment', "ethics legislation", "ethics review", "research ethics", "ethics policy", "ethics code", "ethical guidelines", "research integrity", "responsible research", "responsible research and innovation", "RRI", "scientific integrity", etc. Search results were filtered and the most relevant items were presented after vetting for relevance to scope (i.e., pertaining to ethics assessment of research and innovation) by the SATORI team via the SATORI newsletter. Policy developments in ethics of R&I were also monitored using scans of Google News Feeds on a weekly basis.

Monitoring of Twitter feeds

We monitored official institutional (e.g., Council of Europe, European Commission, European Data Protection Supervisor (EDPS), European Parliament, United Nations, national policy and ethics assessment bodies) and personal Twitter accounts of people influential in ethics assessment (e.g., academics, politicians, researchers), RRI, ethics of innovation and new technologies etc.

The challenges in finding the information

One of the key challenges was being able to find information for the non-English speaking countries. This was surmounted to some extent by monitoring of such sources by partners well-versed in the specific local language.

4. Key policy actors at the global, EU and national level

Policy actors include global, EU and national governmental institutions and agencies that set up, support ethics policies, create conditions to support ethics assessment of R&I by establishing standards, codes, declarations, and other soft-law instruments; capacity-building for regional ethics assessment; providing forums for international collaboration and reflection; providing advisory services.[9] Here we list examples key policy actors at the global, EU and national level that influence ethics assessment of R&I.

[9]Rangi, Sudeep, Siya Bhatt, "Ethics Assessment and Guidance at the Global Level", SATORI, 2015, p 4. http://satoriproject.eu/media/5.b-EA-and-Guidance-at-the-Global-level.pdf

Global level

- Council for International Organizations of Medical Sciences **(**CIOMS**)**
- Joint International Association of Universities- Magna Charta Observatory (IAU-MCO) Working Group on Ethics in Higher Education
- Organisation for Economic Co-operation and Development (OECD)
- United Nations (UN)
- UNESCO:
    - Intergovernmental Bioethics Committee (IGBC)
    - International Bioethics Committee (IBC)
    - World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)
- World Health Organization (WHO)

EU-level

- Council of Europe, Bioethics committee (DH-BIO)
- European Commission
- European Data Protection Supervisor (EDPS)
- European Group on Ethics in Science and New Technologies (EGE)
- European Parliament, Science and Technology Options Assessment (STOA)

National level

A variety of key policy actors were identified at the national level in SATORI work package 1 inventory of ethics assessment (i.e., sections on: governmental institutions for ethics assessment and national laws and policies for ethics assessment)[10]. Below we present actors identified during the work package 9 policy developments monitoring. The list is illustrative, and does not exhaustively cover all the government bodies that may make or influence ethics or RRI policy. More detailed information is available in the individual SATORI country reports.[11]

AUSTRIA

- Austrian Bioethics Commission (ABC)
- Austrian data protection authority (*Datenschutzbehörde)*
- Ministry of Science, Research and Economy
- Ministry of Transport, Innovation and Technology

FINLAND

- Advisory Board on Biotechnology (BTNK)
- Board for Gene Technology (GTLK)

[10] 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.

[11] Available at: http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/

- Committee for Public Information in Finland (TJNK)
- Council of Finnish Academies (TANK)
- Finnish Advisory Board for Research Integrity (TENK)
- National Advisory Board on Social Welfare and Health Care Ethics (ETENE)
- National Committee on Medical Research Ethics (TUKIJA)
- The Cooperation Group for Laboratory Animal Sciences (KYTÖ)
- The Federation of Finnish Learned Societies (TSV)

FRANCE

- Advisory Committee on the Treatment of Research Information in the Health Field
- Committees of Protection of Persons (CPP)
- Common advisory committee for ethics in agricultural research
- Commission Nationale de l'Informatique et des Libertés (CNIL)
- French Health Authority
- French National Agency for Safety of Medicine and Health Products
- High Council on Biotechnology
- Ministry for the Economy, Industry and Digital Affairs
- Ministry of Education, Higher Education and Research (MENESR)
- National Centre for Scientific Research (CNRS)
- National Committee for Ethics in Animal Research (CNREEA)
- National Consultative Ethics Committee for Health and Life Sciences (CCNE)
- Parliamentary Office for Evaluation of Scientific and Technological Choices

GERMANY

- Bundestag "study commissions" (EnqueteKommissionen)
- Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (TAB)/Office of Technology Assessment
- Council of Science and Humanities (Wissenschaftsrat)
- Die Bundesbeauftragte für den Datenschutz und die Informationsfreiheit
- Federal Ministry for Education and Research
- Federal Ministry of Economics and Technology
- Federal Ministry of Health
- German Ethics Council (Deutscher Ethikrat)
- German Reference Centre for Ethics in the Life Sciences (Das Deutsche Referenzzentrum für Ethik in den Biowissenschaften - DRZE)

ITALY

- Italian Parliament
- Comitato Nazionale di Bioetica (National Bioethics Committee[12]
- Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita (National Committee for Biosecurity, Biotechnologies and Life Sciences - CNBBSV)[13]
- Comitato per le Pari Opportunità del Consiglio Nazionale delle Ricerche (Committee for Equal Opportunities at the National Research Council)[14]

[12] http://presidenza.governo.it/bioetica/pubblicazioni_comitato.html
[13] http://presidenza.governo.it/biotecnologie/documenti.html
[14] www.cpo.cnr.it

- Comitato Etico del CNR (National Research Council Ethics Committee)[15]

THE NETHERLANDS

- Advisory Council for Science and Technology and Innovation (Adviesraad voor Wetenschap, Technologie en Innovatie; AWTI)
- Autoriteit Persoonsgegevens
- Advisory Council for Science and Technology and Innovation (AWTI)
- Health Council of the Netherlands (Gezondheidsraad; GR)
- Ministry of Economic Affairs (Min. EZ)
- Ministry of Education, Culture and Science (Min. OC&W)
- National Institute for Public Health and the environment (RIVM)
- Netherlands Advice Committee on Animal Experimentation Policy (Nationaal Comité advies dierproevenbeleid; NCad)
- Netherlands Advice Committee on the Environment and infrastructure (Adviesraad Leefbaarheid en Infrastructuur; RLI)
- Netherlands Centre for Ethics and Health (Centrum voor Ethiek en Gezondheid; CEG)

POLAND

- Ministry of Development
- Ministry of Science and Higher Education
- Ministry of Digitization
- Commissioner for Human Rights
- Inspector General for Personal Data Protection
- National Science Centre
- National Centre for Research and Development

RUSSIA

- Rosminzdrav (Росминздрав) – the Ministry of Healthcare of the Russian Federation[16];
- Roszdravnadzor (Росздравнадзор) – the federal service with oversight responsibility in healthcare[17];
- Rospotrebnadzor (Роспотребнадзор) – the federal service with oversight responsibility in consumer rights protection and human well-being[18];
- Rosprirodnadzor (Росприроднадзор) – the federal service with oversight responsibility in environmental protection[19];
- Roskomnadzor (Роскомнадзор) – the federal service for the supervision of communications, information technology and mass media[20]
- S*cientific-technical councils* (in Russian: *научно-технические советы*) operating within various research, technological and industrial institutions at the federal government level, e.g., ROSATOM (in Rus.: POCATOM) – state corporate body for

[15] https://www.cnr.it/it/ethics
[16] Ibid.
[17] http://www.roszdravnadzor.ru/en
[18] http://www.rospotrebnadzor.ru/en/
[19] http://rpn.gov.ru/node/161
[20] https://eng.rkn.gov.ru/

nuclear industry[21]; ROSTEC (in Rus.: РОСТЕХ) – state corporate body for high-tech industry[22]; Bach Institute of Biochemistry RAS (in Rus.: Институт биохимии им. А.Н. Баха)[23]; Winogradsky Institute of Microbiology RAS (in Rus.: Институт микробиологии им. С.Н. Виноградского)[24]; Center of Bioengineering RAS (in Rus.: Центр Биоинженерии)[25]

UNITED KINGDOM

- Animal and Plant Health Agency (APHA)
- Animals in Science Committee (ASC)
- Department for Business, Innovation & Skills (BIS)
- Department for Culture, Media & Sport (DCMS)
- Department for Education
- Department for Environment, Food & Rural Affairs (DEFRA)
- Department of Energy & Climate Change (DECC)
- Food Standards Agency
- Home Office Animals in Science Regulation Unit (ASRU)
- Human Fertilisation and Embryology Authority (HFEA)
- Human Tissue Authority (HTA)
- Information Commissioner's Office (ICO)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Ministry of Defence (MOD)
- National Health Service (NHS) Health Research Authority (HRA)
- Office for Standards in Education (Ofsted)
- United Kingdom Ethics Committee Authority (UKECA)

UNITED STATES

- Food and Drug Administration (FDA)
- National Institutes of Health
- Office for Human Research Protections (OHRP)
- President's Council of Advisors on Science and Technology (PCAST)
- The Alaskan Professional Teaching Practices Commission
- The Office of Research Integrity (ORI) Division of Education and Integrity (DEI)
- The Presidential Commission for the Study of Bioethical Issues (the Bioethics Commission)
- U.S. Department of Energy (DOE)
- U.S. Department of Health and Human Services
- White House

Thus, we see a variety of policy actors active at the national level in making policies for ethics assessment of R&I. These include parliaments, commissions, science technology, industry or field-specific ministries, departments, regulatory authorities (such as data protection authorities), agencies, advisory committees, boards, commissions, federal services, and

[21] http://www.rosatom.ru/about/nauchno-tekhnicheskiy-sovet/ (see also: http://www.rosatom.ru/en/about-us/governance/public-council/)
[22] http://rostec.ru/research/council
[23] http://www.fbras.ru/about/nauchno-texnicheskie-sovety
[24] Ibid.
[25] Ibid.

councils set up specifically to regulate ethical aspects. Countries vary in their set-ups, role and influence of such actors.

5. Policy developments impacting ethics assessment of R&I at the global level

This section provides a summary of key policy developments impacting ethics assessment of R&I at the global level, prepared based on the SATORI report on *Ethics Assessment and Guidance at the global level*[26], the SATORI newsletter, and the deliberations in the SATORI policy workshop held in Brussels on 23 May 2017.

Key policy developments in ethics of R&I at the global level

The increased presence and interactions between global-level ethics assessment bodies, discussions, and development of standards has facilitated increasing harmonisation and debates on proper and viable ethics assessment practices. For example, UNESCO's Assisting Bioethics Committee programme creates a model for bioethics committees across different countries with differing social climates grounded in similar ethics principles. Recent global discussions and actions in ethics assessment align with the rise of multinational R&I corporations and actors, and necessitating greater global reflection.

The main role of global-level governmental and government-funded or controlled organisations and institutions, in this context, is to help provide the conditions for ethics assessment (or ethics review) to take place. To create these conditions, their activities include:

- Establishing internationally recognised standards, codes, declarations and other soft-law instruments to support ethics assessment,
- Building capacity for regional ethics assessment,
- Providing forums for international collaboration, dialogue and reflection, and
- Advising governments.

The creation process of internationally recognised soft-law and legal provisions addressing ethics assessment takes various forms. The most prominent role of global-level governmental and government-funded controlled organisations and institutions is to **create global platforms** where discussion of current and relevant ethics principles and concerns can take place, involving all parties with vested interests. This often leads to the production of international benchmark documents, for example, the 2005 UNESCO Universal Declaration on Bioethics and Human Rights. Revisions of benchmark documents also take place e.g., UNESCO is currently in the process of revising its 1974 Recommendation on the Status of Scientific Researchers. As another example, the World Health Organization (WHO) engages in ethics assessment in various capacities. It helps set standards and norms, oversees the ethical review of research being conducted, and helps build capacity. Notably, it also has a process for ethics committee accreditation.

Alongside the above-mentioned developments, there has been an accompanying **rise in collaborative efforts between ethics committees from different regions**. The "Global

[26] Rangi, Sudeep, & Siya Bhatt, "Ethics assessment and guidance at the global level", SATORI, June 2015. http://satoriproject.eu/media/5.b-EA-and-Guidance-at-the-Global-level.pdf

Summit of National Ethics/Bioethics Committees", a biennial forum for national bioethics representatives to share information and experiences on ethical issues in health and public health,[27] is a good example of such efforts.

Another key policy development related to ethics of R&I at the global level that is noteworthy is the 2016 revision of the CIOMS (Council for International Organisations of Medical Sciences) international guidelines for health-related research involving humans.[28] They are a good example of guidelines including ethics assessment in their process. Other examples include: the adoption of the Brussels Declaration on ethics and principles for science and society policy-making in 2017 during a symposium at the American Association for the Advancement of Science's Annual Meeting,[29] and the launch of a new standards project, IEEE P7000, which will "define a process model by which engineers and technologists can address ethical consideration throughout the various stages of system initiation, analysis and design".[30]

On the other hand, our review shows one revised version of a code and one new code do not include any reference to 'ethics assessment' or 'ethical impact assessment', i.e.,

- The revised edition of the European Code of Conduct for Research Integrity,[31] (published by the European Federation of Academies of Sciences and Humanities) - a document that serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings.
- The Global Chemists' stakeholders Code of Ethics (GCCE),[32] guided by The Hague Ethical Guidelines and the Code of Conduct Toolkit collaboratively drafted in April 2016 at a collaborative workshop (with 30 scientists from 18 countries) organised by ACS International Activities.

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

The administration of the UN Global Compact[33], the administration of the OECD Guidelines for Multinational Enterprises would be relevant policy-makers to contact along with the UNESCO ABC programme and the European Commission to inform them of the main results of the SATORI project, specifically, the SATORI CEN Workshop Agreement and the SATORI Roadmap.

[27] http://www.who.int/ethics/partnerships/globalsummit/en/
[28] http://www.cioms.ch/index.php/12-newsflash/400-cioms-inernational-ethical-guidelines
[29] https://www.knaw.nl/nl/actueel/nieuws/BrusselsDeclaration.pdf
[30] IEEE project, P7000 - Model Process for Addressing Ethical Concerns During System Design. https://standards.ieee.org/develop/project/7000.html
[31] ALLEA, The European Code of Conduct for Research Integrity, revised edition, 2017. http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf
[32] https://www.acs.org/content/acs/en/global/international/regional/eventsglobal/global-chemists-code-of-ethics.html
[33] The UN Global Compact is a purely voluntary initiative that aims to help companies "Do business responsibly by aligning their strategies and operations with Ten Principles on human rights, labour, environment and anti-corruption; and Take strategic actions to advance broader societal goals, such as the UN Sustainable Development Goals, with an emphasis on collaboration and innovation". See https://www.unglobalcompact.org/what-is-gc/mission

One beneficial step might be to contact associations representing industry, beginning with pharmaceutical companies as they are already familiar with ethics assessment. More specifically, SATORI could engage with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) at the global level, and the European Federation of Pharmaceutical Industries and Associations (EFPIA) at the European level.

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

Today, though policies and soft-laws in ethics do exist at the global level, ethics assessment takes place to a large extent at the regional and national levels. One notable exception is research projects funded by the WHO which are being assessed at the global level.

The global dialogue provides the backdrop in which ethics assessment practices occur. International guidelines are frequently cited by regional-level organisations, such as ethics review committees, and by national level agencies such as the U.S. Food and Drug Administration (FDA), and even by EU Directives.

While global standards may exist, their implementation varies across countries. The different priorities of regional actors mean differential commitments to international ethics standards. For example, the U.S. FDA no longer cites the current WMA Declaration of Helsinki as a reference point to the use of placebos in clinical trials. Instead, it refers to a prior revision (the 1996 version adopted at its fourth revision).

There are also practical barriers. The Council on Health Research for Development (COHRED) and European & Developing Countries Clinical Trials Partnership (EDCTP) both identify lack of capacities to perform ethics reviews due to local deficiencies and practical barriers to international ethics assessment compliance.[34]

Efforts to harmonise ethics assessment across across the world (or the EU) need to consider the significant differences in institutions, values, legal frameworks, and cultural practices that exist between different regions and countries. These differences do not automatically imply that no harmonisation is possible, but they may imply that not every element of ethics assessment can be harmonised, and that there should be flexibility in the formulation and interpretation of international standards. This is something that has informed, inspired and underpinned the development of the SATORI ethics assessment framework – the framework has been presented in way that can be generalisable across disciplines, countries and institutions and thus, it could be a good model for wider application even at the global-level.

6. Policy developments impacting ethics assessment of R&I at the EU-level

This section outlines the key EU-level policy developments between 2014-2017 that impact ethics of R&I. It determines if new policy initiatives are adopting ethics assessment or ethical impact assessment as part of their policy development process; it identifies the key policy activities, developments, and initiatives where it may be appropriate for the SATORI consortium to intervene by making their views known to policy-makers; and shows which areas

[34] Rangi, op. cit., 2015.

(fields, sectors, or topics) there is a utility to introduce the SATORI ethics assessment framework.

This section was prepared based on data sourced from SATORI WP1 EU-level report[35], Task 9.1 policy developments monitoring data, institutional sources (a scan of EU institutional websites including publications, news, events, and other relevant pages). This section adds to the previous research in SATORI connected to ethics policy[36].

Key policy developments in ethics of R&I at the EU-level

There have been many significant developments in ethics of R&I at the EU-level in key EU institutions and bodies during the period 2014-2017. This section covers these under the various policy organisational clusters.

European Commission

The European Commission is a key player driving research and ethics assessment policies in the EU. Its policy activities, in this regard, include:

- **proposals for regulations** and regulatory amendments (e.g., proposal for new e-Privacy Regulation[37]; proposal to modernise EU copyright rules[38])
- **issue and publication of Communications**[39]
- **adoption of bilateral agreements** (e.g., EU-U.S. Privacy Shield to protect the rights of those in the EU whose personal data is transferred to the United States[40])
- **public stakeholder consultations** (e.g., interim evaluation of Horizon 2020[41]);
- **Commission decisions** (e.g., EU 2016/835 of 25 May 2016 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies – EGE [42])

[35] Shelley-Egan, Clare & Rowena Rodrigues, "Ethics Assessment and Guidance at the European Union Level", Annex 5.a, *Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries*, Deliverable 1.1, SATORI, June 2015. http://satoriproject.eu/media/5.a-EA-and-Guidance-at-the-EU-level.pdf

[36] e.g., that conducted in SATORI Work Package 3 Legal aspects and impacts of globalization. See http://satoriproject.eu/work_packages/legal-aspects-and-impacts-of-globalization/

[37] See https://ec.europa.eu/digital-single-market/en/news/proposal-regulation-privacy-and-electronic-communications

[38] http://europa.eu/rapid/press-release_IP-16-3010_en.htm

[39] European Commission, Communication on Building a European Data Economy, 2017. https://ec.europa.eu/digital-single-market/en/news/communication-building-european-data-economy; European Commission, Commission Communication on Next steps for a sustainable European future, 2016. http://ec.europa.eu/europeaid/commission-communication-next-steps-sustainable-european-future_en

[40] http://ec.europa.eu/justice/data-protecti on/article-29/press-material/press-release/art29_press_material/2016/20160726_wp29_wp_statement_eu_us_privacy_shield_en.pdf

[41] http://ec.europa.eu/research/consultations/interim_h2020_2016/consultation_en.htm. The aim was to help improve the implementation of Horizon 2020 and set the scene for the future discussions on the next EU research and innovation funding post-2020).

[42] *OJ L* 140, 27.5.2016, p. 21–25. The EGE acts as a key reference point for the 28 National Ethics Councils in the EU and further afield within the international ethics framework)

- **organisation of events** (e.g., conference on the role of research in addressing radical ideologies and violent extremism Brussels, 26 September 2016 marking the completion of a policy review on the topic[43])
- **commissioning of research** on topics such as ethics, research integrity, data protection, responsible R&I[44]
- **expert group/committee reports**[45]
- **Opinions**[46]
- **scientific and technical research reports**[47], etc.

As one expert in philosophy of science and technology highlights, there has been a movement in EU policy from focussing on "responsible research and innovation or RRI" to Open Innovation, Open Science and Open to the World.[48] The three Os vision for Europe was first discussed by Commissioner Moedas in a speech in June 2015[49] and covered in the book *Open Innovation, Open Science, Open to the World - a vision for Europe*[50].

EU Parliament

There are several examples of the European Parliament's engagement with ethics of R&I since 2014. The European Parliament has debated and voted on draft legislation e.g., clinical trials: clearer rules, better protection for patients[51]. There has been a call by its Legal Affairs Committee for EU-wide rules to fully exploit the economic potential of robotics and artificial

[43] http://ec.europa.eu/research/conferences/2016/addressing_extremism/index.cfm

[44] See for example the Horizon 2020 Work Programme 2016-2017 (http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-work-programmes-2016-17) which highlights the need to strengthen research integrity for policy-makers, research funders, research institutions and researchers (p1); protection of fundamental right to data protection" (p 9), promotion of Responsible Research and Innovation (RRI) as a cross-cutting issue. The Horizon 2020 Work Programme 2014-2015 stated "Horizon 2020 funded activities will support the relationships between science and society through the promotion of Responsible Research and Innovation (RRI) as a crosscutting issue and through part 16 of the Work Programme, 'Science with and for society'. http://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/main/h2020-wp1415-intro_en.pdf, p. 17

[45] E.g., European Economic and Social Committee, "The ethics of Big Data: Balancing economic benefits and ethical questions of Big Data in the EU policy context, Study, 2017. http://www.eesc.europa.eu/resources/docs/qe-02-17-159-en-n.pdf; European Commission Directorate-General for Research and Innovation, *Report from the Expert Group on policy indicators for responsible research and innovation, Indicators for promoting and monitoring responsible research and innovation,* 2015. http://ec.europa.eu/research/swafs/pdf/pub_rri/rri_indicators_final_version.pdf

[46] E.g., Opinion No. 29 of the European Group on Ethics in Science and New Technologies (EGE), *Ethics of New Health Technologies and Citizen Participation, 2015.* https://ec.europa.eu/research/ege/pdf/opinion-29_ege.pdf#view=fit&pagemode=none; Opinion No. 28 of the European Group on Ethics in Science and New Technologies (EGE), *Ethics of Security and Surveillance Technologies,* 2014. http://bookshop.europa.eu/en/ethics-of-security-and-surveillance-technologies-pbNJAJ14028/

[47] Boucher, Philip, Susana, Figueiredo Do Nascimento, Lucia Vesnic Alujevic, Angela Martinho Guimaraes Pires Pereira, *Ethics dialogues: Experiencing ethics through 'things': open IoT, civil drones and wearable sensors,* Publications Office of the European Union, Luxembourg, 2014.

[48] Rip, Arie, "The many lives of responsible research and innovation", *Euroscientist,* 14 December 2016. http://www.euroscientist.com/rri-fashion/

[49] Moedas, Carlos, Commissioner for Research, Science and Innovation, European Commission, "Open Innovation, Open Science, Open to the World", Speech, 22 June 2015. http://europa.eu/rapid/press-release_SPEECH-15-5243_en.htm

[50] European Commission, Directorate-General for Research and Innovation, *Open innovation, open science, open to the world, A vision for Europe, Publications office of the European Union*, Luxembourg, 2016.

[51] http://www.europarl.europa.eu/news/en/news-room/20140121IPR33307/clinical-trials-clearer-rules-better-protection-for-patients

intelligence and to guarantee a standard level of safety and security and a request to create a European agency for robotics and artificial intelligence to supply public authorities with technical, ethical, and regulatory expertise.[52] The European Parliament has also raised questions about ethical considerations relating to EU funding for research[53], e.g., on algorithmic accountability and transparency in Europe's digital economy framework[54]. Parliament has carried out public consultations e.g., on the future of robotics and artificial intelligence (February 2017-April 2017)[55].

STOA is the EU Parliament's *Science and Technology Options Assessment* unit. STOA provides policy advice to decision-making bodies concerning the impact of science and technology on EU policy.[56] STOA projects aim to provide scientific evidence to underpin policy decisions, based upon a state-of-the-art overview of cross-cutting topics that have a scientific, technological and ethical dimensions such as mass surveillance of citizens, teaching and learning technologies, e-government, smart energy grids and eco-efficient transport.[57] STOA studies and options briefs cover aspects such as: collaborative economic, scientific foresight, mass surveillance risks, robot safety, ethical aspects of cyber-physical systems etc. STOA events have focused on topics related to ethics assessment of R&I such as (most recent first):

- The future of science through citizens' engagement (2017)[58]
- Ethical and social challenges of agricultural technologies - issues for decision-makers (2017) [59]
- Language equality in the digital age towards a Human Language Project (2017)[60]
- Understanding the human brain - a new era of big neuroscience (2016) [61]
- Science meets Parliaments (2016)[62]
- Improving outcomes for critically ill children: innovation and research translated to save lives (2016)[63]
- Waste management – a key player in the transition to a circular economy (2016)[64]
- Adapting to the changing world through science, technology and innovation (2016)[65]
- The gender dimension of technology and science (2016)[66]
- STOA Working Breakfast - A European Approach to Human Enhancement (2016)[67]
- Responsible governance of science and technologies (2014)[68].

[52] http://www.europarl.europa.eu/news/en/news-room/20170110IPR57613/robots-legal-affairs-committee-calls-for-eu-wide-rules
[53] http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2015-002405&format=XML&language=EN
[54] Jaakonsaari, Liisa, "Who sets the agenda on algorithmic accountability?", *Euractiv,* 26 October 2016. https://www.euractiv.com/section/digital/opinion/who-sets-the-agenda-on-algorithmic-accountability/
[55] http://www.europarl.europa.eu/committees/en/juri/public-consultation-robotics-introduction.html
[56] http://www.europarl.europa.eu/stoa/cms/home/about
[57] http://www.europarl.europa.eu/stoa/cms/home/panel/projects
[58] http://www.europarl.europa.eu/stoa/cms/home/workshops/engagement
[59] http://www.europarl.europa.eu/stoa/cms/home/workshops/ethical
[60] http://www.europarl.europa.eu/stoa/cms/home/workshops/language
[61] http://www.europarl.europa.eu/stoa/cms/home/workshops/neuroscience2016
[62] http://www.europarl.europa.eu/stoa/cms/home/workshops/sciencemeets2016
[63] http://www.europarl.europa.eu/stoa/cms/home/workshops/pediatric
[64] http://www.europarl.europa.eu/stoa/cms/home/workshops/waste
[65] http://www.europarl.europa.eu/stoa/cms/home/workshops/sts2016
[66] http://www.europarl.europa.eu/stoa/cms/home/workshops/genport
[67] http://www.europarl.europa.eu/stoa/cms/home/workshops/enhancement2016
[68] http://www.europarl.europa.eu/stoa/cms/home/workshops/responsible

Council of Europe

The Council of Europe is also a significant policy player in the ethics of R&I. The Council's Committee on Bioethics (DH-BIO) is responsible for the tasks assigned by the Convention on Human Rights and Biomedicine and for the intergovernmental work on the protection of human rights in the field of biomedicine.[69] The Council's activities over the monitored period include: adoption of Recommendations[70], Statements[71], commissioning and publication of studies on topics with ethical impacts[72], public consultations[73], seminars/training activities related to bioethics, gender mainstreaming activities[74], events on topics such as emerging technologies and human rights[75], etc. The Council also has a Platform on Ethics, Transparency and Integrity in Education.[76]

Other significant developments at the EU-level include: adoption of the Brussels Declaration Towards Ethics & Principles of Science-Policy Making[77], finalisation of the Code of conduct on privacy for mobile health apps, provision of open access by the European Medicines Agency (EMA) to clinical reports for new medicines for human use authorised in the EU[78], ALLEA (the European Federation of Academies of Sciences and Humanities) Working Group Science & Ethics Meeting: revision of the ALLEA Code of Conduct (December 2016)[79]; European Data Protection Supervisor (EDPS) making known views on innovation, ethical assessment and encouraging long term ethical analysis and prospective thinking towards technological innovation[80]; publication of Science Europe guide to improve gender equality in research organisations to facilitate mutual learning between Science Europe member organisations[81].

[69] https://www.coe.int/en/web/bioethics/dh-bio

[70] Recommendation CM/Rec(2016)8 on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests was adopted by the Committee of Ministers (26 October 2016); Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin.

[71] DH-BIO adopted a Statement on Genome Editing Technologies during its 8th meeting in Strasbourg (2 December 2015); The Ministers' Deputies adopted on 9 July 2014 the Statement by the Committee of Ministers on the prohibition of any form of commercialisation of human organs.

[72] DH-BIO published a study on the challenges posed to the rights of the child by scientific and technological developments in biomedicine. The study will be used to analyse existing international legal instruments, assess their relevance to address challenges, and where appropriate, define further action at IGO level. https://www.coe.int/en/web/bioethics/-/study-on-the-rights-of-children-in-biomedici-1

[73] E.g., the 2015 public consultation on a working document on the protection of human rights and dignity of persons with mental disorder with regard to involuntary placement and involuntary treatment. https://www.coe.int/en/web/bioethics/-/public-consultation-on-a-working-document

[74] Council of Europe Gender Equality Unit, *Gender mainstreaming activities at the Council of Europe,* 5th Edition, March 2017. https://rm.coe.int/16806b6c87. See also the Council of Europe's Gender Equality Glossary (2016) and the Gender Equality and Women's Rights - Council of Europe Key Standards (2015).

[75] http://www.coe.int/t/dg3/healthbioethic/Conferences_and_symposia/Photos.pdf

[76] http://www.coe.int/en/web/ethics-transparency-integrity-in-education/publications

[77] http://www.euroscientist.com/wp-content/uploads/2017/02/Brussels-Declaration.pdf

[78] http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fnews_and_events%2Fnews%2F2016%2F10%2Fnews_detail_002624.jsp&mid=WC0b01ac058004d5c1

[79] http://www.allea.org/events/allea-working-group-meeting-3/

[80] https://secure.edps.europa.eu/EDPSWEB/edps/site/mySite/An_ethical_approach_to_fundamental_rights

[81] http://www.scienceeurope.org/wp-content/uploads/2017/01/SE_Gender_Practical-Guide.pdf

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

The EU has a wide range of policy activity on a diverse range of topics from human rights to transport and trade.[82] The one most relevant to us is Horizon 2020 – the EU Framework Programme for Research & Innovation. In Horizon 2020, ethics self-assessment is part of a project's grant agreement, and may give rise to binding obligations[83] that can be evaluated through ethics checks, reviews and audits. Researchers are actively encouraged to consider ethics issues that arise in their areas of research and to start thinking about ethics while designing research protocols".[84] Where research can have a potential impact on human rights (e.g., research on surveillance technologies, new data-gathering and data-merging technologies, social or genetic research that could lead to discrimination or stigmatisation), a human rights impact assessment is recommended as a risk mitigation measure. However, there is no mention of 'ethical impact assessment'.[85]

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

This section identifies some key policy developments and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers.

Open Innovation 2.0

The European Commission states "Open Innovation is an important component of the foreseen European Innovation System, where all stakeholders need to be involved and create seamless interaction and mash-up for ideas in innovation ecosystems[86]". It sees five key elements in the new Open Innovation process: networking; collaboration (involving partners, competitors, universities, and users); corporate entrepreneurship (enhancing corporate venturing, start-ups and spin-offs); proactive intellectual property management (creating new markets for technology); and research and development (R&D) (achieving competitive advantages in the market).[87] The SATORI consortium could interact with, and/or make its views known to the

[82] https://europa.eu/european-union/topics_en

[83] See Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC. It states that research and innovation activities supported by Horizon 2020 should respect fundamental ethical principles and should take into account: the opinions of the European Group on Ethics in Science and New Technologies, Article 13 TFEU, the use of animals in research and testing should be reduced, with a view ultimately to replacing their use. All activities should be carried out ensuring a high level of human health protection in accordance with Article 168 TFEU. It further states that Horizon 2020 should have due consideration for equal treatment and non-discrimination in research and innovation content throughout all stages of the research cycle. Relevant articles include Article 14 (mentions responsible research and innovation); Article 19 deals with ethical principles; Article 16 (gender equality) and Article 18 (open access).

[84] European Commission Directorate-General for Research & Innovation, *H2020 Programme Guidance How to complete your ethics self-assessment*, Version 5.2 12 July 2016. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

[85] Ibid.

[86] Referencing Chesbrough, Henry, *Open Innovation: The New Imperative for Creating and Profiting from Technology,* 2003, and Center for Open Innovation, Berkeley University. http://www.openinnovation.net/Book/NewImperative/

[87] European Commission, "Open Innovation 2.0". https://ec.europa.eu/digital-single-market/en/open-innovation-20

Open Innovation Strategy and Policy Group (OISPG).[88]This could have two benefits: dissemination of the SATORI Framework to a wider audience, and greater support for ethics assessment in the Open Innovation approach.

European Open Science Agenda

The draft *European Open Science Agenda* lists various policy actions – i.e., foster open science, remove barriers, develop research infrastructures for open science, main stream open access to research results, and embed open science in society.[89] Open science has its benefits. However, as pointed out by the RECODE project, it raises some ethical concerns e.g., unintended secondary uses and misappropriation, dual use, violations of privacy and confidentiality, unequal distribution of research results, commercialisation, restriction of scientific freedom[90]. The implementation of the Open Science agenda presents another opportunity for the results of SATORI to be applied.

Areas (fields, sectors, or topics) where there is a utility to introduce the SATORI ethics assessment framework

The SATORI recommendations for ethics committees can be used in areas where ethics committees are less developed but ethical challenges are emerging (e.g., social science and the humanities). There is a large segment of researchers and innovators who operate on the fringes of ethics e.g., many SMEs engage in R&I activities regularly but do not have ethics committees and have little knowledge of what constitutes good practice in setting one up. There is also a need for ethics committees that are well-versed in the ethics of cross-border R&I activities and can make good assessments of such activities.

The SATORI ethical impact assessment could be useful in a wider variety of EU R&I areas that touch upon ethical issues e.g., future and emerging technologies, European research infrastructures, information and communication technologies, nanotech, advanced materials, manufacturing and processing, biotech, space, innovation in small and medium-sized enterprises, health, demographic change and wellbeing, food security, agriculture and forestry, marine and maritime and inland water research, secure, clean and efficient energy, smart, green and integrated transport, climate action, environment, resource efficiency and raw materials, inclusive, innovative and reflective societies, secure societies and science with and for society.[91]

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

There are some potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework at the EU-level. Some of these are common, while others are more specific to the different parts of the framework.

[88] https://ec.europa.eu/digital-single-market/en/open-innovation-strategy-and-policy-group
[89] http://ec.europa.eu/research/openscience/pdf/draft_european_open_science_agenda.pdf - view=fit&pagemode=none
[90] Finn, Rachel, Kush Wadhwa, Mark Taylor, Thordis Sveinsdottir, Merel Noorman, and Jeroen Sondervan, *Legal and ethical issues in open access and data dissemination and preservation*, Deliverable D3.1, 2014. http://recodeproject.eu/wp-content/uploads/2014/05/D3.1-legal-and-ethical-issues-FINAL.pdf
[91] SATORI Policy brief, *Ethical Impact Assessment,* 2017.

One of the common challenges is improving the visibility of the framework through linguistic translations. Currently, the framework is only available in English but the EU has 24 official and working languages.[92] It would be extremely useful and imperative for its wider acceptability that the Commission promotes the translation of the framework into its working languages. Another challenge will be finding the political will to support the use and implementation of the framework. Financial costs might also have a bearing. There might be political challenges to any mandatory, top down prescriptions of the framework. Other specific challenges or barriers include:

- In relation to SATORI ethics committee guidance: shortage of resources; national and local differences; scope of ethics assessment activities and limited mandates; support from policy actors.
- In relation to SATORI ethical impact assessment (EIA): infantile and ad hoc nature of EIAs in R&I; lack of institutional support and positive attitudes to EIAs; ineffective implementation of EIA recommendations; lack of sharing ('closed doors') of ethical impact assessment good practice.

7. Major policy developments at the national level

The SATORI report *Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries* (2015)[93], inter alia comprised an analysis of ethics assessment structures and agents in both the public and private sectors in 11 countries, namely eight European Union countries and one candidate for membership (Serbia), the United States and China. Each country was studied in detail regarding the organisational structures, laws, policies and procedures established for ethical assessment; the ways in which publicly funded and private R&I systems address ethical issues in R&I; and the role ethical assessment plays in the activities of professional groups and associations for R&I and civil society organisations.

The SATORI country reports included basic information about the country's research and development landscape, and the historical development of ethics assessment institutions in the country. The aim of the analysis was to compare the ethics assessment infrastructure in the respective countries, to understand those structures and agents that comprise the ethics assessment landscape, in addition to their funding and scope. Some key conclusions of the SATORI country analyses were:

- Countries are currently expanding ethics assessment and guidance infrastructure.
- The expansion of ethics assessment in non-medical areas is especially noteworthy.
- Greater efforts are being made to address ethical issues by governments, universities, research funding organisations, civil society organisations, and industry.
- There are significant differences in the extent to which ethics of R&I is institutionalised, ranging from limited (e.g., China, Poland, Serbia) to extensive (e.g., Austria, Germany, Netherlands).

[92] http://ec.europa.eu/education/official-languages-eu-0_en

[93] Shelley-Egan, Clare, Philip Brey, Rowena Rodrigues, David Douglas, Agata Gurzawska, Lise Bitsch, David Wright & Kush Wadhwa, *SATORI Deliverable D1.1 Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries*, June 2015.

- There are national differences in the types of ethical principles and R&I issues that receive attention.
- The role of government in ethics assessment and guidance is different, ranging from strong (China) to little (US) regulation.
- Governments stimulate corporate social responsibility (CSR) for industry to different degrees and with different means**.**
- The role of civil society organisations in government policy, representation in ethics assessment panels and committees, and in conducting ethics assessment varies considerably.[94]

This section covers major policy developments for the period 2014-2017 at the national and local levels in the following countries: Austria, Finland, France, Germany, Italy, the Netherlands, Poland, Russia, the UK, and the USA. Most of these countries featured in the SATORI inventory of ethics assessment practices except for Italy and Russia (which represents an added value). These countries represent a sampling of different levels of R&I ethics assessment practices, technological development and geography, and which SATORI could effectively monitor with allocated resources during the work carried out in work package 9. These are also the countries where there is significant opportunity to promote the SATORI framework, as the following analysis will show. Each country analysis covers the following key questions:

- What are the key policy developments in ethics of R&I?
- Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?
- What are the key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers?
- In which areas (fields, sectors or topics) is there a utility to introduce the SATORI ethics assessment framework?
- What are the potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework?

7.1. Austria

This subsection outlines some of the key policy developments (2014-2017) that impact the ethics of R&I in Austria. It was developed based on sources such as institutional and government websites, publications, news, events and other relevant pages (as mentioned below).

Key policy developments in ethics of R&I

This section highlights the key policy developments in the ethics of R&I in Austria for the period 2014-2017. It first introduces the overall governmental approach towards ethics in R&I as it manifests in two important strategic documents, the government's innovation strategy and the strategy of the Austrian Council. The section continues with the developments of important actors in R&I.

[94] Ibid.

Overall governmental approach towards ethics

Both, the Austrian government[95] and the Austrian Council[96] (an advisory body to the government) in their respective R&I strategies highlight the issue of ethics and demand high standards in this respect.

Federal Ministry of Science, Research and Economy (BMWFW)

In 2015, the BMWFW initiated an "Alliance for Responsible Science".[97] Several organisations[98] joined on 17 June 2015. The Alliance describes 'Responsible Science' – an alternative term used for 'responsible research and innovation (RRI) to emphasise the teaching aspect of RRI, as well as an important concept for institutions to act in a future-oriented way[99]. The Alliance's partners declare that they will start a shared communication and development process to strengthen, reflect upon and develop 'Responsible Science' in research, teaching and societal engagement. The Science Ministry on its part will support these activities by initiating and funding a competence network for Responsible Science. In its memorandum of understanding, the partners seek:

- To create spaces in academia and wider society for meeting, interacting and getting into dialogue to inspire science and the arts by various systemic and societal perspectives;
- To translate societal challenges and guiding principles into scientific and scientific/artistic projects and institutional strategies, concepts or project;
- To operationalise the concept of "societal relevance" (and to develop a "societal impact factor");
- To encourage researchers to overcome disciplinary and institutional barriers, to fathom boundary areas of research and take uncharted routes in research;
- To create opportunities for researchers to combine societal engagement, research and teaching;
- To create lasting partnerships between research organisation to exploit strategic and financial synergies;
- To strengthen excellent research and teaching by inter-and transdisciplinary approaches in Responsible Science;
- To reflect upon and integrate relevant concepts such as citizen science, crowd sourcing and open innovation;
- To disseminate the results from research and arts to politics, public administration, economy, media and civil society.[100]

[95] Bundeskanzleramt, Bundesministerium für Finanzen, Bundesministerium für Unterricht, Kunst und Kultur, Bundesministerium für Verkehr, Innovation und Technologie, Bundesministerium für Wirtschaft, Familie und Jugend, Bundesministerium für Wissenschaft und Forschung (2011): Der Weg zum Innovation Leader. Strategie der Bundesregierung für Forschung, Technologie und Innovation. Wien.
[96] Austrian Council, Strategie 2020, Vienna, 2009.
[97] BMWFW, Memorandum of Understanding der Initiative Mit der Gesellschaft im Dialog Responsible Science (Allianz für Responsible Science), Wien, 2015.
https://www.fwf.ac.at/fileadmin/files/Dokumente/News_Presse/News/MoU_Responsible-Science.pdf
[98] The first signees are BMWFW, Universities Austria, Association of Universities of Applied Sciences, Austrian Academy of Science, Ludwig Boltzmann Society, FWF, Austrian Institute of Technology, Museum of Natural History Vienna, OeAD, INNOC – Austrian Society for Innovative Computer Sciences, Federal Institute for Education of Blind Persons, Red Cross Austria, naturschutzbund.
[99] BMWFW, op. cit., 2015.
[100] BMWFW, op. cit., 2015.

Austrian Science Fund (FWF)

The FWF is the main funding body for basic research in Austria. According to its mission statement the FWF "is dedicated to ensuring that the rules of scientific practice and internationally accepted ethical standards are observed within the fund's sphere of influence".[101] Procedures for grant applicants include ethics. Applicants must declare whether and how their project might raise ethical issues, and how these will be addressed in the project. The FWF considers ethics as an additional soft criterion in the evaluation process, the main hard criterion being scientific excellence. The FWF does not have its own ethics assessment unit but relies on clearance from the body that is responsible within the applicant's own institution. Recent developments at the FWF between 2014-2017 include: launch of pilot programme on open research data (2016-17)[102], Guidelines for the prevention of corruption (July 2016), report on Austrian Science Fund (FWF) Open Access Compliance Monitoring 2015 (June 2016)[103], Science Europe High Level Workshop (13 April 2015)[104], and an event on AM PULS Nr. 39 "BIG Data - Chancen & Risiken (Social) Media als Quelle smarter Information?" (29 April 2014)[105].

Austrian Bioethics Committee (ABC)

The ABC is an expert advisory body for policy making at the federal level. It was established in 2001 and advises the Federal Chancellor on policies concerning ethical issues in biomedicine. Between 2014 and 2017, the ABC has published opinions on the reform of the reproductive medicine law[106], end of life[107], ethical aspects of vaccination[108], and participative medicine[109]. It has organised public sessions on robotics and care, economy and medicine, end of life decisions and vaccination. In addition to these issues, it has discussed in its internal meetings topics such as trans- and intersexuality, and genome editing/CRISPR-Cas9.

Bottom-up initiatives

Recently, there have been many bottom-up initiatives concerning ethics in universities and non-university organisations. These are relevant as they have the potential to feed into policy.

[101] https://www.fwf.ac.at/en/about-the-fwf/corporate-policy/
[102] https://www.fwf.ac.at/en/news-and-media-relations/news/detail/nid/20170313-2233/
[103] https://zenodo.org/record/55249 - .WVJk-MaZPq0
[104] https://www.fwf.ac.at/en/news-and-media-relations/past-events/detail/eventreview/science-europe-high-level-workshop-2015/eventpid/921/back/256/
[105] https://www.fwf.ac.at/en/news-and-media-relations/past-events/detail/eventreview/am-puls-nr-39-big-data-chancen-risiken-social-media-als-quelle-smarter-information/eventpid/921/back/256/ - undefined
[106] Geschäftsstelle der Bioethikkommission, Fortpflanzungsmedizinrechts-Änderungsgesetz 2015 – FMedRÄG 2015 Stellungnahme der Bioethikkommission beim Bundeskanzleramt zum Entwurf eines Bundesgesetzes, mit dem das Fortpflanzungsmedizingesetz, das Allgemeine bürgerliche Gesetzbuch und das Gentechnikgesetz geändert werden (Fortpflanzungsmedizinrechts-Änderungsgesetz 2015 – FMedRÄG 2015). http://archiv.bundeskanzleramt.at/DocView.axd?CobId=57878
[107] Geschäftsstelle der Bioethikkommission, Sterben in Würde. Empfehlungen zur Begleitung und Betreuung von Menschen am Lebensende und damit verbundenen Fragestellungen, Stellungnahme der Bioethikkommission vom 9 February 2015. http://archiv.bundeskanzleramt.at/DocView.axd?CobId=58509
[108] Geschäftsstelle der Bioethikkommission, Impfen – ethische Aspekte. Stellungnahme der Bioethikkommission vom 1. Juni 2015. http://archiv.bundeskanzleramt.at/DocView.axd?CobId=59751
[109] Geschäftsstelle der Bioethikkommission, Partizipative Medizin und Internet, 2015. http://archiv.bundeskanzleramt.at/DocView.axd?CobId=60026

- Several non-university research institutes and a few universities initiated the RRI Platform Austria[110] which organised in December 2016 a symposium on "Ethics in Research Practice."[111]
- In April 2015, the Institute for Molecular Biotechnology (IMBA) organised its first Bioethics Symposium, which addressed, specifically, the ethical challenges of research on organoids.[112]

Research projects promoting ethics

Research projects funded by the European Commission within H2020 are important conveyer belts to promote the idea of ethics assessment and RRI in Austria to research-performing and research-funding organisations and policy-makers. They connect Austrian researchers with their European and global peers and thus contribute innovative and state of the art ideas about ethics, ethics assessment and RRI in the Austrian research and innovation (funding) landscape. Since 2012, e.g., the Institute for Advanced Studies (IHS) is involved in several projects on Responsible Research and Innovation (RRI) which also address ethics.

- The "Responsible Research and Innovation in a Distributed Anticipatory Governance Frame. A Constructive Socio-normative Approach" (Res-AGoRA[113]) project developed a web application for monitoring and visualising data and information on RRI in 16 European countries. This application also provides information about how the issue of ethics is approached in Austria on general RRI policies, in research councils, private research foundations, universities, private companies and civil society organisations.[114]
- The "Integrating RRI in Higher Education Institutions" (HEIRRI)[115]project aims to develop RRI curricula for which will be piloted at two Austrian Higher Education Institutions.
- The "European Network of Research Ethics and Research Integrity" (ENERI) project establishes an operable platform of actors in the fields of research ethics and research integrity.[116]

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

The above study shows that 'responsible science' in research, teaching and societal engagement is a key thrust. Given this, it is possible that universities and non-university research organisations that so far don't have ethics assessment units, will establish new ones or be motivated to adopt improved ethics assessment practices and create processes for ethical impact assessment.

[110] https://www.rri-platform.at
[111] https://www.rri-plattform.at/wp-content/uploads/2016/11/Ethik-in-der Forschungspraxis_12.12.16_Programm.pdf
[112] https://www.rri-plattform.at/wp-content/uploads/2016/11/Ethik-in-der-Forschungspraxis_12.12.16_Programm.pdf
[113] http://res-agora.eu/news/
[114] https://rritrends.res-agora.eu/reports/custom/#/
[115] http://heirri.eu/
[116] http://eneri.eu/

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

To create a greater impact, it might be appropriate to address the following institutions[117] and inform them about SATORI and its outcomes:

- The Austrian Bioethics Committee[118] (a previous SATORI partner). The ABC might be interested in the ethics committee recommendations and process of ethics assessment.
- The Federal Ministry of Science, Research and Economy (BMWFW). It is within the Ministry's responsibility to negotiate mid-term service contracts with universities; ethics is one issue in this process.
- The Austrian Ministry for Transport, Innovation and Technology (BMVIT). The Ministry might be interested in the SATORI CWA because of its open innovation strategy.
- The two research funding agencies FFG and FWF. They could use the CWA as an input in their evaluation process.
- Individual universities and universities of applied science. Universities might be interested in the SATORI CWA to set up or develop ethics assessment committees or to carry out ethical impact assessments.
- Universities Austria[119]. The association of Austrian universities may be interested in the SATORI CWA as it provides guidance on how to set up an ethics committee and how to carry out ethical impact assessment.
- Forum Österreichischer Ethikkommissionen.[120] This is an association of Austrian medical ethics committees; they might be interested in the project results as an inspiration for their work.

Areas (fields, sectors, or topics) where there is a utility to introduce the SATORI ethics assessment framework

Some key areas in which there is a utility to introduce or leverage the SATORI ethics assessment framework might be those made explicit in the Alliance for Responsible Science Memorandum of Understanding i.e., citizen science, crowdsourcing and open innovation.

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

The following potential challenges or barriers exist for the uptake of the project results by Austrian institutions:

- One challenge is the narrow understanding of ethics that is limited to ethics in medical research and/or research integrity; ethics in this understanding does not cover broader societal impacts of research, technology and innovation.
- Often there is a lack of awareness of, or resistance to considering the ethical aspects of science, technology and innovation due to fears of a loss of academic freedom, business opportunities, and creation of excessive bureaucracy that might burden researchers.

[117] Includes non-policy actors to maximise uptake and impact.
[118] https://www.bka.gv.at/bioethikkommission.
[119] https://uniko.ac.at/index.php?lang=EN
[120] http://www.ethikkommissionen.at/

Frequently, there is a concern that "too much red tape" might overburden researchers and impede R&I. In addition, often scientific excellence is considered the sole criterion for research funding.

- Several institutions (e.g., universities, research funding organisations, and advisory bodies) have pre-established ethics committee procedures. Although the SATORI CWA might help improve these processes, there might be limited openness to change.
- Many ethics committees lack the resources for implementing a thorough and comprehensive approach (as proposed by the SATORI project). Most ethics committee members work in an honorary capacity i.e., in addition to their other academic or other professional duties, and ethics committees lack adequate staff for administrative support.
- A number of ethics committees emphasise pragmatism and service. They want to provide ethics clearance as quickly as possible and don't want to hinder research. The comprehensive approach recommended by the SATORI CWA may be considered too ambitious, and time consuming.
- In industry, there is a narrow understanding of ethics in research, technology and innovation i.e., as corporate social responsibility (CSR) and business ethics. This might conflict with the understanding of ethics promulgated in the SATORI CWA.

7.2. Finland

This section was prepared based on data sourced from institutional websites of several related actors including:

- Advisory Board on Biotechnology (BTNK)
- Board for Gene Technology (GTLK)
- Committee for Public Information in Finland (TJNK)
- Council of Finnish Academies (TANK)
- Finnish Advisory Board for Research Integrity (TENK)
- National Advisory Board on Social Welfare and Health Care Ethics (ETENE)
- National Committee on Medical Research Ethics (TUKIJA)
- The Cooperation Group for Laboratory Animal Sciences (KYTÖ)
- The Federation of Finnish Learned Societies (TSV)

The section adds to the previous research in SATORI connected to ethics policy.

Key policy developments in ethics of R&I

There have been some notable developments related to ethics of R&I in Finland during 2014-2017. These include amendments of legislation, issue of instructions and position statements, publication of guidelines and reports, and organisation of events.

- The Finnish Advisory Board on Research Integrity's guideline on responsible conduct of research and procedures for handling allegations of misconduct in Finland had a total of 75 committed signatories by the end of 2014, including universities, majority of universities of applied sciences, nearly all research institutes and additionally 11 other bodies.[121]

[121] http://www.tenk.fi/sites/tenk.fi/files/media/TENK_2014_su.pdf

- The Finnish Advisory Board on Research Integrity's guideline on ethical principles of research in the humanities and social and behavioural sciences and proposals for ethical review, had a total of 62 universities, universities of applied sciences and research institutes committed by the end of 2014.[122]
- An education working group consisting of representatives from Finnish universities and the Finnish Advisory Board on Research Integrity completed its instructions on research integrity education with the objective of reinforcing the position of research integrity education and increasing educational uniformity.[123]
- The Finnish Advisory Board on Research Integrity identified the coordination of education on research integrity at higher education institutions and research organisations as the most important task of the ending three-year term in 2014.[124]
- The Finnish Social Science Data Archive (FSD) published Data Management Guidelines in 2014.[125]
- The Gene Technology Act was amended in 2014.[126]
- The Finnish Advisory Board on Research Integrity and the Committee for Public Information initiated a joint two-year 'Information Sharing Creates Impact' project, focusing on issues related to responsible scientific communication and definition of authorship in 2015.[127]
- The Committee for Public Information in Finland published a survey report concerning harassment experienced by researchers in 2015.[128]
- The Finnish Social Science Data Archive's (FSD) revised its Data Management Guidelines and published them also in English in 2015.[129]
- The Finnish Advisory Board for Research Integrity published its action plan for 2016-2019 in 2016. Most important priorities listed include:
    - Promoting responsible conduct of research within research institutions by developing the process and working continuously to raise awareness of it
    - Formulating national recommendations concerning agreements on the authorship of scientific publications
    - Creating a network of advisory and support personnel within research integrity
    - Clarifying the position of whistle-blowers in cases of misconduct and, if necessary, creating a system of protection, and
    - Building an online "ethics library", in collaboration with the Committee for Public Information.[130]
- The Finnish Advisory Board on Research Integrity and Universities Finland (UNIFI) published research integrity recommendations for universities on dissertation supervision and review in 2016.[131]

[122] http://www.tenk.fi/sites/tenk.fi/files/media/TENK_2014_su.pdf
[123] http://www.tenk.fi/sites/tenk.fi/files/media/TENK_2014_su.pdf
[124] http://www.tenk.fi/sites/tenk.fi/files/media/TENK_2014_su.pdf
[125] http://www.tenk.fi/fi/node/95
[126] http://www.finlex.fi/fi/laki/alkup/2014/20140766; http://etene.fi/documents/1429646/1556041/Lausunto+geenitekniikkalain+muuttamista+koskevasta+hallituksen+esityksen+luonnoksesta.pdf/60caaa49-2ffe-4583-9947-df2697543af1
[127] http://www.tenk.fi/sites/tenk.fi/files/media/TENK_toimintakertomus_2015.pdf
[128] http://www.tjnk.fi/fi/tutkijoiden-kokema-häirintä-tjnkn-kyselyn-tulokset
[129] http://www.fsd.uta.fi/en/news/index.html - 2015; http://www.tenk.fi/fi/node/107
[130] http://www.tenk.fi/sites/tenk.fi/files/media/TENK_action_plan_2016_2018.pdf
[131] http://www.academies.fi/vaitoskirjaprosessin-tutkimuseettinen-suositus-on-julkaistu/; http://www.tenk.fi/fi/node/114

- The Finnish Advisory Board for Research Integrity organised a seminar for ethics councils on the challenges of ex-ante ethical evaluation of international research projects in 2016.[132]
- The Finnish Advisory Board for Research Integrity, commissioned by the Ministry of Education and Culture, prepared a report on promoting good scientific practice and strengthening of the science fraud control in 2016. The commissioning of the report was related to public attention to suspected science fraud.[133]
- The National Advisory Board on Social Welfare and Health Care Ethics issued a position statement on the ethical issues concerning experimental care in 2016.[134]
- The Act on genetic resources enforcing the Nagoya Protocol (also known as the ABS-Act) came into force in Finland in 2016.[135]
- The Finnish Advisory Board for Research Integrity invited organisations committed to the responsible conduct of research guidelines to discuss about support personnel system for research integrity and other current issues regarding good scientific practise process in 2017.[136]
- The Council of Finnish Academies and Finnish Advisory Board for Research Integrity organised a discussion seminar regarding the meaning of the European Federation of Academies of Sciences and Humanities' revised edition of the European Code of Conduct for Research Integrity for the science community in 2017.[137]
- The Committee for Public Information in Finland released for comments a draft recommendation on science communication: *Communicate boldly, influence responsibly*, in 2017.[138]
- The Council of Finnish Academies will host the 7th Human Rights and Science Symposium in 2017.[139]

Additionally,

- The Finnish Advisory Board on Research Integrity arranges an Ethics Day seminar annually. The themes of the seminar include: research and business cooperation, who owns research data, good and bad information, and science, ethics, politics – decision-making based on research data.[140]
- The National Committee on medical research ethics organises seminar of Medical Research Ethics and Ethics committees' national meeting annually.[141]

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

Based on the number of actors committed to ethical principles of research not only in medical field, but also in the humanities and social and behavioural sciences, and proposals for ethical review and responsible conduct of research and procedures for handling allegations of misconduct in Finland (see above), we can conclude that ethics is taken seriously in Finland.

[132] http://www.tenk.fi/fi/node/157
[133] http://www.tenk.fi/fi/node/115
[134] http://etene.fi/en/article/-/asset_publisher/kokeellinen-hoi-1
[135] http://geenitekniikanlautakunta.fi/en/article/-/asset_publisher/geenivaralaki-voimaan-1-9-2016
[136] http://www.tenk.fi/en/node/159
[137] http://www.tenk.fi/fi/content/keskustelutilaisuus-uudistetusta-tutkimuseettisestä-ohjeistuksesta-452017
[138] http://www.tjnk.fi/fi/kommentoi-tiedeviestinnän-suosituksia
[139] http://www.academies.fi/en/tapahtuma/arctic-the-7th-human-rights-and-science-symposium/
[140] http://www.etiikanpaiva.fi/
[141] http://tukija.fi/en/seminar-materials

A clear framework for the ethical evaluation of research also exists.[142] The figure below summarises the Finnish framework – main actors and their subject areas in ethics assessment in Finland.[143]

Fig 1: The Finnish framework for ethics assessment (source: *Ethical evaluation of research in Finland)*

However, the term 'ethical impact assessment' as such, did not come up in our review.

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

This section identifies where it may be appropriate for the consortium to make their views known to policy-makers.

From the above, it is evident that the Finnish Advisory Board on Research Integrity, nominated by the Ministry of Education and Culture, is a pivotal actor in activities related to research ethics in Finland. The Board organises with other central actors, an annual Ethics Day seminar and discussion seminars for appropriate audiences, regarding international recommendations and other issues it considers important. By capturing the Board's interest the consortium could quickly gain great visibility for its results.

Areas (fields, sectors, or topics) where there is a utility to introduce the SATORI ethics assessment framework

Finland clearly has a good framework for ethical review of R&I. However, the SATORI ethics assessment framework could be put to good use in evaluating the assessment i.e., making impacts of the assessment visible and under systematic scrutiny and assuring the quality of the process. In addition, the SATORI recommendations could be useful in the areas where ethical challenges are emerging, and in the ethics of cross-border R&I activities. Such areas could include artificial intelligence, cybernetics, genomics, platform economy, and synthetic biology.

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

Common challenges in introducing the ethics assessment framework include the level of ethics awareness and resources needed to carry out the assessment; this is potentially the case in Finland too. While the awareness of ethics in general is rising, ethics is not yet a subject in all faculties or polytechnics. This was underlined in a doctoral thesis study[144] which concluded that young engineers do not give great weight to ethics, but the older the engineers get, the

[142] http://www.tenk.fi/sites/tenk.fi/files/EthicalEvaluationofResearchinFinland.pdf
[143] http://www.tenk.fi/sites/tenk.fi/files/EthicalEvaluationofResearchinFinland.pdf
[144] Taajamaa, V, O-CDIO: Engineering Education Framework with Embedded Design Thinking Methods. Doctoral thesis, University of Turku, 2017.

more important the ethics becomes. This may generate a real challenge in situations where young engineers invent new technologies and solutions without considering ethics in their work or the solution they invent.

Another challenge relates to having the right expertise and knowledge available for the ethics assessment. Especially, emerging technologies may imply ethical issues which only subsequently become obvious. In these cases, existing procedures may not be sufficient and SATORI could offer systematics and guidance to tackle the issue.

7.3. France

The following information was prepared based on the SATORI newsletter and the documents available from the French National Assembly online repository after a search on ethics and research, followed by manual screening. In the cases where these documents led to the identification of additional relevant material external to the work of the Assembly, these were included too.

Key policy developments in ethics of R&I

The debate on research and ethics in France has traditionally been centred on bioethics and medicine. For instance, in 2016, a decree was published to enforce a law dated 12 March 2012, bringing to life new norms on research protocols on human beings.[145] This development is in line with EU regulations.

In 2015, a National Charter on Research Ethics[146] was adopted by the Conference of University Presidents (Conférence des Présidents d'Université), and seven other national research organisations. This short charter does not make explicit mention of processes of ethics assessment or ethical clearance but reminds researchers of good practice.

In 2016, the debate on ethics and R&I became very active.

Firstly, two decisions were taken about simplifying the reporting of data processing in health research projects.[147] Secondly, a change of focus in ethics related policy development occurred, with more and more attention being drawn to fields other than bioethics and health. The French legislators seemed to be preoccupied with the development of technology, building on results of scientific research. French members of parliament (MPs) addressed a resolution proposal on science and progress to the National Assembly, describing a series of actions to be undertaken so that science has a prominent place in societal debate. Among other considerations, this text underlines that actions preventing impact and risk assessment should be penalised.[148] However, there is no trace yet of discussion of a hard law or proposal to enforce a systematic assessment. Building on these considerations on technology, the Parliamentary office for Scientific and Technological Assessment (OPECST) has produced a series of reports that partly deal with the

[145] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033394083&dateTexte=&categorieLien=id
[146] http://www.cnrs.fr/comets/IMG/pdf/charte_nationale__deontologie_signe_e_janvier2015.pdf
[147] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033028290; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033028257
[148] http://www.assemblee-nationale.fr/14/propositions/pion4215.asp

societal and economic impact of the new technologies such as artificial intelligence[149] and the Internet of Things.[150]

Thirdly, research and ethics have also been investigated through the lens of "scientific integrity". A report[151] was ordered by the Ministry of Education and Research, following the signature of the National Charter on Research Ethics. The letter ordering this report refers to the reputation of research and science in society. It highlights the need to protect this reputation in order to make research results powerful, hinting at the harm that can be done to the whole area of research by those who commit ethical breaches. The report lists 16 recommendations to reinforce scientific integrity. Among these, the key recommendations relevant to SATORI include:

- The establishment of deontological referents for researchers,
- The need to teach young researchers about integrity,
- The need for public funding organisations to condition grants on the existence of an ethics and integrity policy in beneficiary institutions, and the subsequent need to establish controls for the implementation of such policies.

Another key recommendation is the establishment of a structure to oversee matters linked to scientific integrity, which was created in 2017.[152] The implementation of other recommendations from this report should be monitored.

Some major developments are yet to occur. The revision of the law on bioethics is planned for 2018, leading to the production of opinions from different organisations. For instance, opinions from the National Consultative Ethics Committee for Sciences of Life and Health (CCNE) are due in 2017 and are expected to address questions linked to assisted reproductive technologies.

Finally, and despite reports focusing on recommendations applicable at the national level, the President of the OPECST and MP Jean-Yves Le Déaut, recommends that an international convention is adopted and hints at the possibility of extending the Oviedo Convention to other disciplines[153]. This indicates that France might be receptive to a pan-European approach such that proposed by SATORI.

New policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process

Ethics assessment or ethical impact assessment is not central to policy development in France so far. However, the reports informing policy-making and developed by MPs or consultative institutions refer to societal and ethical impact of scientific research and technology development.

[149] http://www.assemblee-nationale.fr/14/cr-oecst/16-17/c1617088.asp
[150] http://www.assemblee-nationale.fr/14/rap-info/i4362.asp
[151] http://cache.media.enseignementsup-recherche.gouv.fr/file/Actus/84/2/Rapport_Corvol_29-06-2016_601842.pdf
[152] http://www.cnrs.fr/comets/IMG/pdf/20170320_cp_hceres_creationofis.pdf
[153] http://www.assemblee-nationale.fr/14/cr-oecst/16-17/c1617088.asp

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

The SATORI ethics assessment framework should be introduced in the fields of bioethics as it is the field that is going to be under scrutiny over the coming months. Although bioethics is a field that is more regulated than others, showing how the SATORI framework fits with current legislation and regulatory objectives can be a good entry point. The discussion could then be extended to other disciplines.

Other developments stemming from the proposals and reports discussed above should be monitored, although it is not clear yet whether their recommendations are going to be implemented.

Areas (fields, sectors or topics) where there is a utility to introduce the SATORI ethics assessment framework

Different types of stakeholders should be introduced to the SATORI framework: policy-makers, consultative institutions, academic institutions, and all institutions concerned with the revision of the law on bioethics.

Firstly, the National Assembly and the Senate have representatives that are involved in discussing ethics from the point of view of medical sciences and the development of technology, who should be made aware of the SATORI framework. The following should be duly considered to make this dissemination more impactful:

1) The SATORI framework can be presented as a way to guarantee the highest ethical research standards, therefore participating in it would help maintain a high reputation for French research, which is one of the worries expressed in the reports to the National Assembly.
2) The media have been discussing breaches of ethics and other research related scandals quite strongly,[154] and capitalising on this could be a way to increase the relevance and timeliness of the SATORI project and its results.
3) It should be stressed in dissemination to policy-makers, that SATORI is a EU-funded project and addresses key points of the Horizon 2020 strategy, which is often referred to in the different reports received so far by the National Assembly. This could increase the perceived relevance of the framework.

However, despite this a priori favourable situation, communication to policy-makers will be quite difficult in the middle of 2017. Indeed, the legislative elections of June 2017 might bring in new MPs interested in ethics and research, new ways of approaching the question, or lead to making it far less salient. Besides, the composition of the Assembly, thematic commissions will be reshuffled, therefore indicating concrete names and structures to communicate with is currently quite difficult.

Secondly, the results of the SATORI project should be disseminated to the Office for Scientific Integrity in so far as it would participate in the debate on how ethical breaches can be avoided. Indeed, the framework provides recommendations on establishing procedures for ethical

[154] https://blogs.mediapart.fr/seraya-maouche/blog/021216/le-plagiat-detienne-klein-un-autre-exemple-du-silence-institutionnel

clearance, accounts for the need to support, protect whistle-blowers, and advocates mechanisms to handle cases of misconduct.

Thirdly, the framework should also be disseminated to academic organisations such as the Conference of University Presidents and the partner institutions who signed the National Charter on Research Ethics. The SATORI ethics assessment framework should be introduced in the academic sector, as there are important gaps in terms of ethics clearance between institutions and disciplines.

Finally, all institutions linked to the revision of the law on bioethics (consultative committees, national assembly, senate, ministries) should be aware of the SATORI project in so far that the procedures for ethical clearance might be of interest to relieve some risks linked to bioethics research. However, doing so will require highlighting the elements of the framework that overlap with what is already in place for bioethics, and the characterisation of the role of each discipline. It may be risky to advocate the SATORI framework which does not focus exclusively on one discipline but takes a multi-disciplinary approach, at a time when the attention of policy-makers might be focused on bioethics only.

In addition, translations of the various SATORI documents and policy briefs into French seems essential.

To sum up, it appears that the debate on ethics for R&I is rather active in France, even though it does not consider procedures of ethical impact assessment. Therefore, the results of the SATORI framework can have a significant impact, filling a gap at a time when the country is getting equipped with more institutions, charters, and regulation, on research ethics. The challenge is to communicate the results of the project to the appropriate individuals and organisations, following the presidential and parliamentary election period.

7.4. Germany

This section was prepared based on data sourced from SATORI WP1 Germany country report[155], complemented in SATORI work package 9 with the results of monitoring RRI and ethics policy documents, publications and news in Germany, including three expert interviews[156]. As the country report states, there is a "plethora of organisations in Germany engaging in ethics assessment and promoting responsible and ethical research. Socially responsible and ethically acceptable research is a political goal".[157] The following section adds to the previous research in SATORI and connects it to ethics policy. It covers these developments by responding to the key outlined questions, in various organisational and thematic clusters in terms of themes and activities of ethics assessment units in Germany.

Key policy developments in ethics of R&I

Key developments in ethics of R&I for the period 2014-2017 include: draft legislation, readings and amendments to legislation, issue of declarations and recommendations, organisation of

[155] Nagel, Saskia K., Michael Nagenborg, Wessel Reijers, Rok Benčin, Gregor Strle, Boštjan Nedoh, "Ethics Assessment in Different Countries – Germany", SATORI, June 2015. http://satoriproject.eu/media/4.e-Country-report-Germany.pdf

[156] See interviews conducted for SATORI Task 6.4, *An Improved Framework for Ethics Review* with Randy Wallmichrath, Juliane Leverenz, and Martin O'Malley.

[157] Ibid.

events including public meetings) on R&I topics of ethical significance, publication of reports and policy briefs etc. These developments are listed below (most recent first):

- Update of road traffic laws for automated driving (30 May 2017)[158]
- Sharing responsibility – shaping the future together - State Secretaries' Committee for Sustainable Development, Declaration (24 April 2017)[159]
- Draft law amending the substantive conditions of admissibility of medical compulsory measures and strengthening the self-determination right of assisted persons (20 February 2017)[160]
- First reading of the new data protection legislation in German Bundestag (09 March 2017)[161]
- Expert report on research, innovation and technological performance of Germany (17 February 2017)[162]
- Environmental report of the Council for the Environment: Impulses for an integrated environmental policy (26 May 2016)[163]
- Public expert talk on "Synthetic biology, genome editing, biohacking - challenges of new gene technologies" (29 September 2016), meeting of the Committee on Education, Research and Technology Assessment[164]
- New electronic media and addiction behavior, TAB-Fokus no. 9 regarding no. 166, (April 2016)[165]
- Report of the Committee on Education, Research and Innovation and Technology Synthetic Biology - the next stage of bio and gene technology (20 February 2016)[166]
- Policy brief to the German Bundestag on the opinion of the German Ethics Council Patient wellbeing as an ethical benchmark for the hospital (7 Jun 2016)[167]
- 25 Years of Scientific Policy Advice – Technology Assessment at the German Bundestag and discussion on dissolution of Boundaries between Humans and Machines"– a subject of technology assessment (02 December 2015)[168]
- Biosecurity and dual use, proposal of German Green Party (30 September 2015)[169]
- Approval by the Federal Government of the draft IT Security Act (02 April 2015)[170]
- The new High-Tech Strategy for innovations for Germany (August 2014)[171]

[158] https://www.bundestag.de/dokumente/textarchiv/2017/kw13-de-automatisiertes-fahren/499928
[159] https://www.bundesregierung.de/Content/EN/StatischeSeiten/Schwerpunkte/Nachhaltigkeit/Anlagen/2017-04-24-erklaerung-sts-ausschuss-nachhaltige-entwicklung_en.pdf?__blob=publicationFile&v=4
[160] http://dipbt.bundestag.de/doc/btd/18/112/1811240.pdf
[161] https://www.bundestag.de/dokumente/textarchiv/2017/kw10-de-datenschutz/493934
[162] http://dipbt.bundestag.de/dip21/btd/18/112/1811270.pdf
[163] http://dipbt.bundestag.de/doc/btd/18/085/1808500.pdf
[164] https://www.bundestag.de/blob/461844/57b82904160f6a786441968b98c16418/programm-data.pdf
[165] http://www.tab-beim-bundestag.de/en/pdf/publications/tab-fokus/TAB-Fokus-009.pdf
[166] http://dipbt.bundestag.de/doc/btd/18/112/1811240.pdf
[167] http://dipbt.bundestag.de/doc/btd/18/088/1808843.pdf
[168] https://www.bundestag.de/blob/397262/0607c0998d6f2a1083df7f8426c5d360/25jahre_programm_en-data.pdf
[169] http://dip21.bundestag.de/dip21/btd/18/062/1806204.pdf
[170] https://www.enisa.europa.eu/about-enisa/structure-organization/national-liaison-office/news-from-the-member-states/germany-federal-government-approves-draft-it-security-act
[171] https://www.bmbf.de/pub/HTS_Broschuere_eng.pdf

The Office of Technology Assessment at the German Bundestag (Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag) - TAB

- Responsible research and innovation as an approach for research, technology- and innovation policies – background and developments (report)[172]
- White Biotechnology – Innovation Analysis Part II: Current status and perspectives of the industrial biotechnology: potential for environment and sustainability (report)[173]
- White Biotechnology – Innovation Analysis Part I: Current status and perspectives of the industrial biotechnology: procedures, applications, economic perspectives (report)[174]
- Technologies and Visions of human-machine delimitation (report)[175]
- Synthetic Biology – the next step of the bio- and genome technology (report)[176]
- Big data in the cloud (report)[177]
- Evaluation of biodiversity? (report)[178]

German Ethics Council (Deutscher Ethikrat)

The work programme of the German Ethics Council for 2017 focuses on two major themes: big data and benevolent coercion[179]. Of specific interest are the regular trilateral meetings of the national ethics councils of France, Germany, and Great Britain. The following are the key policy focus areas:

- Do we need a new genetic engineering definition? Natural sciences, ethical and legal perspectives of the regulation of genome-edited plants? Conference by German Ethics Council with DFG and Leopoldina (February 2017)[180]
- Patient welfare as ethical standard for hospitals, Opinion (April 2016)[181]
- Genome editing/trilateral meeting of NECs in Germany, France, Great Britain (December 2016)[182]
- Embryo donation, embryo adoption and parental responsibility, position paper (March 2016)[183]
- Global science and global ethics? Public meeting, German Ethics Council & Leopoldina (December 2015)[184]
- Brain death and decisions regarding organ donation, opinion paper (February 2015)[185]
- Biosecurity –freedom and responsibility of research, opinion paper (May 2014)[186]

[172] http://www.tab-beim-bundestag.de/de/pdf/publikationen/berichte/TAB-Hintergrundpapier-hp022.pdf
[173] http://www.tab-beim-bundestag.de/de/pdf/publikationen/berichte/TAB-Arbeitsbericht-ab169.pdf
[174] http://www.tab-beim-bundestag.de/de/pdf/publikationen/berichte/TAB-Arbeitsbericht-ab168.pdf
[175] http://www.tab-beim-bundestag.de/de/pdf/publikationen/berichte/TAB-Arbeitsbericht-ab167.pdf
[176] http://www.tab-beim-bundestag.de/de/pdf/publikationen/berichte/TAB-Arbeitsbericht-ab164.pdf
[177] http://www.tab-beim-bundestag.de/de/pdf/publikationen/berichte/TAB-Hintergrundpapier-hp019.pdf
[178] http://www.tab-beim-bundestag.de/de/pdf/publikationen/berichte/TAB-Arbeitsbericht-ab161.pdf
[179] http://www.ethikrat.org/topics
[180] http://www.ethikrat.org/dateien/pdf/tagung-14-02-2017-simultanmitschrift.pdf
[181] http://www.ethikrat.org/dateien/pdf/stellungnahme-patientenwohl-als-ethischer-massstab-fuer-das-krankenhaus.pdf
[182] http://www.ethikrat.org/veranstaltungen/weitere-veranstaltungen/trilaterales-treffen-2016?set_language=en
[183] http://www.ethikrat.org/dateien/pdf/stellungnahme-embryospende-embryoadoption-und-elterliche-verantwortung.pdf
[184] http://www.ethikrat.org/dateien/pdf/tagung-03-12-2015-simultanmitschrift.pdf
[185] http://www.ethikrat.org/dateien/pdf/stellungnahme-hirntod-und-entscheidung-zur-organspende.pdf
[186] http://www.ethikrat.org/files/opinion-biosecurity.pdf

- Stem cell research – new challenges for the ban on cloning and treatment of artificially created germ cells. Recommendation (April 2014)[187]

German Research Foundation

- Scientific freedom and scientific responsibility; Recommendations for handing security-relevant research, (March 2016) (DFG and Leopoldina), especially relevant is the list of contact persons and commissions in Germany responsible for ethics committees concerning security-relevant research.[188]
- International Graduate School 1879: Human Rights under pressure – ethics, law and policies (2014)[189]
- DFG Research Group: Urban Ethics Conflicts around good urban life in the 20th and 21st century (2014)[190]

The Council of Science and Humanities (Wissenschaftsrat)

- Recommendations for Research Integrity (2015)[191]

The German Reference Centre for Ethics in the Life Sciences (Deutsches Referenzzentrum für Ethik in den Biowissenschaften-DRZE)

- Aging, expert report (February 2017)[192]
- Animals in research, expert report (April 2016)[193]
- Deep Brain Stimulation, expert report (April 2016)[194]

National contact point (NCP) in H2020 Science with and for Society (SWAFS)

- The German NCP H2020 organised a special event for multipliers – the ethical review process in H2020 projects, Berlin (17 March 2017)
- NCP Academy Training on RRI and Ethics in Horizon 2020 (3 to 5 April 2017)[195]

The German national contact point in Horizon 2020 Science with and for Society (SwafS) also adopts and encourages the use of ethics assessment (or ethics review)[196]. Although the term

[187] http://www.ethikrat.org/files/recommendation-stem-cell-research.pdf
[188] German Research Foundation (Deutsche Forschungsgemeinschaft), Academy of Sciences Leopoldina (Nationale Akademie der Wissenschaften Leopoldina), Scientific Freedom and Scientific Responsibility. Recommendations for Handling Security-Relevant Research, 2014. http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf; http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG_Leopoldina_Wissenschaftsfreiheit_-verantwortung_bilingual.pdf
[189] http://www.dfg.de/foerderung/programme/listen/projektdetails/index.jsp?id=215932069
[190] http://www.dfg.de/foerderung/programme/listen/projektdetails/index.jsp?id=240207984
[191] https://www.wissenschaftsrat.de/download/archiv/4609-15.pdf
[192] http://www.drze.de/publikationen/sachstandsberichte/band-16/site_data/Dokumente/Publications/Berichte/Inhaltsverz_sbdrze_16.pdf
[193] http://www.drze.de/publikationen/sachstandsberichte/band-17/site_data/Dokumente/Publications/Berichte/Inhaltsverz_sbdrze_17.pdf
[194] http://www.drze.de/publikationen/sachstandsberichte/band-18/site_data/Dokumente/Publications/Berichte/Inhaltsverz_sbdrze_18.pdf
[195] SATORI interview with NCP.
[196] NKS H2020: Special event for multipliers – the ethical review process in H2020 projects, on 17 March 2016 in Berlin; NCP Academy Training on RRI and Ethics in Horizon 2020 on 3 and 5 April 2017.

'ethical impact assessment', as such, is not used, its seminars and workshops address topics related to ethical impacts in R&I.

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

Overall SATORI may be observed as "a recent, interesting and concrete example of the convergence of ethics and technology assessment".[197] The concept and meaning of RRI is recognised by the Office of Technology Assessment at the German Bundestag (TAB). The TAB background paper *Responsible Research and Innovation as an approach for research-, technology and innovations policies*[198] states, "a large number of institutions, […] have a great content-conceptual proximity and partial agreement both with procedural as well as substantive aspects of RRI". The background paper concludes:

> The potential added value of RRI could develop mainly in two ways. On the one hand, RRI as an integrative approach that combines existing procedures and methods in the area of analysis, assessment and assessment of technology development and innovation, helping to generate more coherence and links between the various procedures of technology assessment, risk assessment, foresight, etc. One the other hand, RRI does not mean the limitation of diversity, but, on the contrary, fosters productive cross-connections and the combination of different perspectives, and promotes cumulative learning. RRI is seeking the broadening and pluralization of the research and innovation-related assessment and decision-making bases. This opening provides additional perspectives, sets of values and interests and could be a catalyst to support a more transparent, inclusive and ultimately more democratic debate on different innovation paths. Ultimately, the relationship between industry, research and society could be more responsive in this way to make innovations more socially robust and economically more sustainable.[199]

Referring to the normative turn in the R&I policy landscape, the authors of the paper argue, "Ultimately, RRI could create a paradigm shift in the governance of research and innovation by eliminating questions from technology- and innovations-induced risks and their reactive-regulation to questions how, in a as much as possible democratic and inclusive agreement about, *which* future should be advanced".[200] Lindner et al state, that due to limits in space, "institutionalised ethics assessment"[201] is addressed only briefly, but considered expandable, especially in a European comparison. What is necessary is the integration of sources of knowledge, which are beyond the scientific and technocratic level, and the effective use of participatory procedures to increase deliberation. The participatory approach of the SATORI framework and methodological and practical aspects outlined in SATORI *D.2.1: Report (Handbook) of participatory processes* could be especially valuable.[202]

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[197] Nielsen, R. Ø., L. Bitsch, M. V. Nielsen, "On the Convergence of TA with Ethics in RRI", in C. Scherz, T. Michalek, L. Hennen, L. Hebakova, & S. B. Seitz (eds.), *The Next Horizon of Technology Assessment: Proceedings from the PACITA 2015 Conference in Berlin*, Prague, p. 81-86, p. 83.

[198] Lindner, Ralf, Kerstin Goos, Sandra Güth, Oliver Som, Thomas Schröder: *Responsible Research and Innovation als Ansatz für die Forschungs-, Technologie- und Innovationspolitik – Hintergründe und Entwicklungen,* TA Vorstudie, Hintergrundpapier Nr. 22, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, 2016, p. 24, 26. http://www.tab-beim-bundestag.de/de/pdf/publikationen/berichte/TAB-Hintergrundpapier-hp022.pdf

[199] Lindner, op. cit., 2016,

[200] Lindner, op. cit., 2016.

[201] "institutionalisierte ethische Urteilsbildung" translated as institutionalised ethics assessment.

[202] Shelley-Egan, Clare, David Wright, Rok Benčin, Jelica Šumič Riha, Gregor Strle, Daniela Ovadia, Adelina Pastor Cañedo, Christine Angeli, Menelaos Sotiriou, "Report (handbook) of participatory processes", SATORI Deliverable D2.1, July 2014. http://satoriproject.eu/media/D2.1_Report-handbook-of-participatory-processes_FINAL1.pdf

Lindner et al, argue, that although RRI is in a "dynamic development stage", we must observe and evaluate the experiences the EU and forerunners such as Great Britain and the Netherlands. In this sense, SATORI provides a comprehensive compilation of practices, experiences, as a case to draw upon and learn from, particularly for technology assessment in Germany. This would be in line with Lindner et al who suggest "pilot projects with a timely and sectoral limited scope, in Germany e.g., in publicly funded research organisations, research organisations and universities".[203]

Areas (fields, sectors or topics) where there is a utility to introduce the SATORI ethics assessment framework

The following recent policy initiatives could be good opportunities to introduce and use the SATORI framework, as the framework provides good guidance for ethics committees that should be considered early in the process of establishing ethics committees. The Framework also provides ethical principles that are relevant to consider.

- Ethics Committee for Automated Driving, Federal Ministries for Transport and Digital Infrastructure (BMVI), September 2016[204]
- Report on Scientific freedom and scientific responsibility; Recommendations for handing security-relevant research" (March 2016) (DFG and Leopoldina)[205]. Of special interest is a comprehensive list of research organisations, contact persons and existing and forthcoming commissions in Germany responsible for ethics concerning security-relevant research.[206]

Based on our research in work package 9 and the monitoring of RRI and ethics policy documents, publications and news in Germany, we think the SATORI ethics assessment Framework could be particularly useful in the following four contexts.

First, the SATORI ethics assessment framework (Part I ethics committee guidance) could serve as a tool that could be used to support and advance the state of the art in ethics review in Germany particularly in areas where, for instance, ethics committees have only been recently established (e.g., University of Jena) or are not yet not established (e.g., the office of Joint Committee for the Handling of Security-Relevant Research established by the German National Academy of Sciences Leopoldina and the German Research Foundation (DFG)[207] where a list of contact persons and commissions in Germany responsible for ethics concerning security-relevant research can be found[208]) or good practice guidance is required for their creation. In addition, individual universities and universities of applied science might be interested in the CWA to start or develop their own ethics assessment units.

[203] Lindner, op. cit., 2016.
[204] http://www.bmvi.de/SharedDocs/EN/PressRelease/2016/157-dobrindt-ethics-committee-automated-driving.html
[205] German Research Foundation, Academy of Sciences Leopoldina, *Scientific Freedom and Scientific Responsibility. Recommendations for Handling Security-Relevant Research*, 2014. http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf; http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG_Leopoldina_Wissenschaftsfreiheit_-verantwortung_bilingual.pdf
[206] https://www.leopoldina.org/nc/en/about-us/cooperations/joint-committee-dual-use/list-of-committees/
[207] https://www.leopoldina.org/en/about-us/cooperations/joint-committee-dual-use/
[208] https://www.leopoldina.org/nc/en/about-us/cooperations/joint-committee-dual-use/list-of-committees/

The ethics committee guidance might also be useful for newly established ethics committees to evaluate their performance and review their procedures and processes. With research being increasingly carried out in an interdisciplinary collaborative fashion and across borders, the SATORI framework can be used to help develop a shared understanding of ethics assessment and good practices.

Second, an opportunity to utilise the SATORI ethical impact assessment framework could be in the context of the newly established ethics committee on automated driving.[209] Since the Office of Technology Assessment at the Deutsche Bundestag (TAB) already has publications on RRI by its coordinating organisation the Institute for Technology Assessment and Systems Analysis (ITAS) at Karlsruhe Institute of Technology, they could be a potentially good contact to target.

Third, in addition the SATORI ethics assessment framework could be useful to the Acatech (National Academy of Science and Engineering), especially the thematic network safety[210].

Fourth, the Association of German Engineers (VDI), especially the working group on synthesis of safety and security[211], which kindly requested a member of the SATORI project to join its working group "Synthesis of safety and security" domain overarching analysis and assessment[212], could be interested in the SATORI framework as a useful approach to ethics review into account at beginning of working groups tasks.

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

Based on our research, we list below some general challenges or barriers that might affect the use and implementation of the SATORI *ethics assessment* framework:

- There is a need to embrace researchers working in industry. The report on *Scientific freedom and scientific responsibility*, especially security-relevant research"[213], outlines how industrial research should be performed, and covers the integration of ethics committees in industrial research and qualified in particular by labour law. Since industrial research is about two-third of all research in Germany, embracing researchers in industry is a specific challenge and a barrier at the same time.
- Another challenge is to achieve a wide acceptance for the framework i.e., achieving political legitimisation from the right authorities, especially different normative perspectives and concerns might impact its utilisation.
- There is a need to identify the right opportunities, timing and resources for the use of the framework, and to get buy-in to the framework.

Potential challenges and barriers for the use and implementation of the SATORI *ethical impact assessment (EIA)* framework might include:

[209] https://www.bmvi.de/SharedDocs/DE/Pressemitteilungen/2016/157-dobrindt-ethikkommission.html
[210] http://www.acatech.de/de/themennetzwerke/sicherheit.html
[211] https://www.vdi.de/technik/fachthemen/produkt-und-prozessgestaltung/fachbereiche/sicherheit-und-zuverlaessigkeit/themen/synthese-von-safety-und-secruity/
[212] https://www.vdi.de/artikel/neuer-fachausschuss-zu-safety-und-security/
[213] German Research Foundation, Academy of Sciences Leopoldina, Scientific Freedom and Scientific Responsibility. Recommendations for Handling Security-Relevant Research, 2014. http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf; http://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG_Leopoldina_Wissenschaftsfreiheit_-verantwortung_bilingual.pdf

- Resource constraints: The procedures of need additional financial, administrative and co-ordination resources, e.g., management support, stakeholder participation, training.
- Lack of fitting in with, or conflict with existing obligations: When a full scale, technology-scale EIA is triggered, this would need broad co-ordination and significant resources, which might conflict with already existing obligations. Further research ethics committees, funding organisations, science academies and standards setting bodies already have pre-existing work plans and obligations.
- Overburdening of ethics assessors: Another challenge might be that the EIA process might add to the heavy workload of members of ethics assessment units.
- Organisational inertia: could also impact the uptake and use of the ethical impact assessment.

Acknowledging, that in Germany a plethora of government advisory bodies and institutions in different types of assessment (i.e., technology assessment, environmental impact assessment, social impact assessment, ethics assessment and ethical guidance) exist, the landscape can be described as comparatively well developed. This raises questions about why the SATORI framework should be supported by policy-makers in Germany. The answer lies in the evolution of innovation policies of the last decades providing rationales for policy interventions ranging from market failure, to systems failure and orientation failure.[214]

7.5. Italy

This section was prepared based on an online search of the following keywords: ethics, ethics of research, norms, laws, policies, RRI. We consulted the websites of the Italian Parliament and the following institutions:

- Comitato Nazionale di Bioetica (National Bioethics Committee)[215]
- Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita (National Committee for Biosecurity, Biotechnologies and Life Sciences - CNBBSV)[216]
- Comitato per le Pari Opportunità del Consiglio Nazionale delle Ricerche (Committee for Equal Opportunities at the National Research Council)[217]
- Comitato Etico del CNR (National Research Council Ethics Committee)[218]
- Ente Italiano Normazione (National Standard Body – UNI)[219]

We collected information on ethics and ethics assessment at societal level through the following sources:

- RRI-SIS Conference in Rome, 2014[220]

[214]Daimer, S., M. Hufnagl, and P. Warnke, "Challenge-Oriented Policy-Making and Innovation Systems Theory: Reconsidering Systemic Instruments", in *Innovation System Revisited – Experiences from 40 Years of Fraunhofer ISI Research*, Stuttgart: Fraunhofer Verlag, 2012, pp. 217–234.
[215]http://presidenza.governo.it/bioetica/pubblicazioni_comitato.html
[216] http://presidenza.governo.it/biotecnologie/documenti.html
[217]www.cpo.cnr.it
[218]https://www.cnr.it/it/ethics
[219] http://www.uni.com/index.php
[220]https://www.researchitaly.it/uploads/11284/SIS-RRI-Programme.pdf?v=666094b

- Observa – Annuario Scienza e Società[221]
- Fondazione Giannino Bassetti[222]
- Comitati etici (Ethics committee evaluating biomedical and drug research)[223]

Key policy developments in ethics of R&I

This section highlights some key policy developments related to ethics, covering the period September 2014 to May 2017. Animal research and basic bioethics issues (e.g., artificial insemination, pre-implantation genetic diagnosis on embryos etc.) were among the most debated ethics topics. Some guidelines or norms also cover the use of personal data and the protection of medical records. In 2016, the term 'Responsible Research and Innovation' was mentioned for the first time in the Italian National Research Program. Guidelines were issued to foster the use of good practices and standards in industrial production. We list the key developments below:

- Approval of Decree 26/4 March 2014 to include the EU Directive 2010/63 on Animal research introducing more restrictive norms, temporarily suspended (up to 2019) by a moratorium due to the protests of the scientific community[224]
- Judgment from the Italian Court of Cassation abolishing the ban on heterologous artificial insemination in assisted reproduction that was introduced in Italy by law 40/2004 on assisted reproduction (9 April 2014)
- Publication of Guidelines for the use of personal data by public entities, including those from administrative documents, for advertising and web transparency, National Privacy Authority (15 May 2014)[225]
- Publication of Guidelines for the use of personal data for on line profiling, National Privacy Authority (19 March 2015)[226]
- Publication of Guidelines for the management of medical records, National Privacy Authority (4 June 2015)[227]
- Judgment from the Italian Court of Cassation abolishing the ban on pre-implantation Genetic Diagnosis on embryos that was introduced in Italy by the law 40/2004 on assisted reproduction (5 June 2015)
- Aproval of the National Research Council (CNR) Guidelines for integrity in research (10 June 2015)[228]
- Inclusion, by the National Research Program (PNR) of the Ministry for Education and Research in Italy, of an explicit reference to the Responsible Research and Innovation approach (March 2016)[229]

[221] http://www.observa.it/chi/?lang=en. Observa is a research centre promoting the study and discussion of the interaction among science, technology and society; it publishes a Science and Society Annual Report.
[222] http://www.fondazionebassetti.org/it/focus/categorie.html
[223] http://www.comitatietici.it/home/
[224] http://www.research4life.it/normativa-vigente/
[225] http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/3134436
[226] http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/3881513
[227] http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/4084632
[228] https://www.google.it/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwiUqYDB1PHTAhWDnBoKHcdMA0oQFggnMAA&url=https%3A%2F%2Fwww.cnr.it%2Fsites%2Fdefault%2Ffiles%2Fpublic%2Fmedia%2Fdoc_istituzionali%2Flinee-guida-integrita-nella-ricerca-cnr-commissione_etica.pdf%3Fv%3D1&usg=AFQjCNE2ANvOGnOyHXn7qlWgxMT5ngMCXg&sig2=KrEapNIgmN5EVJeGQ9Kcpg
[229] https://www.researchitaly.it/en/projects/the-2-5-billion-national-research-programme-presented-at-miur/ -null

- Publication of Guidance on the application of UNI ISO 26000 - Social responsibility in organisations, National Standard Body (April 2016)[230]
- Publication of Guidance on the development of ethical reasoning on individual basis – UNI/PdR 21:2016, National Standard Body and Order of Engineers (September 2016)[231]
- Approval of the National Research Council Child Protection Policy and Code of Conduct (24 November 2016)[232]
- Expression of advice by the National Research Council on dual use in scientific research (24 November 2016)[233]
- Approval of the National Research Council Chart of principles for the research in social sciences and humanities and the Code of conduct (16 March 2017)[234]
- Publication of Guidance for management and processes development for responsible innovation UNI/PdR 27:2017, National Standard Body, AIRI[235] and CISE/Chamber of Commerce of Forlì (April 2017)[236]

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

The very low number of policy documents (related to ethics assessment) produced by Italian institutions does not provide a straightforward answer. Some elements of ethics assessment can be retrieved from norms regulating animal research and in some policies on data protection but there is no organised framework for general ethics assessment in Italy.

Key ethical policy activities and policy developments and initiatives in which it may be appropriate for the consortium to intervene by making their views known to policy-makers

The ethical debate in Italy is mainly focused on bioethics and animal research. It could be appropriate for the SATORI consortium to present the SATORI ethics assessment framework to the Italian Drugs Agency (AIFA) as they are developing a harmonised procedure for the evaluation of drug trials under the EU umbrella.

There is also an ongoing strong debate on animal research that could benefit from the introduction of general rules to assess the social suitability of new types of research. The SATORI consortium could interact with Research4Life[237], a consortium of research funding agencies and drug companies, that acts as the local representative of the Basel Declaration[238].

[230] http://uni.com/index.php?option=com_content&view=article&id=4909%3Aindirizzi-applicativi-per-l-implementazione-della-uni-iso-26000-pubblicata-la-nuova-uni-pdr-18-2016&catid=171&Itemid=2612
[231] https://www.google.it/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKEwj4x8qxzfHTAhUFiRoKHYXlCkcQFggyMAE&url=http%3A%2F%2Fwww.sodalitas.it%2Fpublic%2Fallegati%2FPrassi_UNI_ISO_26000-(1)_20165494228448.pdf&usg=AFQjCNERH8u_457mrxzJJrAIIOUuhKRJ9Q&sig2=p8XFqIyAUwdoSK6NYefRPA
[232] https://www.cnr.it/it/documenti-commissione
[233] Ibid.
[234] https://www.cnr.it/it/documenti-commissione
[235] A SATORI project partner.
[236] http://www.uni.com/index.php?option=com_content&view=article&id=5845:innovazione-responsabile-pubblicata-la-nuova-prassi-di-riferimento-uni-pdr-27&catid=171:istituzionale&Itemid=2612
[237] http://www.research4life.it/
[238] Basel Declaration Society, "Basel Declaration, A call for more trust, transparency and communication on animal research". http://www.basel-declaration.org/

The National Research Council (CNR) could be a good partner to help disseminate and publicise the SATORI framework in public-funded research. Other key actors to engage with include the Conference of Italian University Rectors (CRUI, the association of the state and private universities) and the National Agency for the Evaluation of the Academy and Research System (ANVUR).

The National Standard Body (UNI) and AIRI are key institutions to distribute the standardised version of the SATORI ethics assessment framework (i.e., the SATORI CEN Workshop Agreement) in the private industry. The CNR and UNI are working on developing guidelines and norms to introduce RRI principles in many industrial and production fields and could be interested in adopting the SATORI ethics assessment and ethics impact assessment procedures.

Areas (fields, sectors or topics) where there is a utility to introduce the SATORI ethics assessment framework

In Italy, RRI seems to be the main proxy for ethical impact assessment in Italian documents and guidelines. As stated in the report on *Responsible Research and Innovation (RRI)* in Italy[239] published by AIRI and CNR, the concept of RRI, albeit slowly and in a messy way, is reaching Italian public institutions, research organisations, companies and stakeholders. RRI thus represents a good means to deliver ethics assessment.

The AIRI-CNR Report identifies four macro areas as priorities for a consistent development of RRI. These four areas are potentially relevant for the SATORI ethics assessment framework, if they can be successfully tapped into:

1. Development of norms for social, environmental and economic sustainability, with the aim of adding value to innovative research, products and processes.
2. Development of Corporate Social Responsibility (CSR) in relation to the three main aspects: materiality (i.e., identification of priorities), stakeholder engagement (when and how to engage with interested parties) and accountability (communication plan that takes into account the social responsibility of companies).
3. Evaluation of research (ex ante, in itinere, ex-post) in agreement with the RRI principles and based on indicators that take into account the whole life cycle of research or of the development of a new technology (as the SATORI ethics assessment and ethical impact assessment frameworks suggest).
4. Public engagement, to involve, at different levels, the scientific community and the beneficiaries of research and technological innovation in the evaluation of the social interests in innovation and research.

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

Many groups, both from public research institutes and private enterprises, are working successfully to develop RRI in their own working environment, but what is missing is a national strategy. If we consider RRI to be a proxy of ethical impact assessment, it is easy to understand the challenges and barriers the SATORI framework will have to overcome to become truly useful in Italy.

[239] http://www.airi.it/pubblicazioni/report-sulla-ricerca-e-innovazione-responsabile/

RRI activities have developed without being interconnected: the natural consequence is that the development of skills and competences took place only within the European Framework Programs or within initiatives limited to specific production systems.

The inadequacy of good public communication and information processes about scientific progress has certainly influenced (though not in a positive way) the public perception of the possible social benefits deriving from new technologies or innovation. On the other hand, it is now generally accepted that sustainability is one of the key drivers of innovation.

Italian public opinion is well-known for its precautious approach to innovation, due in part to a low scientific literacy and a low esteem of the role that science and the new technologies play in modern society. It is therefore first necessary to encourage an in-depth and appropriate awareness and knowledge of the role of science and technological development in a modern society.

There is a need to create a reference framework to rationalise the different experiences, to contribute to a better efficient use of public resources in R&I, and to create added value in products, processes, and innovative services. The SATORI ethics assessment framework and procedures it outlines, could usefully fit in this plan.

One key challenge in introducing the SATORI ethics assessment framework in Italy is the lack of a centralised structure that could adopt it and introduce it in different fields. Another challenge is the introduction of harmonised procedures in a fragmented system. Such a fragmentation is a barrier at a normative level too, as ethics assessment and evaluation norms can be established at local, national and regional levels by different bodies and institutions. Further, as Italy is facing a sustained economic crisis, the introduction of new steps in the evaluation of the impact of new technologies and innovations might be perceived as an added burden and not one that provides a competitive advantage.

7.6. Netherlands

This section was prepared based on data sourced from SATORI work package 1 Netherlands country report[240], complemented in WP9 with the results of monitoring RRI and ethics policy documents, publications, and news in the Netherlands.

Key policy developments in ethics of R&I

As mentioned in the SATORI work package 1 report Netherlands country report, "the practice of ethics assessment of R&I in the Netherlands is for the most part decentralised and independent from government"[241]. Because of this decentralisation, several organisational bodies are advocating for, in one way or another, a deliberate use of ethics assessment and ethical impact assessment through their activities. As part of the decentralised nature of governance in ethics assessment, many public-private partnerships have been established to represent various stakeholders on important ethical issues in society.

[240] Jansen, Philip, Wessel Reijers, "Ethics Assessment in Different Countries - The Netherlands", June 2015. http://satoriproject.eu/media/4.f-Country-report-the-Netherlands.pdf
[241] Jansen op. cit., 2015.

The following are some of the key policy developments in ethics of R&I in the Netherlands for the period 2014-2017.

- "Collaborate to innovate", a study on cross-national collaboration in the field of research, technology, and innovation[242]
- Considering health in environmental policy[243]
- "Dare to share", an advisory report on open science[244]
- "Dutch show highest returns on EU research funding"[245]
- "Green light for the creation of human embryos for research"[246]
- Important change in the Dutch organ donation system: from opt-in to opt-out[247]
- Letter to the House of Representatives on the progress of open science[248]
- "Priorities for science and society about the influence of ecosystems on well-being"[249]
- "Statutory target again for gender balance on company boards"[250]
- "Support for improving health in all policies"[251]

The above policy developments indicate that there has been a considerable interest in the rights of the individual and society in policy regulations, among other developments. Be it by taking an individual's or societal health centred outlook for further policy development or by providing society with access to information in the field of research, science and technology.
Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

The Netherlands has wide ranging experience in the development of ethics assessment structures. Because of the decentralised nature of ethics assessment in the Netherlands, there is a plethora of organisations advocating a deliberate use of ethics assessment and ethical impact assessment in the development of new policy and review of the current one. Several advisory councils, agencies and institutes have been tasked with making recommendations to the governmental bodies in areas such as animal protection, biotechnology, data protection, environment, health, technology assessment, etc. While there are no explicit provisions on ethics assessment in written law, Dutch practice has revolved around securing liberty and independence of individual researchers. These legal provisions have created an environment where ethics assessment has been closely integrated with the working of these bodies.

[242] The Advisory council for science, technology and innovation (AWTI), *Collaborate to innovate Knowledge and innovation cooperation between Brazil and the Netherlands*, August 2015. https://english.awti.nl/publications/documents/publications/2015/10/15/collaborate-to-innovate
[243] https://www.gezondheidsraad.nl/en/task-and-procedure/areas-of-activity/environmental-health/considering-health-in-environmental-policy
[244] https://english.awti.nl/publications/documents/publications/2016/01/20/dare-to-share
[245] https://www.government.nl/ministries/ministry-of-economic-affairs/news/2014/06/19/dutch-show-highest-returns-on-eu-research-funding
[246] https://www.rijksoverheid.nl/ministeries/ministerie-van-volksgezondheid-welzijn-en-sport/nieuws/2016/05/27/schippers-wil-perspectief-voor-onvruchtbare-mensen
[247] https://www.government.nl/topics/organ-tissue-donation/contents/rules-organ-tissue-donation
[248] https://www.government.nl/ministries/ministry-of-education-culture-and-science/documents/letters/2017/01/19/letter-to-the-house-of-representatives-on-the-progress-of-open-science
[249] http://www.rivm.nl/en/Documents_and_publications/Common_and_Present/Newsmessages/2016/Priorities_for_science_and_society_about_the_influence_of_ecosystems_on_well_being
[250] https://www.government.nl/ministries/ministry-of-education-culture-and-science/news/2016/01/15/statutory-target-again-for-gender-balance-on-company-boards
[251] http://www.rivm.nl/en/Documents_and_publications/Common_and_Present/Newsmessages/2016/Support_for_improving_health_in_all_policies

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

While in the Netherlands a strong bureaucratic culture of ethics assessment is already present throughout the policy cycle, in one form or another, e.g., technology assessment, environmental and social impact assessment, etc., there remain areas, e.g., ethics adoption in small and medium-sized companies, where it would be relevant for the consortium to make its views known to policy-makers. In line with the current practice of having many organisations already in communication with governmental agencies in ethics assessment, the consortium's recommendation would be to further widen the scope of stakeholder engagement. Greater outreach to groups that have a stake in the outcomes of policy-making procedures or the deliberative process that bring them about would democratise and legitimise the policies that are to be enacted. This development has been favoured by the interviewed bodies[252], however it remains in the early stages. Additionally, as there are still some bodies that do not engage in ethics assessment, e.g., the Netherlands Enterprise Agency (the major national organisation for subsidising entrepreneurship), attention could be given to these to spread awareness of the growing importance of ethics assessment.

Areas (fields, sectors or topics) where there is a utility to introduce the SATORI ethics assessment framework

Many areas are still left open for improvement. Specifically, in terms of professional conduct, research practices, and societal impact. While the Netherlands already has a relatively strong ethics assessment culture (e.g., many agencies that take ethics assessment into consideration, legally binding obligations that promote ethical procedures), the SATORI ethics assessment framework can provide additional guidance in areas such as social responsibility, respect for other communities, openness, and stewardship. In areas where such aspects are already considered, work on harmonisation can be carried out for smoother communication, deliberative procedures, and institutional sustainability.

With regard to the SATORI ethical impact assessment framework (EIA), we think that potential positive use could be given in areas of assessing the potential impacts of new projects in order to mitigate ethical risk, determine possible, probable, and/or preferable outcomes, choose the most applicable theoretical method of investigation, and engage stakeholders in all stages of the policy cycle, etc. While we do acknowledge that steps towards these goals have been taken, they mostly come about on an ad-hoc basis and, thus, fail to reach institutional integration due to the decentralised nature ethical impact assessment in the Netherlands.

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

A potential challenge with the introduction of the SATORI ethics assessment framework could be the harmonisation process with the already established Dutch culture of ethical assessment throughout the policy cycle. While the current practice offers involvement in many fields of public policy, this practice tends to be kept up by (quasi-) independent bodies with their own ethics assessment culture. We believe that this creates a dynamic that is viewed as an obstacle for a smooth cooperation between the involved parties but, in fact, opens an area for the implementation of the SATORI guidelines. In other words, the SATORI ethics assessment

[252] Jansen, op. cit., 2015.

framework can be the backbone to overlook and harmonise the workings of the different bodies to reach a common language and conduct that can then positively shape the ethics assessment environment in terms of efficiency and effectiveness. Particularly, the close involvement of Dutch partners in developing and discussing the framework has already brought about close integration of Dutch practices in the SATORI ethics assessment framework.

7.7. Poland

This subsection has been developed based on information derived from sources such as institutional and government websites, publications, news, events and other relevant pages.[253]

Key policy developments in ethics of R&I

Polish R&I policy does not include references to "ethics" as such. At the same time, recent policy initiatives and developments focusing explicitly on the responsibility of science towards the society seem to provide room for intervention. It is however important to point out that currently, the notion of "responsible science" tends to be equated with "popularization of science".[254] The following section will provide an overview of relevant activities of the different institutions.

Ministry of Science and Higher Education

In January 2016, the government established a Council for Innovation composed of 5 Ministers: minister of development, minister of culture and national heritage, minister of science and higher education, minister of digitization, and minister of state treasury.[255]

The Council for Innovation is designed to be the most important inter-ministerial coordinator of the government's innovation policy and a permanent element of the public administration system. The Council coordinates national policy regarding innovation.

In September 2016, the Ministry of Science and Higher Education on behalf of the Council presented the Innovation White Paper.[256] It includes proposals for changes, which are expected to contribute to solving the problems with implementing innovation. However, the White paper does not refer to ethics assessment or ethical impact assessment.

Moreover, a new strategy for Polish science and higher education sectors was announced in September 2016 where growing focus has been placed on the need to invest and develop innovation. The strategy is constituted by three pillars including "Innovation for the Economy" and "Science for You". The latter will encompass several undertakings and programmes, and aims to increase social responsibility of science. According to the strategy, science should serve

[253] E.g., http://www.nauka.gov.pl/, https://www.rpo.gov.pl/, http://scienceinpoland.pap.pl/en/

[254] The new strategy for Polish science published in September 2016 includes a reference to social responsibility of science. However, the activities falling under this pillar currently focus on education.

[255] http://www.nauka.gov.pl/aktualnosci-ministerstwo/kierunek-nowatorskosc-powolano-rade-ds-innowacyjnosci.html

[256] http://scienceinpoland.pap.pl/en/news/news,411330,ministry-of-science-presented-the-innovation-white-paper.html

the society. At this point however, the envisaged projects seem to focus on science popularization and education.[257]

In addition, in October 2016, the Minister of Science and Higher Education established an advisory expert group on the protection of human rights in view of developments in biological and medical sciences.

It may be important to note that a new law on innovation was adopted at the end of 2016.[258] The law focuses, however, on removing bureaucratic barriers to innovation; it does not refer to ethics.[259]

National Science Centre (NCN)

NCN, a government agency, supervised by the Ministry of Science and Higher Education, set up in 2011 to support basic research in Poland published recommendations for research involving human subjects (March 2016). The goal is to ensure that scientific research funded by the NCN complies with high ethical standards and to support researchers in resolving ethical dilemmas related to the design and conduct of research. The Council recommends that applicants that are planning to conduct types of research specified in the recommendation obtain a positive opinion of a Research Ethics Committee.

Commissioner for Human Rights

A conference on selected aspects of human rights and bioethics was organised by the Commissioner for Human Rights (Ombudsperson) in June 2016. The conference, which is to take place annually, creates a space to discuss the desired and necessary legal and policy developments concerning ethical aspects of research and technological innovation.

Reform of the law on animal experimentation

A new law governing the field of animal experimentation was adopted in 2014 (The Act on Protection of Animals Used for Scientific and Educational Purposes) to implement the directive 2010/63/EU[260]. Authorisation of experiments involving animals is carried out by local ethics committees. According to the newly established provisions, these committees will be composed of six members from biology, pharmaceutical sciences, medicine, agricultural sciences, veterinary sciences; 3 members from humanities or social sciences, especially from the fields of philosophy, ethics or law, including one member from a non-governmental organisation, that deals with patients' rights protection; and 3 members from non-governmental organisations dealing with animal protection.

[257] http://www.nauka.gov.pl/aktualnosci-ministerstwo/nowa-strategia-dla-nauki-i-szkolnictwa-wyzszego.html
[258] http://www.nauka.gov.pl/aktualnosci-ministerstwo/ustawa-o-innowacyjnosci-podpisana-przez-prezydenta.html; The law is available at the following link: http://orka.sejm.gov.pl/opinie8.nsf/nazwa/789_u/$file/789_u.pdf
[259] http://orka.sejm.gov.pl/opinie8.nsf/nazwa/789_u/$file/789_u.pdf
[260] European Parliament and the Council, Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, *OJ L* 276, 20.10.2010, p. 33–79.

The reform of the law on animal experimentation triggered a public debate on the insufficient ethical control exercised over the experiments, which results in unnecessary suffering of animals.[261]

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

As stated above Polish R&I policy does not include references to ethics assessment. Except for the recommendations for research involving human subjects published by the National Science Centre, the new policy initiatives did not refer to ethics, ethics assessment or ethical impact assessment.

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

It might be appropriate for the consortium to intervene and make their views known to members of the ministerial Council for Innovation and the National Science Centre. The SATORI ethics assessment framework could assist in making the recommendations of the latter more concrete, as currently they are very general and do not include any detailed guidelines (they merely advise scientists to obtain a positive opinion of a REC)

Areas (fields, sectors, or topics) where there is a utility to introduce the SATORI ethics assessment framework

As at the EU-level, in Poland the SATORI recommendations for ethics committees could potentially be used in areas where ethics committees are not yet developed but ethical challenges are present (social sciences, industry). Moreover, even in areas where ethics committees do function, SATORI recommendations could assist in harmonizing the practice of different bodies, where there are no common procedures (e.g., ethics committees established at universities). That would however require a shared dedication of institutions of higher education (a bottom-up approach) or a policy choice by the government (top-down approach).

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

Despite the concept of social responsibility of science entering the realms of policy, the notion tends to be understood in a rather simplistic manner, namely as synonymous with "popularization of science". This shows that there is still lack of awareness concerning the ethical aspects of R&I. Other potential barriers include lack of funding and required expertise.

At the same time the steps taken by the National Science Centre seem to suggest a growing awareness of a need to widen the scope of ethical assessment of research beyond the field of medical research. The steps taken in that direction are however sporadic and exist in isolation.

[261] See for example, http://wyborcza.pl/1,75400,20162508,doswiadczenia-na-zwierzetach-to-zbytki-naukowcow-sadystow.html

7.8. Russia

This subsection aims to outline some of the key policy developments that impact the ethics of R&I in the Russian Federation. It was developed based on national institutional sources (see lists below) such as institutional and government websites, publications, news, events and other relevant pages.

Key policy developments in ethics of R&I

In general, ethics assessment of R&I in Russia is structured based on a top-down approach with the ethics assessment and regulation of R&I being primarily carried out by governmental bodies. For instance, in medical and healthcare-related research, the Ministry of Healthcare[262] is one of the central institutional bodies with oversight responsibility to ensure the development, implementation and the coordination of scientific research programs in health care. Some of the main federal governmental institutions involved in the regulation of R&I include:

- Rosminzdrav (Росминздрав) – the Ministry of Healthcare of the Russian Federation[263]
- Roszdravnadzor (Росздравнадзор) – the federal service with oversight responsibility in healthcare[264]
- Rospotrebnadzor (Роспотребнадзор) – the federal service with oversight responsibility in consumer rights protection and human wellbeing[265]
- Rosprirodnadzor (Росприроднадзор) – the federal service with oversight responsibility in environmental protection[266]
- Roskomnadzor (Роскомнадзор) – the federal service for the supervision of communications, information technology and mass media[267].

In addition to the above governmental bodies, many so-called 'scientific-technical councils' (in Russian: *научно-технические советы*) operate within various research, technological and industrial institutions at the federal government level, including:

- ROSATOM (in Rus.: РОСАТОМ) – state corporate body for nuclear industry[268]
- ROSTEC (in Rus.: РОСТЕХ) – state corporate body for high-tech industry[269]
- Bach Institute of Biochemistry RAS (in Rus.: Институт биохимии им. А.Н. Баха)[270]
- Winogradsky Institute of Microbiology RAS (in Rus.: Институт микробиологии им. С.Н. Виноградского)[271]
- Center of Bioengineering RAS (in Rus.: Центр Биоинженерии)[272]

[262] https://www.rosminzdrav.ru/ru
[263] Ibid.
[264] http://www.roszdravnadzor.ru/en
[265] http://www.rospotrebnadzor.ru/en/
[266] http://rpn.gov.ru/node/161
[267] https://eng.rkn.gov.ru/
[268] http://www.rosatom.ru/about/nauchno-tekhnicheskiy-sovet/. See also: http://www.rosatom.ru/en/about-us/governance/public-council/
[269] http://rostec.ru/research/council
[270] http://www.fbras.ru/about/nauchno-texnicheskie-sovety
[271] Ibid.
[272] http://www.fbras.ru/about/nauchno-texnicheskie-sovety

These scientific-technical councils, however, do not make explicit references to ethics assessment. Overall, institutionalised assessment and review of R&I based on ethical principles seem to be more prevalent within the medical field (including pharmacological, psychiatric and psychological research)[273] as opposed to the natural, social sciences and the humanities, where practices of ethics assessment have only recently begun to emerge.

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

As of writing, ethics assessment practices are being adopted within a few internationally-oriented universities and academic institutions, such as the Moscow Higher School of Economics (HSE), Moscow State University. For example, in September 2013, the Academic Council of the Moscow Higher School of Economics established the School's first ever Committee on Interuniversity Surveys and Ethical Assessment of Empirical Research, which is considered to be an analogue of the ethics committees that exist in foreign universities (Institutional Review Board, Ethical Review Board, Independent Ethics Committee, and others).[274] The Committee in question primarily focuses on performing the following two tasks: (1) performing ethical assessment of research projects by evaluating the extent to which a research project conforms to ethical standards in modern social sciences; and (2) evaluating the appropriateness of conducting surveys among prospective, graduate and postgraduate students, and faculty of the HSE. Remarkably, the establishment of the committee has been prompted by the need to meet the standards set by foreign (non-Russian, international) journals, which often require authors to confirm that the research that is to be published conforms to relevant ethical standards.[275]

Another recent trend is the emergence of several state-independent scientific research and professional associations in the medical, psychiatric and psychological research areas, which began to offer their independent ethics assessment of research projects within relevant areas of R&I.

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

There are some initiatives and activities where it may be appropriate for the SATORI consortium to intervene by making their views known. For example, in September 2014, around eighty participants attended the EU–Russia researchers' mobility forum organised in Brussels.[276] The event was entirely dedicated to mobile researchers considered to be a crucial link for scientific cooperation, knowledge transfer, and creation of lasting partnerships. Events such as this, including other bilateral or multilateral academic collaborations and partnerships provide forums for the SATORI consortium to disseminate their views and findings.

[273] http://www.psyrus.ru/en/structure/ethics_committee.php; https://www.rosminzdrav.ru/documents/7025-federalnyy-zakon-ot-21-noyabrya-2011-g-323-fz-ob-osnovah-ohrany-zdorovya-grazhdan-v-rossiyskoy-federatsii
[274] https://www.hse.ru/org/hse/irb/about
[275] https://www.hse.ru/org/hse/irb/ethics
[276] http://ec.europa.eu/research/iscp/pdf/newsletter/international-research-update_50_november-2014.pdf

Areas (fields, sectors or topics) where there is a utility to introduce the SATORI ethics assessment framework

The SATORI recommendations for research ethics committees can be used in many areas where there is a growing awareness of the need for research ethics assessment practices and institutions. The case of the Committee on Interuniversity Surveys and Ethical Assessment of Empirical Research also shows the growing need for research ethics assessment practices in internationally-oriented universities and academic institutions in Russia.

The SATORI ethics assessment framework could be useful in numerous state (federal) and private (corporate) R&I projects, organisations and institutions. Furthermore, the SATORI impact assessment framework could be useful in research and development areas with emerging ethical and societal issues, such as emerging biotechnologies, nanotechnologies, space and nuclear technologies, agricultural and food research and development.

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

There are a few challenges and barriers that would need to be overcome in introducing the SATORI ethics assessment framework in the Russian Federation. In general, these obstacles pertain to the geo-political, cultural and linguistic specificity of the country. The implementation of the framework and the ability of ethics committees to follow SATORI recommendations could be affected by factors such as lack of resources, absence of support from policy-makers, lack of institutional commitment, cultural and institutional differences, scope of ethics assessment activities, and their potentially limited mandates.

7.9. UK

This section was prepared based on data sourced from SATORI WP1 UK country report[277], Task 9.1 policy developments monitoring data, institutional sources (a scan of UK institutional websites including publications, news, events, and other relevant pages). This section adds to the previous research in SATORI connected to ethics policy.

Key policy developments in ethics of R&I

There have been various policy developments relating to ethics of R&I in the UK for the period 2014-2017. These can be classified into the following types:

- **regulatory guidance for specific R&I areas,** e.g., Information Commissioner's Office 2017 update of paper on big data, artificial intelligence (AI) and machine learning[278] and the GDPR self-assessment checklist[279]
- **parliamentary evidence sessions,** e.g., on science and communication[280]

[277] Rodrigues, Rowena & Clare Shelley-Egan, "Ethics Assessment in Different Countries- United Kingdom", SATORI, June 2015. http://satoriproject.eu/media/4.j-Country-report-UK.pdf

[278] https://ico.org.uk/media/for-organisations/documents/2013559/big- data-ai-ml-and-data-protection.pdf

[279] https://ico.org.uk/for-organisations/improve-your-practices/data-protection-self-assessment/getting-ready-for-the-gdpr/

[280] This examined the 'consultation' process in engaging the public, 'responsible research and innovation', the use of scientific advice and the social sciences in policy making.

- **inquiries,** e.g., 2017 inquiry by the UK Science and Technology Committee on research integrity[281]
- **publication of guidance for research,** e.g., Ministry of Defence, Joint Service Publication 536 Ministry of Defence Policy for Research Involving Human Participants[282]; new NHS Health Research Authority[283] and INVOLVE briefing and guidance on public involvement and ethical review[284]
- **joint statements,** e.g., Joint statement on UK implementation of EU Data Protection Regulation[285]
- **publication of POSTnotes[286],** e.g., on Research Integrity, 2017[287], Genome Editing, 2016[288], Trends in ICT, 2015, Regulation of Synthetic Biology, 2015[289], Transparency of Clinical Trial Data, 2014[290]
- **launch of forums,** e.g., launch of the new forum for Responsible Research Metrics[291]
- **development of expectations of best practice**, i.e., launch of the Concordat on Open Research Data, 2016[292]
- **evaluation of guidelines and publication of results,** e.g., 2016 progress report on the Concordat to support research integrity[293]
- **creation of new ethical frameworks,** e.g., British Association for Counselling & Psychotherapy (BACP) new ethical framework for the counselling professions (2016)[294]
- **publication of reports addressing or impacting R&I,** e.g., publication of the Independent Review of Research Excellence Framework (REF) by the UK government in 2016[295]; publication by Nuffield Council on Bioethics of report on public concerns over genome editing technology in 2016[296]

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http://www.parliament.uk/business/committees/committees-a- z/commons-select/science-and-technology-committee/news-parliament- 2015/science-communication-ev4/

[281] http://www.parliament.uk/business/committees/committees-a- z/commons-select/science-and-technology-committee/news-parliament- 2015/research-integrity-inquiry-launch-16-17/

[282] Published:15 September 2016. https://www.gov.uk/government/publications/defence-research-involving-human-participants-jsp-536

[283] The HRA was established as a new, statutory non-departmental public body (NDPB) on 1 January 2015. http://www.hra.nhs.uk/about-the-hra/who-we-are/#sthash.0ktDqxr3.dpuf

[284] Published on 23 May 2016. http://www.hra.nhs.uk/news/2016/05/23/new-hra-and-involve-briefing-and-guidance-on-public-involvement-and-ethical-review/ - sthash.KVZPIwwo.dpuf

[285] Research Councils UK, Joint statement on UK implementation of EU Data Protection Regulation, 24 October 2016. http://www.rcuk.ac.uk/media/news/161024/

[286] POSTnotes are four page summaries of public policy issues based on reviews of the research literature and interviews with stakeholders from across academia, industry, government and the third sector; they are peer reviewed by external experts.

[287] http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-0544?utm_source=website&utm_campaign=PN544#fullreport

[288] http://researchbriefings.files.parliament.uk/documents/POST-PN- 0541/POST-PN-0541.pdf

[289] http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-0497

[290] http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-461/

[291] http://www.rcuk.ac.uk/media/news/160916/

[292] http://www.rcuk.ac.uk/media/news/160728/

[293] http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/concordat-research-integrity-progress-report.aspx

[294] British Association for Counselling and Psychotherapy, Ethical Framework for the Counselling Professions. http://www.bacp.co.uk/ethical_framework/new_ef.php

[295] See https://www.gov.uk/government/uploads/system/uploads/attachment_da ta/file/541338/ind-16-9-ref-stern-review.pdf. Discussion: http://nuffieldbioethics.org/news/2016/stern-review-uk- research-assessment/

[296] http://nuffieldbioethics.org/news/2016/why-when-who-report-of-workshop-on- genome/; http://nuffieldbioethics.org/wp-content/uploads/Public-Dialogue-on-Genome- Editing-workshop-report.pdf

- **approval of new R&I processes,**[297]
- **discussions of relevant topics,** e.g., on Brexit and its impact on science & innovation in UK and Europe[298]

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

New policy initiatives can be seen to be adopting or encouraging the use of ethics assessment (or ethics review). For example, members of parliament have called for a "careful scrutiny of the ethical, legal and societal ramifications of artificially intelligent systems".[299] This is also seen in the government agreement to set up a 'Council of Data Science Ethics' and its initiative to develop "ethical framework for government data science".[300]

While the term 'ethical impact assessment' as such is not used, the call to consider, analyse and address ethical impacts in R&I is becoming recognised is various quarters e.g., Parliament, ministries (e.g., defence, health), Information Commissioner's Office (ICO) etc.

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

It would be relevant for the consortium to make its views known to policy-makers in the UK concerning the following areas: improving the functioning of ethics committees particularly in the humanities and social science sector, and in the SMEs involved in R&I activities.

While good efforts have already been made via the SATORI London mutual learning workshops (November 2016) and dissemination of information by partners in the UK via stakeholder interviews, social media and attendance at third party events, further concerted effort might be necessary as part of the heritage and sustainability building exercises to make policy-makers in the UK more familiar with the results of the SATORI project – particularly the Framework and the CEN Workshop Agreement.

Areas (fields, sectors or topics) where there is a utility to introduce the SATORI ethics assessment framework

The SATORI ethics assessment framework (Part I) could be a very useful tool that could support and advance the state of the art in ethics review in the UK particularly in those areas where, for instance, ethics committees are not established (e.g., for research and consultancy SMEs) or good practice guidance is required for their creation. The Framework is also a useful tool to help develop a shared understanding when research is cross-collaborative. The SATORI ethics assessment framework (as suggested by a representative of the Economic and Social Research Council (ESRC) at the SATORI London workshop in November 2016) could be

[297] The Cambridge Central Research Ethics Committee approved genetic modification of human embryos by the Francis Crick Institute (2016). https://www.crick.ac.uk/research/a-z-researchers/researchers-k-o/kathy-niakan/hfea-licence/

[298] http://www.euroscience.org/news/a-discussion-on-brexit/

[299] https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news-parliament-2015/robotics-ai-report-published-16-17/

[300] https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news-parliament-2015/big-data-dilemma-government-response-15-16/

linked in the ESRC Useful Resources page.[301] This is something that should be pursued by the consortium with the ESRC to foster the use of the SATORI Framework in the UK.

The SATORI ethical impact assessment framework (Part II) could be used to judge the ethical impacts of R&I activities, outcomes and technologies, in consultation with stakeholders.[302] It would help identify and evaluate ethical impacts and developing guidelines or making recommendations to mitigate ethical risks and enhance ethical benefits. 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 R&I – both traditional (e.g., medical or engineering research) and emerging (e.g., socio-technical research, human-machine interactions etc.). Based on our research in WP9 and monitoring of UK R&I and ethics policy news, we think the SATORI ethical impact assessment could be particularly useful in the following contexts in the UK: artificial intelligence, robotics, genomics, human cryogenic preservation[303].

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

As SATORI is an EU-funded research project and the framework has been developed under that setting, while it is not highly likely, the effects of Brexit and the UK's withdrawal from the EU might pose a problem to how the framework is viewed and received if it is presented as an EU framework for ethics assessment, particularly given that the UK has its own long and well-established norms and ethics review practices. However, the SATORI project has actively involved stakeholders from the UK in its research (UK country interviews, email consultations, workshops in London for research ethics committees, research funders and science journalists etc.) and has two UK partners (De Montfort University and Trilateral Research). This engagement has enabled the SATORI consortium to consider the perspectives of UK stakeholders at different critical times in the project and this feedback has helped refine, improve the SATORI Framework and make it more widely applicable.

Other challenges include the need to identify the right opportunities for the use of the Framework, to get buy-in to the Framework. One of the UK stakeholders in the London workshop made the point that the SATORI Framework would only be useful if it became a living document and is easy to use.

7.10. USA

This section was prepared based on data sourced from SATORI work package 1 U.S. country report[304], Task 9.1 policy developments monitoring data, institutional sources (a scan of U.S. institutional websites including publications, news, events, and other relevant pages). This section adds to the previous research in SATORI related to ethics policy.

[301] http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/useful-resources/

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

[303] http://www.telegraph.co.uk/news/2016/11/18/cancer-girl-14-is-cryogenically-frozen-after-telling-judge-she-w/

[304] Bitsch, Lise, Jakob Ibsen-Jensen and Anne Kirstine Lygum, "Ethics Assessment in Different Countries-United States of America", June 2015. http://satoriproject.eu/media/4.k-Country-report-USA.pdf

Key policy developments in ethics of R&I

Based on our literature review, we found a variety of key policy developments in ethics of R&I in the U.S. for the period 2014-2017. These include:

- Introduction of specific legislative measures,[305]
- Revisions and changes to policies,[306]
- Provision of guidance to researchers,[307]
- Publication and issue of standards[308], guidelines[309], infographics[310],
- Changes to existing codes and guidelines,[311]
- Publication of reports on new R&I areas (e.g., genome editing[312], big data[313], forensic science in criminal courts[314]) and roadmap to tackle ethical issues,[315]

[305] In March 2017 two bills were introduced: Honest and Open New EPA Science Treatment Act of 2017 (HONEST Act) and the EPA Science Advisory Board Reform Act of 2017. The bills aim to promote an open and honest Environmental Protection Agency (EPA) and preserve the integrity of the scientific review process. https://science.house.gov/news/press-releases/sst-committee- members-introduce-honest-and-open-new-epa-science-treatment-act-0

[306]The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule) (2017). The Final Rule was published in the Federal Register on 19 January 2017. It implements new steps to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/html/2017-01058.htm; The National Institutes of Health proposed policy change to allow funding for scientists to create animal-human hybrids in 2016. https://www.federalregister.gov/articles/2016/08/05/2016- 18601/request-for-public-comment-on-the-proposed-changes-to-the-nih- guidelines-for-human-stem-cell; https://s3.amazonaws.com/public-inspection.federalregister.gov/2016- 18601.pdf;

[307] The U.S. Department of Energy (DOE) provided further guidance on scientific integrity for its researchers in 2017. https://energy.gov/sites/prod/files/2017/01/f34/DOE Scientific Integrity_Policy 01112017.PDF

[308]Publication of the 2017 edition of the International Compilation of Human Research Standards (2017). http://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

[309] The Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) published final guidance on use of electronic informed consent in clinical investigations in 2016. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html; The American Medical Association issued ethical guidelines for telemedicine in 2016. http://www.healthcaredive.com/news/ama-guidelines-offer-roadmap-for-ethical- use-of-telemedicine/422641/

[310] The Office of Research Integrity (ORI) Division of Education and Integrity (DEI) released 12 new infographics on topics related to the responsible conduct of research (RCR) and the handling of research misconduct in 2016. https://ori.hhs.gov/blog/ori-releases-infographics-series

[311] The Alaskan Professional Teaching Practices Commission proposed changes to Code of Ethics to protect transgender students in 2016. https://education.alaska.gov/ptpc/pdf/NoticeofProposedChanges.pdf. Complete text of proposed changes: https://education.alaska.gov/ptpc/

[312] E.g., The National Academy of Sciences (NAS) and the National Academy of Medicine (NAM), *Human genome editing: science, ethics and governance,* 2016. https://www.nap.edu/catalog/24623/human-genome-editing-science-ethics-and-governance

[313] See White House, *Big Data: A Report on Algorithmic Systems, Opportunity, and Civil Rights,* 2016. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2016_0504_data_discrimination.pdf; President's Council of Advisors on Science and Technology (PCAST), *Big Data: A Technological Perspective*, 2014. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_big_data_and_privacy_-_may_2014.pdf

[314] President's Council of Advisors on Science and Technology (PCAST), *Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods,* 2016. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_forensic_science_report_final.pdf

[315] The Presidential Commission for the Study of Bioethical Issues (the Bioethics Commission) laid out a roadmap for tackling tough ethical questions in 2016. https://bioethicsarchive.georgetown.edu/pcsbi/node/5713.html

- Public meetings[316] and consultations[317],
- Training activities[318].

Are new policy initiatives adopting ethics assessment or ethical impact assessment as part of their policy development process?

As seen from the above analysis, ethics review and resolution of ethics issues form an important part of research governance in the USA.

That the consideration of ethical aspects is relevant is something that can be inferred from a reading of the *Strategy for American Innovation* by the National Economic Council and Office of Science and Technology Policy (2015) which states that, "The United States should be making R&D investments in areas that have the potential to be general-purpose technologies, particularly investments that are beyond the time horizons of individual firms" and that "Multi-agency research initiatives are particularly useful because they allow the government to provide complementary and mutually- reinforcing kinds of support, including", "….exploration of the ethical, legal, and societal implications of emerging technologies".[319]

A notable development is the presentation by Bailey et al, of a 'refined ethical impact assessment tool and a case study of its application' in 2012[320]. The tool provides a set of guiding questions to help researchers understand how to apply the Menlo principles – this was before the start of the SATORI project but SATORI engaged with this tool during the project.[321]

Key policy activities, developments, and initiatives where it may be appropriate for the consortium to intervene by making their views known to policy-makers

The SATORI ethics committee recommendations might be useful to share with U.S. institutional review boards in various fields e.g., medical and social sciences.

The SATORI ethical impact assessment framework would be a useful tool to share with U.S. policy-makers, research funders, and research institutions too, given the interest in addressing the ethical impacts of R&I.

[316] The Bioethics Commission held a public meeting to discuss role of deliberation and education in bioethics (2015). https://bioethicsarchive.georgetown.edu/pcsbi/node/4837.html
[317] https://bioethicsarchive.georgetown.edu/pcsbi/node/4400.html; https://bioethicsarchive.georgetown.edu/pcsbi/node/3301.html
[318] U.S. Department of Health and Human Services' Office of Research Integrity (ORI) & Office for Human Research Protections (OHRP) released 'The Research Clinic', a Web-based interactive training video to teach clinical and social researchers how to better protect research subjects and avoid research misconduct, 2014. https://ori.hhs.gov/images/ddblock/march_vol22_no2.pdf
[319] https://obamawhitehouse.archives.gov/sites/default/files/strategy_for_american_innovation_october_2015.pdf
[320] Bailey M., E. Kenneally, D. Dittrich, "A Refined Ethical Impact Assessment Tool and a Case Study of Its Application", In J. Blyth, S. Dietrich, L J Camp (eds) *Financial Cryptography and Data Security,* FC 2012, Lecture Notes in Computer Science, vol. 7398, Springer, Berlin, Heidelberg, 2012.
[321] SATORI Workshop, "On the cost-effectiveness of and risk-benefit analysis in ethics assessment procedures Contributing to the SATORI framework", 30-31 May 2016, Danish Standards, Copenhagen.

Areas (fields, sectors or topics) where there is a utility to introduce the SATORI ethics assessment framework

It would be relevant for the consortium to make its views known to policy-makers in the USA concerning the following areas which have been in the news and where there is a need to consider ethical implications include: animal hybrids, big data, use of eye scanners[322], genomics[323], human- neuroscience, etc.

Potential challenges or barriers to be overcome in introducing the SATORI ethics assessment framework

Given that the SATORI framework is built upon a comprehensive study of ethics assessment and engagement with stakeholders across countries, organisations and fields, it has wide applicability. The USA was one of the countries that SATORI actively considered in its analysis.

One potential challenge or barrier that might need to be overcome in introducing the SATORI ethics assessment framework might be the relationship of the EU and the U.S. A good bilateral relationship would be conducive to the presentation of the SATORI ethics assessment framework and might lead to a better reception from US counterparts. If the relationship between the EU and the U.S. deteriorates, this might present a challenge.

However, as stated in the *SATORI Outline of an Ethics Assessment Framework (D4.2*),[324]

> …the SATORI framework is compatible with the U.S. approach to EA. This compatibility is because many of the principles adopted by the SATORI framework are implicitly based in the ethical assessment framework of the U.S., such as the Belmont Report. The places where the SATORI framework differs from that in the U.S. arise from factors specific to the U.S., including the decentralised R&I system. They do not, however, suggest conflicts of the core values of the system. Research in the U.S. does not always face the level of EA desired by the SATORI framework, which has specific outlines for organising RECs and conducting uniform, transparent EAs.[325]

[322] Munro, Daniel, "The ethics of putting eye scanners in nursing homes", *Macleans,* 7 May 2017. http://www.macleans.ca/society/technology/the-ethics-of-putting-eye-scanners-in-nursing-homes/
[323] Lin, Patrick, "Blockchain: The Missing Link Between Genomics and Privacy?", *Forbes,* 8 May 2017. https://www.forbes.com/sites/patricklin/2017/05/08/blockchain-the-missing-link-between-genomics-and-privacy/ - 2246624b4b77
[324] Callies, I., et al, *Outline of an Ethics Assessment Framework V.2.0, SATORI Deliverable 4.2,* May 2017.
[325] See, for example, SATORI, *A Framework of Ethical Issues and Principles in R&I*, Deliverable 4.2, pp. 64–127.

8. Discussion of developments from section 7

This section summarises and discusses the developments from section 7.

8.1. Good practice developments at national and local levels

Based on our survey of policy developments at the national level, we found some key good practice developments at the national and local levels concerning policy developments in ethics of R&I. These are illustrated in the figure below.

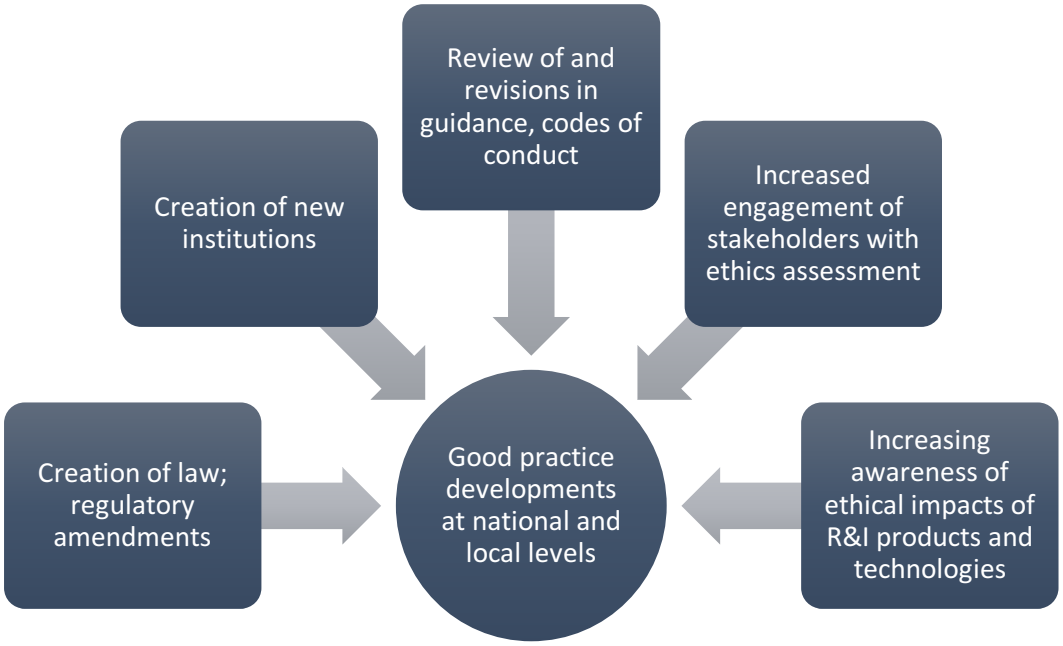

Fig 2: Good practice developments at the national and local levels

These positive developments need to be supported and sustained by policy-makers, particularly as they face many challenges and barriers.

8.2. Ethics assessment and ethical impact assessment in new policies at the national levels

Ethics assessment is addressed at various levels, and by different institutions depending on the country considered. Generally, ethics assessment of R&I is explicitly addressed more systematically at the policy-level in the medical field and in relation to few specific research topics (e.g., research integrity). However, various initiatives are increasingly being considered, in some countries, to implement ethics assessment in other areas (e.g., humanities and social and behavioural sciences in Finland, ethics of emerging technologies, such as artificial intelligent systems and autonomous cars, and more in generally in relation to RRI in Austria, Germany, Italy, Netherlands and the UK).

Ethical impact assessment seems quite a novel concept for most of the organisations and institutions working on ethics of R&I at the country level, as least as emerges from the analysis of this report.

Some countries such as Austria have initiated specific (early stage) policy initiatives on RRI. Both centralised (government-level) and de-centralised (organisation-level) approaches to

ethics assessment co-exist in most of the countries investigated. In few countries, there are networking initiatives on ethics at the government level (mainly related to national ethics committees and research ethics committees), that could be particularly interesting for dissemination of the SATORI framework.

In terms of actors and organisations that should be addressed to disseminate SATORI outcomes, and that could inform new policy developments, the most frequently cited types of organisations emerging from the country analyses include:

- Agencies, councils, advisory and review boards, technical bodies at the government-level informing and advising policy-makers on issues related to: science, R&I strategies, technology assessment, and ethical issues (e.g., scientific and research integrity)
- Associations of ethics committees (e.g., of RECs, NECs)
- Ethics committees at the institutional level (REC, NEC), in research organisations, universities and university associations
- Ministries responsible for innovation, research, science and technology
- Ministries with responsibilities related to specific economic sectors, such as environment, healthcare, ICT, and transport
- Regulatory authorities at the national level, particularly in the medical field (e.g., related to pharmaceuticals and medical devices regulations)
- Research funding organisations
- Scientific research and professional associations (e.g., medicine, psychiatry, psychological research, science and engineering, etc.)

There are some topics that are most frequently considered in policy initiatives related to ethics at the national level. The SATORI ethics assessment framework is relevant and applicable to most of them, and thus could be helpful in these areas. These include:

- Bioethics
- Data protection (e.g., personal data, management of medical records, open data)
- Environment
- Evaluation of research activities
- Health
- Innovative technologies and services e.g., artificial intelligence, automated driving, big data, biotech, cybernetics, internet of things, genomics, human-machine interaction, nanotechnologies, neuroscience, platform economy, robotics, synthetic biology, and other future and emerging technologies
- Research integrity
- Research on humans and animals (e.g., genetic modification)
- Responsible conduct of research and professional conduct
- Scientific freedom and scientific responsibility
- Social responsibility and social assessment.

8.3. Opportunities for the SATORI consortium to intervene at the national levels

Some common aspects emerged from the country analyses, in terms of the potential role that the SATORI framework could play in informing R&I policies and initiatives at the national level. These are:

- Inform the work of ministries and research funding organisations, using SATORI as guidance for evaluating policies related to ethics, science and technology.
- Inform existing ethics assessment activities (e.g., bioethics), using SATORI as a benchmark to evaluate strengths and weaknesses ("assessing the existing ethics assessment approaches");
- Use SATORI results as a guidance to advance the state of the art of ethics review (highlighting both novel aspects of the SATORI approach, and overlaps with existing practices).
- Help developing a structured approach to ethics assessment, using the SATORI framework to facilitate coordination and networking actions on ethics review across organisations and institutions (specifically for countries lacking such initiatives).
- Provide advice on setting up an ethics committee in organisations, or with respect to areas where ethics review is not yet formalised.
- Support ethics review of inter-disciplinary, cross-border science and R&I activities; where SATORI could help to develop a shared understanding of ethics assessment.
- Support the harmonisation of existing practices of ethics assessment across different bodies and agencies at the national level, or even across countries, using SATORI as a guidance providing common and shared principles for EA.
- Improve awareness at the institutional level of the importance of ethics assessment, using SATORI as a tool to facilitate stakeholder engagement and debate on ethics.
- Support assessment of societal impacts in R&I projects, specifically for emerging technologies, using the SATORI EIA framework.
- Strengthen ethics assessment in areas such as social responsibility, respect for other communities, openness, and stewardship.
- Provide guidance on ethics assessment to organisations involved in promoting and supporting entrepreneurship.
- Provide guidance on ethics assessment in areas where ethical challenges are constantly emerging, including the natural sciences, the social sciences and the humanities.

These aspects could be used to underline the benefits that could be achieved by the use and implementation of the SATORI framework within national policies addressing ethics assessment of R&I.

8.4. Potential challenges and barriers to implementing the SATORI EA and EIA Frameworks at national levels

The analysis of country studies indicates several common challenges to implementing the SATORI framework at national levels. The lack of resources has been the most highlighted barrier– i.e., it was highlighted in four out of the ten analysed countries (Austria, Germany, Poland and Russia). Other shared challenges include:

- the low levels of awareness (Austria, Poland)
- the problem of coordinating the implementation of SATORI frameworks with the already established procedures (Austria, Finland, the Netherlands)
- the need for specific expertise, which is currently lacking (Finland, Poland)
- lack of centralised structure/fragmentation of existing structures (Italy, Poland)
- the need to identify the right opportunities (UK, France)
- resistance due to fears of loss of freedom, excessive bureaucracy (Austria) or of loss of competitive advantages (Italy).

In the case of the UK and the US, as SATORI frameworks are based in the EU system (and even though it has a broad and general applicability), this may constitute a slight challenge.

Moreover, there are several other potential challenges identified for specific countries. In Austria, a challenge is the narrow understanding of ethics (typically as medical ethics and in business as CSR or business ethics). Germany shows a lack of, or insufficient legitimisation of the frameworks, and "organisational inertia". Specific challenges identified in the case of Russia include: national specificity (i.e., cultural differences), absence of support from policy-makers, lack of institutional commitment, and limited mandate of the already undertaken ethics assessment activities.

Some guidance on how to overcome these challenges is included in the SATORI policy briefs.[326] These challenges should also be addressed in R&I ethics-related policy discussions at the EU and national levels and further support (i.e., financial, human resources, research, stakeholder dialogue) lent to their alleviation.

9. Conclusion

By drawing on the research findings of the policy developments monitoring, this deliverable has aimed to report on ethics initiatives and policy developments at local, national, and European levels, with a view to giving a thematic description and analysis of the most salient issues for SATORI and making recommendations for future EU (and some national) strategic priorities, and connecting ethics assessment to policy cycles.

The discussion was structured as follows. Following the introductory and methodological sections (1-3), Section 4 identified key policy actors at the global, EU, and national levels i.e., global, regional and local governmental agencies and institutions that set up and support ethics policies, create conditions ethics assessment of R&I by establishing standards, codes, declarations and other policy and legal instruments, and by building capacity for regional and local ethics assessment and providing advisory services.

Section 5 provided a summary of key policy developments impacting ethics assessment of R&I at the global level. The section considered recent policy developments associated with global institutions and agencies such as the WHO, UNESCO, OECD, and CIOMS. A highlight of ethics assessment at the global level is the growing interconnectivity between regional actors. Although there are some examples of international-level policies that touch upon ethics assessment, ethics assessment in practice largely takes place at the national and regional (e.g., EU) levels. Thus, while global standards may exist, their implementation varies across

[326] SATORI, Policy briefs. http://satoriproject.eu/publication_type/policy-briefs/

countries. Different priorities by regional actors mean divergent commitments to international standards. However, the global dialogue provides a useful backdrop in which ethics assessment practices occur. Indeed, international guidelines are frequently cited in their legislation, codes or other guidance, by regional and national level organisations, such as EU organisations, national ethics committees and research ethics committees. The global harmonisation of ethics assessment must consider the significant differences in institutions, values, legal frameworks, and cultural practices that exist between different regions and countries, and there should be flexibility in the formulation and interpretation of international standards. There is a good opportunity for the SATORI ethics assessment framework which is generalisable across disciplines, countries and institutions to be a good model for wider application at the global-level.

Section 6 outlined many significant policy developments at the EU-level between 2014-2017 that impact ethics of R&I. The section set out the main policy developments associated with the key EU institutions, including European Commission, European Parliament, and Council of Europe. The section highlighted certain key policy activities, developments, and initiatives where it may be appropriate for the SATORI consortium to intervene by making their views known to policy-makers. The *European Open Science Agenda* and *Open Innovation 2.0* are two such policy developments that provide good opportunities for the application of the SATORI results.

Section 7 and 8 covered major policy developments for the period (2014-2017) at the national and local levels in the following countries: Austria, Finland, France, Germany, Italy, Netherlands, Poland, Russia, the UK, and the U.S. The discussion therein points to several important recent developments (as highlighted in SATORI work package 1). For example, there have been attempts by certain countries to develop ethics assessment and guidance infrastructure. There has been a noteworthy expansion of ethics assessment in non-medical areas. The comparative analysis of the country-reports showed that there are national differences with respect to: (1) the types of ethical principles and R&I issues that receive attention; (2) the role of government in ethics assessment and guidance (ranging from strong to little regulation); (3) the role of CSO's in government policy; and (4) the extent to which, and how governments stimulate corporate social responsibility (CSR) for industry.

The work package 9 study of policy developments at the national level showed some key good practice developments at the national and local levels concerning policy developments in ethics of R&I, i.e., creation of new laws, and institutions, amendments of existing laws, review of ethics codes and guidance, increasing engagement of stakeholders and increasing ethical awareness. These developments while good, need to be supported and sustained. Further, ethics assessment is explicitly addressed at policy level in the medical field and on specific science and research topics (e.g., integrity of research), initiatives related to ethics assessment of R&I are increasingly considered, at least by some countries. Ethical impact assessment seems quite a novel feature for most of the organisations and institutions engaged in ethics at the country level – this presents a definite opportunity for the SATORI ethical impact assessment framework to find a niche of operation.

The report has identified a significant number of opportunities for intervention at the national level (section 8.3). All these require further funding, support and encouragement by policy-makers at the EU and national level. To add to this, countries face various challenges (Section 8.4) in the use and implementation of the ethics assessment framework. Again, these too need

to be considered and addressed through dialogue, resource allocation and good practice sharing across countries (potentially supported by an EU-level institution, if deemed fit).

There are some additional key take-away messages that we would like to highlight for policy-makers based on the work underpinning this report and the SATORI policy workshop discussion (Annex 1). These are:

- We need to **build upon and leverage existing international, EU and national-level institutions** to enhance ethics assessment practices. Cross-institutional efforts and sharing are the need of the hour.
- While there has been a lot of good practice developed based on medical ethics, there is **a need to look and move beyond a medical ethics-blinkered approach**.
- There is a **need to effectively address the identified challenges of ethics assessment at all levels** – particularly, low awareness of researchers about ethics in social sciences that is compounded by technological innovations.
- We **need to move beyond a pure 'research ethics' approach and address the broader societal issues** – this will enhance social acceptability of research and ensure that societal values underpin R&I outcomes. SATORI has provided some good tools to achieve this need but more work is needed in this area.

ANNEXES

Annex 1: SATORI policy workshop report

ETHICS ASSESSMENT IN RESEARCH & INNOVATION: POLICY ENCOUNTERS

Venue: UNESCO, UN House, 14, Rue Montoyer, B-1000, Brussels

23 May 2017

REPORT

Based on its findings and results, SATORI envisages various roles for policy-makers in supporting ethical research and innovation (R&I). Policy-makers can help promote the use and implementation of the SATORI ethics assessment framework at the EU and Member State level; support future research and the development of the SATORI ethics assessment framework; support the work of existing ethics committees and set up new ethics committees (specially in sectors where these are missing); monitor whether ethics assessment in R&I is achieving its objectives and take corrective measures; incentivise responsible research and innovation (RRI) at the SME level; and increase stakeholder participation and public debate about ethics assessment in R&I.

The SATORI project held a policy workshop at UNESCO, Brussels on 23 May 2017. The aims of the workshop were to discuss SATORI policy recommendations and the means to foster their sustainability; to discuss how policy decisions can nurture or restrict ethics in R&I; and to share how policy-makers can further support and optimise ethics in R&I using SATORI results. The workshop was led by Trilateral Research with support from UNESCO and the SATORI consortium partners.

Representatives of the following organisations attended the workshop: AIRI – Italian Association for Industrial Research (Italy); ANEC - the European consumer voice in standardisation (Belgium); Centre for Applied Ethics, Linköping University (Sweden); Center for the Promotion of Science (Serbia); Council of Europe (France); Danish Board of Technology Foundation (Denmark); Danish Standards Foundation (Denmark); De Montfort University (UK); European Commission, Ethics and Research Integrity Sector (Belgium); European Group on Ethics in Science and New Technologies - EGE (Belgium); European Data Protection Supervisor (Belgium); European Parliament Scientific Foresight Unit - STOA (Belgium); European Union of Science Journalists' Association (France); Helsinki Foundation for Human Rights (Poland); IFIP working group 9.2 (social accountability and ICT) (Belgium); Institut für Höhere Studien/Institute for Advanced Studies (Austria), Technical Research Centre of Finland (Finland); The Francis Crick Institute (UK); Trilateral Research (UK); UNESCO (France); University of Twente (Netherlands); Workgroup "Menswaardige Techniek" Netherlands/Werkgroep menswaardige techniek (Netherlands); Working Group for the revision of the CIOMS Guidelines/University Medical Centre Utrecht (Netherlands).

Registration and welcome took place from 0900 to 0930 am. After participants introduced themselves, Professor Philip Brey co-ordinator of the SATORI project (University of Twente), introduced the SATORI project. Brey introduced the SATORI aims, structure, team, progress and the three recent policy briefs prepared by the consortium. The three policy briefs covered were: Improving the organisation of research ethics committees (RECs); Supporting ethics

assessment in research and innovation; and Ethical Impact Assessment – enhancing responsible research & innovation**.** The following points arose in the discussion:

- In practice, researchers are often concerned with social acceptability rather than social responsibility.
- Sure, social acceptability is a more urgent risk than ethical acceptability. Ethical acceptability, however, may be viewed as a part of social acceptability. In any case, younger researchers are more aware of ethical issues, in part regarding institutional pressures.
- This opinion cannot be shared - medical research has been subject to ethics committee reviews for forty years, but no real change of mindset has occurred. There is still a purely formal understanding of compliance – no deeper understanding of ethical issues.
- Ethics is of course part of responsible research & innovation (RRI) which brings many different pressures at once. This may be the wave that shapes the next generation.

This was followed by a session focussing on '**Policy encounters with ethics in R&I**', moderated by David Wright, Trilateral Research.

Dr Rieke van de Graaf, Secretary of the Working Group for the revision of the CIOMS guidelines, University Medical Center Utrecht at the Julius Center, Department of Medical Humanities gave a presentation on the '**New CIOMS ethical guidelines for health-related research involving humans'**. She introduced CIOMS and the CIOMS research ethics guidelines, and the substantive (conceptual) changes in the latter. The substantive conceptual changes relate to: scientific and social value and respect for rights; research conducted in low-resource settings; potential benefits and risks of research; caring for participants' health needs; community engagement; research involving vulnerable persons; research involving individuals who are incapable of giving informed consent; research involving children and adolescents; women as research participants; pregnant women and lactating women as research participants. Major changes in the Guidelines touch upon aspects of equitable distribution of benefits and burdens in the selection of groups of participants; choice of control in clinical trials; collaborative partnership and capacity building; modifications and waivers of informed consent; reimbursement and compensation for research participants; treatment and compensation for research-related harms; research in disasters and disease outbreaks; cluster randomized trials; use of online environment and digital tools; research ethics committees and review; public accountability; and conflicts of interest.

The discussion that followed covered the following points:

- Until this far CIOMS Guidelines were neglected unless triggered, this has been clarified regarding sources of derivation of the guidelines.
- What is the relation between the Guidelines, human rights and social value? It's good to know that human rights win but what standards do you have in mind when you say a study should not proceed? There is a general statement in the Guidelines; one must be sensitive to issues of justice and fairness. The overall idea is not to approve a study (even if it's an interesting project) that does not respect human rights.
- On the value of duplicate studies: Duplicate studies might have a value anyway or is there no social value whatsoever in duplicate studies? This depends on what the study is built on, and whether it's not an exact copy. There are studies to replicate findings e.g., to validate or build on research findings. Often replication studies are not the same,

so it is often not an exact copy. There is a difference between me-too studies and replication studies.

- How are the Guidelines being disseminated? This is done via meetings. Consultations with the Secretary General are ongoing. The Guidelines are downloadable.

Professor Elmar Doppelfeld MD, Member of the German Delegation to DH-BIO, Council of Europe, Chairman of European Network of Research Ethics Committees (EUREC) spoke about the **'The role of the Council of Europe in biomedical research'.** He introduced the Council of Europe and its engagement in bioethics. He covered the accepted ethical principles i.e., respect for persons; beneficence; justice; respect for persons; beneficence; non-maleficence. He touched upon data protection and ethics in R&I; and the Council of Europe provisions for Biomedical Research[327]. One of the questions that arose in discussion was whether the bias towards the use of RECs is more cultural than economic and the conclusion was that it was more cultural. Other topics of discussion related to: whether there were overlaps between the Council's guidelines, CIOMS', those of the European Commission, etc.; how dialogue between the underlying processes took place (this occurred via invitations to other actors to contribute their views; some engage and some do not); harmonisation versus national traditions and cultures.

Professor Jim Dratwa, Head of the European Group on Ethics in Science and New Technologies (EGE) Office, European Commission, covered '**Ethics in science and new technologies at the European Commission and beyond'**. He introduced the EGE and put ethics in the EU context (referring to the EU Charter of Fundamental Rights, the EU as a union or community of shared values; the rise to prominence of EU values). Ethics is a reticulated institutional landscape and important considerations are: what are ethical frameworks applicable? Whose ethics do we talk about and what brings us together? Universal values add wider international level. He highlighted the need to look at the ethics lifecycle and the way ethics is framed. The ethical dimension of the research agenda is also important as is that of public policy. Some other questions raised during the ensuing discussion include: Can we move on from social or ethical acceptability to social impact considerations? What does it mean to do ethics impact assessment, and what is its relation to other types of assessment (e.g., technology assessment)?

This talk also brought to the fore how there are so many activities that go on in parallel, particularly at EU level, which could and ought to be connected. The basic strategy should be to build on already existing organisational structures – i.e., to find ways for parallel activities to work together through building better connections. Reference was made to the white paper on the *Future of Europe*[328]. Questions were raised about what topics the EGE might focus on in the future – this would depend on the letter from the President. Indications not received but some potential topics might revolve around future society, artificial intelligence (AI) etc. Another point made by one of the participants made was that while it was good to ask what is ethics, it seems that nobody wants to learn – everybody wants to apply ethics. The deep thinking underlying ethics (from Kant to Bentham to social traditions) remains decisive in defining the

[327] E.g., Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo,4.IV.1997 (ETS No 164); Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Strasbourg, 25.I.2005 (CETS No 195); Recommendation CM/Rec(2016)6 of the Committee of Ministers to member states on research on biological materials of human origin, Guide for Research Ethics Committee Members.

[328] https://ec.europa.eu/commission/sites/beta-political/files/white_paper_on_the_future_of_europe_en.pdf

difference between countries. To the question as to who are the EGE's stakeholders, the point was made that the EGE may address all societal groups, including, for example, industry. The EGE is moving beyond 'research ethics' into broader societal issues.

Ms. Louiza Kalokairinou, Policy Officer, Ethics & Research Integrity sector, DG Research & Innovation, European Commission (EC) gave a presentation on '**Promoting an Ethics Framework for Research and Innovation'.** She covered ethics rules and procedures in H2020, compliance of research projects with contractual ethical obligations, ethics appraisal procedure (self-assessment, review, other checks). Also in focus was the H2020 1291/2013[329]. Article 19 (ethical principles) mentions inter alia principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection, and excludes the following areas from the scope of financing: research activity aiming at human cloning for reproductive purposes; research activity intended to modify the genetic heritage of human beings which could make such changes heritable; research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer. The level of ethics scrutiny in H2020 depends on many factors. Two independent ethics reviewers carry out the screening and the common result is conditional clearance for project. The EC may impose certain requirements, such as requirement to constitute and ethics advisory board or checks at a later stage. The challenges include: low awareness of researchers about ethics especially in social sciences and new challenges stemming from IT and emerging technologies. In some part this could be attributed to the "tyranny of the biomedical model". The low awareness of what is ethical hampers the effectiveness of self-assessment. There is also a tension between ethics and law (even though the two are closely connected) and a need not to reduce ethics appraisal to a legal compliance exercise.

In the ensuing discussion, the following points were raised:

- Is the EC losing a competitive advantage by excluding the three areas mentioned above from the scope of financing (given developments in the other parts of the world e.g., in relation to cloning)? Maybe the discussion on this will need re-opening at some point.
- What happens when the methodology of a research project is contrary to ethical principles? It is a very problematic situation when an ethics board demands changes to methodology, so this is something that requires in-depth consideration. Sometimes the project is not approved. Changes to methodology would change the nature of the project plus the project would not go back for scientific evaluation. Ethics panels' try to advise things that do not change the fundamental nature of the projects.
- What is the relationship between dual use and misuse? Dual use refers to when something normally used for civilian purposes may have military application. Dual use is framed as legal issue covered under international law; misuse is the ethical part. Misuse is broader than dual use. Misuse is broad. But there is a big confusion but this does create some debate on the issue.
- In the context of EC, ethics review is linked with legal obligations.

[329] European Parliament and the Council, REGULATION (EU) No 1291/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC.

- Barely any proposals have been rejected (one or two). The Commissions does not reject proposals unless they are fundamentally wrong. Serious omissions are dealt with in dialogue. The aim is to engage the research community and make practices better. Dialogue and ongoing interaction is important – we try not to have an either/or decision. The more proactive researchers are the better. However, not addressing ethics issues properly in proposals can cause delays and create budget issues (e.g., if a project needs to create an ethics advisory board). There may be consequences for funding.
- Compliance with ethics requirements during a project: This is largely under control of project officer via reporting and ethics checks. There are no random checks. Checks are as planned.
- Looking forward to FP9, are there any specific ethical challenges that the EC would like handled? These might potentially be in relation to big data and AI, where further guidance is required.
- Will the unit (EC), use the SATORI results i.e., the CWA? Is there a way we can work together? The unit is already thinking about how it can use the SATORI results. It has a sui generis review process. It is certainly willing to disseminate the final outcomes of the project.

Ms. Claire Gayrel, Legal Officer, European Data Protection Supervisor (EDPS) spoke about '**Regulating data protection in R&I: an ethical perspective'**. She covered the work of the EDPS, and its Ethics Advisory Group which leads the reflection of the impacts of digitalisation of society. As a data protection authority, the EDPS wants to use guidance for itself from the work it undertakes. In 2018, the EDPS will host the 18th International Conference of Data Protection and Privacy Commissioners in Brussels – this is particularly significant given the debate on the ethical dimension of data protection in the digital era. Ms Gayrel shared about the General Data Protection Regulation (GDPR) special provisions for research and how it seeks to facilitate (adopts a lighter touch with safeguards) and not create an excessive nightmare for researchers.

The GDPR adopts no definition of scientific research but outlines enumerations of it. It refers to ethical and responsible research in Article 33. There are special rules for consent in research (broad consent is accepted). In relation to data protection impact assessment (DPIA), there is no derogation for research. Here there is an opportunity for DPIA to be merged with the SATORI EIA framework. But note, a DPIA is not an ethical assessment, it is a legal and human rights matter. Yet, we need to consider the broader impact on rights other than data protection. It is good to have a connection with ethical principles.

One of the points that came up in the discussion was whether the GDPR had gone too far in adopting a liberal approach to research, particularly since some national systems are not as well developed as advanced knowledge economies to deal with the situation. Stronger lobbying succeeded in getting a light touch in. Note, the liberal approach is balanced by increased demands for accountability, e.g., through assessment.

Another point that was made is trend to substitute ethical or other legal issues with data protection compliance (e.g., in smart borders technology solutions). Maybe because of the success of data protection, sometimes compliance with data protection hides broader issues of privacy and other.

Another question that came up was in relation to the clarity of distinctions and distinct regimes in research. I.e., the grey zone of 'what is research' and qualifies for more liberal rules? Does

this open a problematic area? Is there any guidance for research? The Article 29 WP is expected to discuss this and issue guidance. Data protection authorities need to find consensus on issues and this will take time. There is need to define what we mean by research in the GDPR sense.

Another question was if the GDPR is too liberal towards R&I and work is carried out in a country without a strong ethics overview, does R&I not fall into an institutional void? The EDPS may have an opinion, the same with the data protection authority (DPA), but it does not make an ethics assessment. This is a problem that can only be solved at the national level; but the DPA will not and should not develop to engulf that role. The EDPS may release guidance – a code of conduct to provide guidance across Europe on common data protection practices. But on aspects of ethics, others will have to take up the role of providing guidance.

To a question about to what extent EDPS is dealing with use of information by governments, Ms Gayrel clarified that national security is covered by Member State law) and the 'little sister' of the GDPR i.e., the law enforcement directive.

Re a question about compliance by non-EU companies and the applicability of extraterritorial effect, Ms Gayrel clarified that the GDPR applies if the body has an EU presence. Even if they have no establishment, if they sell services or fulfil the other criteria of applicability, the GDPR would apply.

Another discussion point related to whether compliance would be successful. This is affected by limited resources and under resourced data protection authorities. There are more incentives, e.g., sanctions (some infringements can incur fines amounting to up to 4% of total worldwide annual turnover), which companies will take more seriously. There is a greater focus on compliance without enforcement and incentivising via sanctions. There is also the consideration of complaints (see *Schrems* judgment). Data protection authorities now must consider every complaint. Courts are now keen to push data protection authorities to enforce.

Rowena Rodrigues, Trilateral Research gave a presentation on '**Enhancing ethics assessment in R&I at the national level'.** The presentation highlighted the findings of the SATORI WP1 country analyses and the results of the policy developments work package. The presentation mainly focussed on the country policy developments scan. It identified the key actors driving policy at the national level and the key R&I ethics issues in the national news (July 2016-April 2017). It summarised the good practice developments at national and local levels, the challenges and barriers, and the opportunities for the SATORI consortium. At the end of the session, participants were invited to complete (and return) the following set of three questions (the data will be considered in Deliverable 9.1):

1. What can you/your organisation do in your country to support the dissemination and use of the SATORI Framework at the national level? List two or three key actions.
2. What scientific fields and areas should the SATORI framework (recommendations for ethics committees and ethical impact assessment) be promoted in?
3. Identify challenges to implementing the Framework (in your country) and suggest how these could be overcome?

Lunch followed.

Dr Ingrid Callies, UNESCO gave a presentation on '**Policy developments impacting ethics assessment of R & I at the global level'.** The session outlined the need to discuss further

capacity building for ethics assessment at the regional level and the need to ensure there are fora to discuss developments. SATORI is a platform itself for discussion. A review of some global policy initiatives showed that some of these do not specifically mention 'ethics assessment' or 'ethical impact assessment'. There is a need for greater connectivity between international actors. We need to build SATORI global level heritage. There also seems to be a need for SATORI II.

The following points were made in the ensuing discussion:

- SATORI should contact associations of industry in those areas that are not already well established w.r.t. ethics assessment and management i.e., not necessarily in the medical field (pharmaceuticals) as they have their own set up, and interact with these groups.
- Publishers of medical journals have made a difference and completely changed the way things were done. Publishers outside the medical field could also play an important role by making demands (parallel to medical journals).
- Sometimes other actors can help us have an impact.
- It is important to move away from medical ethics territory, which is well-established.
- There are similarities with mainstreaming of corporate social responsibility (CSR). In CSR, in creating an epistemic community – shared understanding between practitioners and policy-makers – one must give up a lot. SATORI is too precise and we may have to bite off a few off our fingers to develop a shared understanding across the board.
- In parallel to CSR development, we need to build an epistemic community of groups that are related in a general manner (integrity, ethics, responsibility, all in one pile).
- We also need institutional legitimation through non-ethics institutions, e.g., UN Global Compact. An ethics-dedicated organisation will have its own approach to ethics, whereas institutions in other areas have other concerns into which the SATORI outcomes may fit.
- We also need to consider how we can better communicate our documents.
- It's a lot for an organisation to take all this (i.e., SATORI recommendations) and apply – it implies big commitments. It might be more useful for some organisations to take bits and pieces of it.
- SATORI should create clear messages on how to use its different results. We must develop a more targeted strategy for dissemination of final results to target different organisations and help actors to select the results that are most valuable to them. We do need packages of reports, dedicated brochures, etc. aimed at specific types of organisations.
- It would be better start at the EU level.
- SATORI should contact the EU Member State representations in Brussels, discuss SATORI with them, and disseminate it to them. Some countries might be more open or less.
- SATORI should contact ALLEA (the European Federation of Academies of Sciences and Humanities).
- SATORI should push national level dissemination to countries that are in the process of developing ethics assessment and need guidance e.g., Poland, where there is room for intervention. However, the political situation may make it slightly difficult.
- The SATORI heritage work could set up a research ethics network or ambassadors in each country to push the SATORI agenda forward. SATORI could offer a logo or certificate to the organisations that offer to take up its results.

A break followed.

Raija Koivisto, VTT Technical Research Centre of Finland and Stéphanie Gauttier, University of Twente presented '**Roadmap for the implementation and use of the ethics assessment framework'**. The presentation outlined the vision of the SATORI roadmap, its process, and the role of various actors in its implementation and use (e.g., the EU, national governments) and some required actions to foster appetites for ethics. Participants were pointed towards SATORI D4.3 Roadmap towards adoption of a fully developed ethics assessment framework (2017).[330]

During the discussion that followed, it was hoped this vision would become a reality. The following points were made:

- Trying to establish national ethics committees (NECs) across all of Europe has been attempted for 30 years. Many people and committees have worked on this, lobbying parliament, etc. The result is that not all countries have one, and in those countries that have them, mandates remain tied to bioethics, etc. W.r.t capacity building: who is going to pay for it? Where is the pressure going to come from? National public purse? Parliaments? Or fees, research organisations? W.r.t. the role of professional organisations, EUREC is interested in expanding its activities beyond medical research, in line with Commission priorities.
- This is a very optimistic roadmap. The biggest factor in creating change is scandals; this could be used as leverage pressure and the roadmap ought to include mechanisms to avoid that serious scandals are swept under the rug. Many institutions are in the sweeping-under-the-rug business. This point was seconded. The institutions responsible for use of ethics codes and implementations of tools like ours are often reactive. They do what they should have been doing only when pressure mounts; from scandals and public attention; (threats of) regulation or if they are falling behind other organisations. The pressures need to be right.
- CSOs (and science journalists) need to get information about R&I; we need to build channels of communication between R&I and these actors.
- SATORI is in favor of working with EUREC in the common months. If funding is an issue, it could come from other projects – both we and EUREC are already part of numerous projects. We need to work more with European Universities Association (EUA). We still need to talk to industry, if possible. We could attempt a presentation to European Parliament via Science and Technology Options Assessment (STOA). And other than that, we need to maintain good dissemination efforts.
- Will the SATORI website shut down after the project ends? Can we connect with other platforms? The website will be maintained for some years after the project ends. There is a potential for feeds from new projects after the end.
- Re the CEN publication of the SATORI Framework: The use of the CEN Workshop Agreement (CWA) is open to anyone and the CWA will be downloadable from SATORI. Plus, all deliverables will go into the open access platform.
- We need a post-project funding meeting, not only to brainstorm, but where participants are prepared for the use of the Framework.
- There is a funding tool under the Europe for Citizens programme, which supports European-level think tanks. This might be one of the options to explore.

[330] http://satoriproject.eu/media/D4.3_SATORI_Roadmap.pdf

- Funding dependencies of the organisations we are relying on to help us implement the Framework are going to be a challenge.
- We have come a long way from where we were a while back. E.g., sustainability awareness has grown. In the ethics assessment area too, we would like to see this happen.
- There is the possibility of writing a peer-reviewed article reviewing the use of the SATORI Framework a year down the line. Trilateral Research & University of Twente are interested parties.
- There was a recommendation to EC Ethics and Integrity sector to consider providing some funding to review of the use of SATORI Framework.

Discussion on policy newsletter

The participants discussed about whether the SATORI newsletter on policy developments in ethics of R & I could be handed over to another partner or project after the end of the work package. Since the methodology used will be outlined in Deliverable 9.2 of the project, it should be easy to replicate the efforts carried out in compiling the newsletter. One possibility was that SATORI partners set apart a couple of hours each month to continue the newsletter. The newsletter could be connected to another related ethics project such as ENERI, SIENNA (to be explored) or it could be a joint newsletter of different projects who would each hold editorial responsibility for their content (while being managed by one of them). This was tried before but EC does not fund that effort.

Engineers and others use open mailing lists. Is that a good model for continuing the newsletter?

Ms Louiza Kalokairinou (EC) will check and advise on other related projects, newly funded projects with whom we could open dialogue in relation to the newsletter. An open question was whether the EGE be interested. Participants were invited to consider options and advise.

Final conference

Professor Philip Brey tabled the plans for the SATORI Final Conference. The final conference will be held in Brussels, 18-19 September 2017. We need to finalise the programme and invitees. All participants should make recommendations of potential invitees. There will be SATORI presenters, but we are also looking for external speakers and discussants. There will be a plenary session on ethics in EU Research & Innovation with EC (Mr Isidorios Karatzas), another EC invitee, EGE, EU Parliament STOA, and a Member of European Parliament. There will be several parallel sessions. One of the sessions will be on policy (national and/or international): UNESCO, Council of Europe etc. We also hope to have one session on science journalism (led by Daniela Ovadia). Another proposal was for a session on "Women in ethics of R&I" (Rowena will make a proposal). One session will focus on Universities and include speakers from leading Universities and universities where ethics assessment is not so well developed. There are plans for an industry session with industry associations and companies. We will invite out Advisory Board Member Mr George Gunn (Novartis), and a person from the Facebook ethics assessment team. Other potential invitees might be Ericsson. We could consider the manufacturing industry. We will not have a panel dedicated to civil society but we could mainstream civil society in the programme by ensuring they are represented in panels and in the Conference. There will be a session on scientific fields: Humanities and social sciences, Medical and life sciences, Engineering, IT.

We could invite Nobel Prize winners. University of Twente has some connections. Ingrid Callies (UNESCO) has contacts with the Nobel prize winner [discovery of **human immunodeficiency virus**] **Françoise Barré-Sinoussi and will try and contact him. Another potential invitee is** Professor Bartha Maria Knoppers - CGP Centre of Genomics and Policy (Prof. Doppelfeld- recommendation).

There will be two categories of participants: by invitation and registrants. There will be an open call to register. There is no conference fee. SATORI will fund around 40 participants. Total number might be 100-120/150. We should ensure we invite those who need to buy into/use the Framework and are not yet engaged with it. We also need to ensure we have a sufficient overspill to account for drop outs and to ensure we get maximum intended.

The Conference is organised by CPN. University of Twente is responsible for the content and technical materials.

To summarise, SATORI has already presented some good results. But, we have a lot to do in the coming months – we need to work on heritage and outreach especially via the final conference and post-project actions with SATORI and non-SATORI partners.

Report prepared by Trilateral Research with inputs from the Danish Board of Technology Foundation.

Annex 2: SATORI policy workshop questionnaire results

This Annex documents the results of the questionnaires filled in by participants at the SATORI policy workshop held at UNESCO, Brussels on 23 May 2017.

Proposed organisational actions to support the dissemination and use of the SATORI Framework

Organisation & country	Proposed actions
AIRI, Italy	• Disseminate amongst members of the association • Use it in future projects • Disseminate to national, regional ethics committees.
Centre for Promotion of Science, Serbia	• Invite people involved in ethics assessment to the SATORI Final Conference • Spread the word through website and public presentations
Centre for Applied Ethics, Linkoping University, Sweden	• Send information to bodies working with ethics e.g., research councils, Central Ethics Board etc. • Inform other ethics institutions in Sweden.
Danish Standards, Denmark	• Post on website • Share in our network • Put on our newsletter
EUREC, Germany	• Improve awareness of the SATORI Framework in other than medical fields • Address organisations of companies in non-pharmaceutical sectors
Institute for Advanced Studies (IHS), Austria	• RRI-Platform dissemination • Funding agency contact • Science ministry dissemination. • Initiate pilot action at the university level.
Menswaardige Techniek (Humancentric Technology), Netherlands	• Offer a link on website
The Francis Crick Institute, UK	• As part of a network of Head of Grants office, we can ensure some awareness i.e. around postdocs via training sessions, and reaching many organisations • Public engagement is strong and powerful in the UK. SATORI outcomes could definitely be advertised.
The Danish Board of Technology Foundation, Denmark	• Targeted meetings with university administrations w.r.t. their practices and organisational capacity (based on the CWAs) • Invite RECs to meetings to discuss the Framework and its relevance in the Danish context
Trilateral Research, UK	• Publicise the Framework to our national contacts. • Consideration of Framework for internal use.
University of Twente, Netherlands	• Working with the national network of research ethics in IT • Informing relevant Dutch organisations of our work • Use connections to get insights, commitment to the Framework • Have a dialogue with French MPs as they are thinking about ‘morality’ and ‘ethics’

What scientific fields and areas should the SATORI Framework be promoted in?

SATORI Ethics Committee Guidance (CEN Workshop Agreement Part 1)	• Technology development (Austria) • Artificial intelligence (Austria) • Engineering sciences (Denmark) • Nzevnet for Videnskablig – this is a committee being established right now. As it is new, it might be susceptible to suggestions (Denmark) • Social sciences (France) • Biotechnology (Italy) • Medical field (Italy) • Research ethics committees could take notice of it, but their procedure etc., are regulated by state law (Germany) • All fields through relevant networking (Netherlands) • Social sciences and humanities (Serbia) • Regional and central boards for ethical vetting of research (Sweden) • Funding institutions (Sweden) • Life sciences (UK)
SATORI Ethical Impact Assessment Framework (CEN Workshop Agreement Part 2)	• Technology development (Austria) • Artificial intelligence (Austria) • Financial services and digitalisation (Austria) • Mission-oriented/challenge oriented research (Denmark) • All fields through relevant networking (Netherlands) • Research institutions, funding organisations, maybe professional associations (if relevant for them) (Italy) • Life sciences (UK)

Challenges to implementing the SATORI Framework and how they might be overcome

Country	Challenge	How it might be overcome
Austria	Ignorance	Find interested journalists
Austria	Lack of awareness, scandals	Connection made to need for EIA.
Denmark	Conflation of integrity with research ethics	Trying to start a debate with the relevant institutions.
Denmark	Universities like to do things their own way	Present the Framework in the right way
Denmark	Difficulty in reaching all organisations that do research	DS has a large network when it comes to companies.
France	Funding of RECs and making researchers apply new principles, a new part of their job (new responsibilities)	Not specified.
Germany	Doubtful whether commercial companies will accept voluntarily any kind of implementation	Need for a binding provision
Italy	Fragmented approach at national level on ethics assessment; not very easy to find appropriate organisations (interested in ethics assessment)	Need to have specific messages for different types of stakeholders for targeted dissemination.

Country	Challenge	How it might be overcome
Netherlands	No national REC organisations except for medical and IT	Work through other organisations
Netherlands	Low interest in ethics assessment in research funding organisations	Talk to them and Dutch universities.
Netherlands	Human centric questions carrying ethical behaviour for anybody	By internet publicity, workshops and the encouragement to companies to use ethics codes.
Serbia	Uncoordinated work of different ethics committees; unregulated areas; lack of interest among scientists and researchers	Dialogue with policy- makers; Proactive awareness raising.
UK	Scientists live in a bubble; it is difficult to reach them.	Engagement should be addressed around this specific population and a very precise way to communicate with them should be defined.